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**MEDICAL EXAMINING BOARD**  
**Room 121A, 1400 East Washington Avenue, Madison**  
**Contact: Tom Ryan (608) 266-2112**  
**June 15, 2016**

*The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.*

**AGENDA**

**8:00 A.M.**

**OPEN SESSION – CALL TO ORDER – ROLL CALL**

- A) Adoption of Agenda (1-4)**
- B) Minutes of May 18, 2016 – Review and Approval (5-10)**
- C) Administrative Updates**
  - 1) Department and Staff Updates
  - 2) Board Members – Term Expiration Dates
    - a) Mary Jo Capodice – 07/01/2018
    - b) Greg Collins – 07/01/2016
    - c) Rodney Erickson – 07/01/2015 (Appointed for Second Term)
    - d) Suresh Misra – 07/01/2015
    - e) Carolyn Ogland Vukich – 07/01/2017
    - f) Michael Phillips – 07/01/2017
    - g) David Roelke – 07/01/2017
    - h) Kenneth Simons – 07/01/2018
    - i) Sridhar Vasudevan – 07/01/2016
    - j) Timothy Westlake – 07/01/2016
    - k) Russel Yale – 07/01/2016
    - l) Robert Zondag – 07/01/2018
    - m) Bradley Kudick – Effective 07/01/2016 (Public Member)**
    - n) Michael Carton – Effective 07/01/2016 (Public Member)**
  - 3) Introductions, Announcements and Recognition
  - 4) Wis. Stat. § 15.085 (3)(b) – Affiliated Credentialing Boards’ Biannual Meeting with the Medical Examining Board to Consider Matters of Joint Interest
  - 5) Informational Items
- D) Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments**
- E) Legislation and Rule Matters – Discussion and Consideration (11-593)**
  - 1) Guidelines Regarding Best Practices in Prescribing Controlled Substances
    - a) Review Guidelines from Other Sources (**12-529**)
    - b) Guidelines Drafting Points for Consideration (**590-593**)
  - 2) Med 13 Relating to Continuing Medical Education for Prescribing Opioids
    - a) Review Other States CME Requirements (**530-587**)
    - b) Proposals for Revising Med 13 (**588**)
  - 3) Update on Pending Legislation and Possible Pending Rulemaking Projects

- F) Interstate Medical Licensure Compact Commission – Report from Wisconsin’s Commissioners**
- G) Federation of State Medical Boards (FSMB) Matters**
  - 1) Appointment of Dr. Simons to FSMB Workgroup on Board Education, Service and Training
  - 2) Other
- H) Speaking Engagement(s), Travel, or Public Relation Request(s), and Report(s)**
- I) Screening Panel Report**
- J) Newsletter Matters
- K) Limited Licenses – Discussion and Consideration**
- L) Informational Items
- M) Items Added After Preparation of Agenda
  - 1) Introductions, Announcements and Recognition
  - 2) Administrative Updates
  - 3) Elections, Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments
  - 4) Education and Examination Matters
  - 5) Credentialing Matters
  - 6) Practice Matters
  - 7) Future Agenda Items
  - 8) Legislation/Administrative Rule Matters
  - 9) Liaison Report(s)
  - 10) Newsletter Matters
  - 11) Annual Report Matters
  - 12) Informational Item(s)
  - 13) Disciplinary Matters
  - 14) Presentations of Petition(s) for Summary Suspension
  - 15) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
  - 16) Presentation of Proposed Decisions
  - 17) Presentation of Interim Order(s)
  - 18) Petitions for Re-Hearing
  - 19) Petitions for Assessments
  - 20) Petitions to Vacate Order(s)
  - 21) Petitions for Designation of Hearing Examiner
  - 22) Requests for Disciplinary Proceeding Presentations
  - 23) Motions
  - 24) Petitions
  - 25) Appearances from Requests Received or Renewed
  - 26) Speaking Engagement(s), Travel, or Public Relation Request(s), and Reports
- N) Future Agenda Items
- O) Public Comments

**CONVENE TO CLOSED SESSION to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats. and § 448.02 (8), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.).**

- P) APPEARANCE – DLSC Attorney Yolanda McGowan and Scott Hathaway, D.O. – Review of Administrative Warning WARN00000470/DLSC Case Number 15 MED 052 (594-598)**
- Q) Full Board Review**
  - 1) Application of Adnan Qureshi, M.D. (599-664)

- R) Full Board Review of Visiting Physician Licensure**
- 1) Shivashankar Damodaran, M.D. **(665-741)**
- S) Request for Waiver of 24 Months of ACGME/AOA Approved Post Graduate Training**
- 1) Robert J. Abatecola, M.D. **(742-797)**
  - 2) Alan Beamsley, D.O. **(798-826)**
- T) Voluntary Surrender Requests**
- 1) Wayne C. Belling, D.O. **(827-828)**
  - 2) Kendall L. Capecci, M.D. **(829-830)**
  - 3) Ileen A. Gilbert, M.D. **(831-832)**
  - 4) Jason B. Terrell, M.D. **(833-835)**
- U) Deliberation on Division of Legal Services and Compliance (DLSC) Matters**
- 1) Monitoring
  - 2) Complaints
  - 3) Administrative Warnings**
    - a) 15 MED 102 – M.P.G. **(836-837)**
    - b) 15 MED 407 – G.Z. **(838-839)**
    - c) 16 MED 069 – S.M.H. **(840-841)**
  - 4) Proposed Stipulations, Final Decisions and Orders**
    - a) 14 MED 261 – Mark C. Bender, P.A. **(842-848)**
    - b) 14 MED 308 – David M. Hammond-Koskey, P.A. **(849-856)**
    - c) 15 MED 098 – Meenakshi S. Bhillakar, M.D. **(857-863)**
    - d) 15 MED 263 – Slawomir J. Puzkarski, M.D. **(864-870)**
    - e) 15 MED 430 – Peter M. Ruess, M.D. **(871-877)**
    - f) 16 MED 015 – Hongyung Choi, M.D. **(878-883)**
  - 5) Case Closings**
    - a) 15 MED 214 **(884-888)**
    - b) 15 MED 294 **(889-892)**
    - c) 15 MED 319 **(893-897)**
    - d) 16 MED 018 **(898-911)**
    - e) 16 MED 095 **(912-915)**
- V) Order Fixing Costs – Discussion and Consideration**
- 1) Victor Ruiz, M.D. **(916-921)**
  - 2) Dale Tavis, M.D. **(922-926)**
- W) Open Cases**
- X) Consulting With Legal Counsel**
- 1) PLANNED PARENTHOOD OF WISCONSIN, INC., et al., Plaintiffs-appellees, v. BRAD D. SCHIMEL, Attorney General of Wisconsin, et al., Defendants-Appellants
- Y) Deliberation of Items Added After Preparation of the Agenda**
- 1) Education and Examination Matters
  - 2) Credentialing Matters
  - 3) Disciplinary Matters
  - 4) Monitoring Matters
  - 5) Professional Assistance Procedure (PAP) Matters
  - 6) Petition(s) for Summary Suspensions
  - 7) Proposed Stipulations, Final Decisions and Orders
  - 8) Administrative Warnings
  - 9) Proposed Decisions

- 10) Matters Relating to Costs
- 11) Complaints
- 12) Case Closings
- 13) Case Status Report
- 14) Petition(s) for Extension of Time
- 15) Proposed Interim Orders
- 16) Petitions for Assessments and Evaluations
- 17) Petitions to Vacate Orders
- 18) Remedial Education Cases
- 19) Motions
- 20) Petitions for Re-Hearing
- 21) Appearances from Requests Received or Renewed

**RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

- Z) Open Session Items Noticed Above not Completed in the Initial Open Session
- AA) Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate
- BB) Delegation of Ratification of Examination Results and Ratification of Licenses and Certificates

**ADJOURNMENT**

**ORAL EXAMINATION OF CANDIDATE(S) FOR LICENSURE**

**ROOM 124D/E**

**10:30 A.M., OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING**

**CLOSED SESSION** – Reviewing Applications and Conducting Oral Examinations of three (3) Candidates for Licensure –Dr. Erickson & Dr. Roelke

**NEXT MEETING DATE JULY 20, 2016**

**MEDICAL EXAMINING BOARD  
MEETING MINUTES  
MAY 18, 2016**

**PRESENT:** Mary Jo Capodice, D.O., Greg Collins; Rodney Erickson, M.D.; Suresh Misra, M.D.; Carolyn Ogland Vukich, M.D.; David Roelke, M.D.; Kenneth Simons, M.D.; Sridhar Vasudevan, M.D.; Timothy Westlake, M.D.; Russell Yale, M.D.; Robert Zondag

**EXCUSED:** Michael Phillips, M.D.

**STAFF:** Tom Ryan, Executive Director; Nifty Lynn Dio, Bureau Assistant; and other Department staff

**CALL TO ORDER**

Kenneth Simons, Chair, called the meeting to order at 8:00 a.m. A quorum of eleven (11) members was confirmed.

**ADOPTION OF AGENDA**

**Amendments to the Agenda:**

- *Removed: Item R.3.c – 15 MED 371 – Administrative Warnings*

**MOTION:** Suresh Misra moved, seconded by David Roelke, to adopt the agenda as amended. Motion carried unanimously.

**MINUTES OF APRIL 20, 2016 – REVIEW AND APPROVAL**

**Amendments to the Minutes:**

- *Correction: Page 8: Add to reject..*

**MOTION:** Sridhar Vasudevan moved, seconded by Suresh Misra, to approve the minutes of April 20, 2016 as amended. Motion carried unanimously.

**APPOINTMENTS, REAPPOINTMENTS, CONFIRMATIONS, AND COMMITTEE, PANEL  
AND LIAISON APPOINTMENTS**

**Screening and Examination Panels Roster**

**MOTION:** Sridhar Vasudevan moved, seconded by David Roelke, to adopt the Screening Panel appointments. Motion carried unanimously.

**Consider an Appointment to the Vacancy of Dr. Vasudevan in the Controlled Substances Committee**

**MOTION:** Sridhar Vasudevan moved, seconded by Timothy Westlake, to disband the Controlled Substances Committee and have those responsibilities assumed by the Full Board. Motion carried unanimously.

**LEGISLATIVE/ADMINISTRATIVE RULE MATTERS**

**Revised Scope Statement for Med 1 and 14 Relating to General Update and Cleanup of Rules**

**MOTION:** Sridhar Vasudevan moved, seconded by David Roelke, to approve the revised Scope Statement on Chapters Med 1 and 14 relating to general update and cleanup of rules for submission to the Governor's Office and publication, and to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

### **SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS**

**MOTION:** David Roelke moved, seconded by Sridhar Vasudevan, to authorize Timothy Westlake to speak to staff at the Department of Health Services regarding opioid prescribing guidelines. Motion carried unanimously.

### **NEWSLETTER MATTERS**

#### **Spring 2016 Newsletter Content**

**MOTION:** Sridhar Vasudevan moved, seconded by David Roelke, to approve the content of the 2016 Newsletter and authorize the Chair to approve any additional changes. Motion carried unanimously.

### **CLOSED SESSION**

**MOTION:** Timothy Westlake moved, seconded by David Roelke, to convene to Closed Session to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats. and § 448.02 (8), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). The Chair read the language of the motion aloud for the record. The vote of each member was ascertained by voice vote. Roll Call Vote: Mary Jo Capodice – yes; Greg Collins – yes; Rodney Erickson – yes; Suresh Misra – yes; Carolyn Ogland Vukich – yes; David Roelke – yes; Kenneth Simons – yes; Sridhar Vasudevan – yes; Timothy Westlake – yes; Russell Yale – yes; and Robert Zondag – yes. Motion carried unanimously.

The Board convened into Closed Session at 9:03 a.m.

### **RECONVENE TO OPEN SESSION**

**MOTION:** Suresh Misra moved, seconded by Robert Zondag, to reconvene in Open Session at 10:43 a.m. Motion carried unanimously.

### **VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION**

**MOTION:** David Roelke moved, seconded by Rodney Erickson, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

### **FULL BOARD REVIEW OF CANDIDATES FOR LICENSURE**

#### **Kent Brockmann, M.D.**

**MOTION:** Sridhar Vasudevan moved, seconded by Suresh Misra, to deny the application of Kent Brockmann, M.D., for reinstatement of his license to practice medicine and surgery. **Reason for Denial:** Pursuant to Order number 2627 dated 9/18/2013. Additionally, the applicant's license to practice medicine in New York State was revoked, which constitutes unprofessional conduct and is another basis for denial. Wis. Stat. § 448.06(2) and Wis. Admin. Code § Med 10.03(3)(c). Motion carried unanimously.

## **FULL BOARD REVIEW FOR VISITING PHYSICIAN LICENSURE**

### **Viktor Hraska, M.D.**

**MOTION:** Russell Yale moved, seconded by David Roelke, to approve the application of Viktor Hraska, M.D., for a license to practice medicine and surgery, once all requirements are met. Motion carried. Abstained: Vasudevan

*(Kenneth Simons recused himself and left the room for voting and deliberation in the matter concerning Victor Hraska, M.D.)*

## **DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS**

### **Monitoring**

*Roman Berezovski, M.D.*

**MOTION:** Timothy Westlake moved, seconded by Suresh Misra, to approve the request of Roman Berezovski, M.D. for full unrestricted licensure. Motion carried unanimously.

*(Sridhar Vasudevan recused himself and left the room for deliberation and voting in the matter concerning Roman Berezovski.)*

*Stephen Haughey, M.D.*

**MOTION:** Rodney Erickson moved, seconded by Greg Collins, to approve the request of Stephen Haughey, M.D. for reduction of drug screens to 24 and one hair test, and deny the request for access to controlled substances. The Board will not consider further petitions prior to May 19, 2017. **Reason for Denial:** The seriousness of the facts underlying the issuance of the original Final Decision and Order. Motion carried unanimously.

*Devinder Sidhu, M.D.*

**MOTION:** David Roelke moved, seconded by Robert Zondag, to approve the request of Devinder Sidhu, M.D. for reduction of drug screens to 24 and one hair test. Motion carried unanimously.

### **Complaints**

*15 MED 178 – C.S.W., M.D.*

**MOTION:** Sridhar Vasudevan moved, seconded by Greg Collins, to find probable cause to believe that C.S.W., DLSC Case No. 15 MED 178, has committed unprofessional conduct, and therefore to issue the Complaint and hold a hearing on such conduct pursuant to Wis. Stat. § 448.02(3)(b). Motion carried unanimously.

**Administrative Warning**

*15 MED 147 – D.P.H.*

**MOTION:** Suresh Misra moved, seconded by Russell Yale, to issue an Administrative Warning in the matter of DLSC Case No. 15 MED 147 against D.P.H. Motion carried. Opposed: Vasudevan, Roelke

*(Kenneth Simons recused himself and left the room for deliberation and voting in the matter concerning D.P.H., DLSC Case No. 15 MED 147.)*

*15 MED 171 – L.M.A.*

**MOTION:** Timothy Westlake moved, seconded by Mary Jo Capodice, to issue an Administrative Warning in the matter of DLSC Case No. 15 MED 171 against L.M.A. Motion carried unanimously.

**Proposed Stipulations, Final Decisions and Orders**

*14 MED 127 – Bradley S. Boettcher, M.D.*

**MOTION:** Greg Collins moved, seconded by Suresh Misra, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Bradley S. Boettcher, M.D., DLSC Case No. 14 MED 127. Motion carried unanimously.

*14 MED 220 – Virendra K. Misra, M.D.*

**MOTION:** May Jo Capodice moved, seconded by Russell Yale, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Virendra K. Misra, M.D., DLSC Case No. 14 MED 220. Motion carried unanimously.

*14 MED 412 – Kenechi Anuligo, M.D.*

**MOTION:** Mary Jo Capodice moved, seconded by Suresh Misra, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Kenechi Anuligo, M.D., DLSC Case No. 14 MED 412. Motion carried unanimously.

*15 MED 011 – Michael J. Flanigan, M.D.*

**MOTION:** Sridhar Vasudevan moved, seconded by Carolyn Ogland Vukich, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Michael J. Flanigan, M.D., DLSC Case No. 15 MED 011. Motion carried unanimously.

*15 MED 150 and 15 MED 151 – Troy D. Schrock, D.O.*

**MOTION:** Suresh Misra moved, seconded by Greg Collins, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Troy D. Schrock, D.O., DLSC Case No. 15 MED 150 and 15 MED 151. Motion carried unanimously.

*15 MED 273 – Scott C. Hicks, M.D.*

**MOTION:** Timothy Westlake moved, seconded by Suresh Misra, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Scott C. Hicks, DLSC Case No. 15 MED 273. Motion carried unanimously.

*(Sridhar Vasudevan recused himself and left the room for deliberation and voting in the matter concerning Scott C. Hicks, M.D., DLSC Case No. 15 MED 273.)*

### Case Closings

#### **CASE CLOSING(S)**

**MOTION:** Carolyn Ogland Vukich moved, seconded by Suresh Misra, to close the following cases according to the recommendations by the Division of Legal Services and Compliance:

1. 14 MED 523 (RC) – **No Violation**
2. 14 MED 617 (KS) – **No Violation**
3. 15 MED 121 (L.H.M.J.) – **Insufficient Evidence**
4. 15 MED 159 (J.H.L.) – **No Violation**

Motion carried unanimously.

*15 MED 411*

**MOTION:** Carolyn Ogland Vukich moved, seconded by Robert Zondag, to close DLSC Case No. 15 MED 411 against C.J.H. for *No Violation*. Motion carried unanimously.

#### **ORDER FIXING COSTS**

### Giuditta Angelini, M.D.

**MOTION:** Timothy Westlake moved, seconded by Greg Collins, to adopt the Order Fixing Costs in the matter of disciplinary proceedings against Giuditta Angelini, M.D., Respondent, DHA Case No. SPS-14-0027, DLSC Case No. 11 MED 315. Motion carried unanimously.

#### **DELEGATION OF RATIFICATION OF EXAMINATION RESULTS AND RATIFICATION OF LICENSES AND CERTIFICATES**

**MOTION:** Timothy Westlake moved, seconded by Mary Jo Capodice, to delegate ratification of examination results to DSPS staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

#### **ADJOURNMENT**

**MOTION:** Sridhar Vasudevan moved, seconded by Rodney Erickson, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:44 a.m.

DRAFT

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Dale Kleven</b> <b>Administrative Rules Coordinator</b>		2) Date When Request Submitted:  <b>6/3/16</b> Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections:  <b>Medical Examining Board</b>			
4) Meeting Date:  6/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Legislation and Rule Matters – Discussion and Consideration</b> <b>1. Guidelines Regarding Best Practices in Prescribing Controlled Substances</b> a. Review Other States Guidelines b. Report From Dr. Westlake on the June 7, 2016 Meeting of the Controlled Substances Board <b>2. Med 13 Relating to Continuing Medical Education for Prescribing Opioids</b> a. Review Other States CME Requirements b. Proposals for Revising Med 13 <b>3. Update on Pending Legislation and Possible and Pending Rulemaking Projects</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled?  <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			
11) <i>Dale Kleven</i> Signature of person making this request		Authorization  <i>June 3, 2016</i> Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

**OTHER  
STATES  
GUIDELINES**

## Guidelines for the use of controlled substances for the treatment of Pain

### ALABAMA STATE BOARD OF MEDICAL EXAMINERS RULES & REGULATIONS

#### 540-X-4-.09 Requirements for the Use of Controlled Substances for the Treatment of Pain.

##### (1) Preamble.

(a) The Board recognizes that principles of quality medical practice dictate that the people of the State of Alabama have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of tolerance, dependence or addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these requirements have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and should include the use of both pharmacologic and non-pharmacologic modalities. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board is obligated under the laws of the State of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) PHYSICIANS SHOULD NOT FEAR DISCIPLINARY ACTION FROM THE BOARD OR OTHER STATE REGULATORY OR ENFORCEMENT AGENCY FOR PRESCRIBING, DISPENSING OR ADMINISTERING CONTROLLED SUBSTANCES, INCLUDING OPIOID ANALGESICS, FOR A LEGITIMATE MEDICAL PURPOSE AND IN THE USUAL COURSE OF PROFESSIONAL PRACTICE. THE BOARD WILL CONSIDER PRESCRIBING, ORDERING, ADMINISTERING OR DISPENSING CONTROLLED SUBSTANCES FOR PAIN TO BE FOR A LEGITIMATE MEDICAL PURPOSE IF BASED ON ACCEPTED MEDICAL KNOWLEDGE OF THE TREATMENT OF PAIN . ALL SUCH PRESCRIBING MUST BE BASED ON CLEAR DOCUMENTATION AND IN COMPLIANCE WITH APPLICABLE STATE OR FEDERAL LAW.

(f) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation. The goal is to reduce pain and/or improve patients' function.

(g) Physicians are referred to the Federation of State Medical Boards' Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013, as amended from time to time, and the Drug Enforcement Administration Office of Diversion Control manual, Narcotic Treatment Programs Best Practice Guidelines, as amended from time to time.

(2) Requirements. The Board requires the following when a physician evaluates the use of controlled substances for pain control:

(a) Evaluation of the Patient. A medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of the patient. Alternative non-opioid treatment modalities or a rehabilitation program may be necessary and should be considered.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. Written agreements between physician and patient outlining patient responsibilities should be utilized for all patients with chronic pain, and should include:

1. Drug screening with appropriate confirmation;
2. A prescription refill policy; and
3. Reasons for which drug therapy may be discontinued (e.g., violation of agreement).
4. The patient should receive prescriptions from one physician and one pharmacy where possible.

(d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician shall keep accurate and complete records to include:

1. the medical history and physical examination;
2. diagnostic, therapeutic and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

These records shall remain current, be maintained in an accessible manner, and be readily available for review.

(g) Compliance With Controlled Substances Laws and Regulations. To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and must comply with applicable federal and state regulations.

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Board Issued Guidelines		Section 6
Subject:	<b><i>Prescribing Controlled Substances</i></b>	
Implemented:	August 1993	
Updated:	June 28, 1997, November 7, 2015	
<p>November 7, 2015:            The Board adopted the following Guidelines for Prescribing Controlled Substances:</p> <p>The Board recognizes that controlled substances are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain. Physicians are expected to be knowledgeable about best clinical practices, aware of associated risks, and to practice in compliance with applicable state and federal laws and relevant practice standards.</p> <p>The Board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:</p> <ul style="list-style-type: none"> <li>• Practicing pain management without sufficient knowledge, skills, and training, or failure to refer patients to an appropriate pain management physician.</li> <li>• Inadequate attention to initial assessment to determine what, if any, controlled substances are clinically indicated and to determine risks associated with their use in a particular patient.</li> <li>• Inadequate monitoring during the use of potentially abusable medications.</li> <li>• Inadequate attention to patient education and informed consent.</li> <li>• Unjustified dose escalation without adequate attention to risks or alternative treatments.</li> <li>• Continued use of ineffective treatments, or failure to reduce or discontinue medications when indicated.</li> <li>• Excessive reliance on opioids, particularly high dose opioids for chronic pain management.</li> <li>• Not making use of available tools for risk mitigations, including: participation in the state prescription drug monitoring program (in advance of prescribing and for ongoing monitoring); practice in accordance with Specialty Board practice standards; and practice in accordance with the Guidelines issued by the Federation of State Medical Boards (FSMB) in their Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain.</li> </ul>		

# Alaska State Medical Board

## Policies and Procedures

### Previous Guidelines for Prescribing Controlled Substances

#### Updated:

In June 1997, the board adopted the following regulations that place certain prescribing requirements into law:

12 AAC 40.975. PRESCRIBING CONTROLLED SUBSTANCES. When prescribing a drug that is a controlled substance, as defined in AS 11.71.900, an individual licensed under this chapter shall create and maintain a complete, clear, and legible written record of care that includes, at a minimum,

- (1) a patient history and evaluation sufficient to support a diagnosis;
- (2) a diagnosis and treatment plan for the diagnosis;
- (3) monitoring the patient for the primary condition that necessitates the drug, side effects of the drug, and results of the drug, as appropriate;
- (4) a record of drugs prescribed, administered, or dispensed, including the type of drug, dose, and any authorized refills.

In August 1993, the Board implemented the following Guidelines for Prescribing Controlled Substances:

1. Perform a work-up sufficient to support a diagnosis, including all necessary tests.
2. Document a treatment plan that includes the use of non-addictive modalities, and make referrals to specialists within the profession when indicated.
3. Document by history or clinical trial that non-addictive modalities are not appropriate or are ineffective.
4. Identify drug seeking patients. Review records. If the patient is new, discuss drug and chemical use and family chemical history with the patient. If drug abuse is suspected, consider obtaining a chemical dependency evaluation or contacting local pharmacies.
5. Obtain informed consent of the patient before using a drug with the potential to cause dependency. Drug companies, the AMA, and other outlets provide printed material in layman's terms that can be used for patient education.
6. Monitor the patient. It is important to follow the patient for the primary condition that necessitates the drug, and for side effects of the drug, as well as the results of the drug. Drug holidays to evaluate for symptom recurrence or withdrawal are important.
7. Control the supply of the drug. Keep detailed records of the type, dose, and amount of the drug prescribed. Monitor, record, and control refills. Require the patient to return to obtain refill authorization at least part of the time. Records of cumulative dosage and average daily dosage are valuable.
8. Maintain contact with the patient's family as an objective source of information on the patient's response and compliance to the therapy.
9. Create an adequate record of care.

**CALIFORNIA**

**GUIDELINES FOR PRESCRIBING  
CONTROLLED SUBSTANCES  
FOR PAIN**

**MEDICAL BOARD OF CALIFORNIA**

**NOVEMBER 2014**

Edmund G. Brown Jr., Governor  
David Serrano Sewell, J.D., President, Medical Board of California  
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# Guidelines for Prescribing Controlled Substances for Pain

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## PREAMBLE

Protection of the public is the highest priority for the Medical Board of California (Board) in exercising its licensing, regulatory, and disciplinary functions. The Board recognizes that principles of high-quality medical practice and California law dictate that the people of California have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life for patients who suffer from pain, particularly chronic pain.

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." This was used to provide guidance to physicians prescribing controlled substances. Several legislative changes since 1994 necessitated revising these guidelines; most recently in 2007.

In November 2011, the Centers for Disease Control and Prevention declared prescription drug abuse to be a nationwide epidemic. Drug overdose is now the leading cause of accidental deaths, exceeding deaths due to motor vehicle accidents. A majority of those overdose deaths involved prescription drugs. The diversion of opioid medications to non-medical uses has also contributed to the increased number of deaths, although the problem is not limited to the aberrant, drug-seeking patient. Injuries are occurring among general patient populations, with some groups at high risk, (e.g., those with depression). Consequently, the Board called for revision of the guidelines to provide additional direction to physicians who prescribe controlled substances for pain.

These guidelines are intended to help physicians improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain. Opioid analgesics are widely accepted as appropriate and effective for alleviating moderate-to-severe acute pain, pain associated with cancer, and persistent end-of-life pain.<sup>1</sup> Although some of the recommendations cited in these guidelines might be appropriate for other types of pain, they are not meant for the treatment of patients in hospice or palliative care settings and are not in any way intended to limit treatment where improved function is not anticipated and pain relief is the primary goal. These guidelines underscore the extraordinary complexity in treating pain and how long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up, and close supervision are ensured. Since opioids are only one of many options to mitigate pain, and because prescribing opioids carries a substantial level of risk, these guidelines offer several non-opioid treatment alternatives. These guidelines are not intended to mandate the standard of care. The Board recognizes that deviations from these guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Medicine is practiced one patient at a time and each patient has individual needs and vulnerabilities. Physicians are encouraged to document their rationale for each

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<sup>1</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

prescribing decision. Physicians should understand that if one is ever the subject of a quality of care complaint, peer expert review will be sought by the Board. The expert reviewer must consider the totality of circumstances surrounding the physician's prescribing practice (e.g., issues relating to access of care, paucity of referral sources, etc.) Specifically, experts are instructed to "define the standard of care in terms of the level of skill, knowledge, and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question."<sup>2</sup>

In an effort to provide physicians with as many sources of information as possible, these guidelines link to numerous references relating to prescribing. Additionally, numerous appendices are attached. The Board recognizes that some of the links/appendices may not be consistent with either each other or the main text of the guidelines. The intent for including as many sources of information as practicable is so that physicians can consider varying perspectives to arrive at the best patient-appropriate treatment decision. The Board does not endorse one treatment option over another and encourages physicians to undertake independent research on this continuously evolving subject matter.

### **UNDERSTANDING PAIN**

The diagnosis and treatment of pain is integral to the practice of medicine. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives long-term opioid therapy.

The California Medical Association<sup>3</sup> has defined and clarified key concepts relating to pain, excerpted below:

*Pain:* The definition of pain proposed by the International Association for the Study of Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." It has also been said that "Pain is what the patient says it is." Both definitions acknowledge the subjective nature of pain and are reminders that, with the rare exception of patients who intentionally deceive, a patient's self-report and pain behavior are likely the most reliable indicators of pain and pain severity. As a guide for clinical decision-making, however, both of these definitions are inadequate. In addition, it is important to remember that the subjectivity of pain, particularly when the cause is not apparent, can lead to the stigmatization of those with pain.

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<sup>2</sup> Medical Board of California Expert Reviewer Guidelines (rev. January, 2013)

<sup>3</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

*Acute and Chronic Pain:* Traditionally, pain has been classified by its duration. In this perspective, “acute” pain is relatively short-duration, arises from obvious tissue injury, and usually fades with healing. “Chronic” pain, in contrast, has been variously defined as lasting longer than would be anticipated for the usual course of a given condition, or pain that lasts longer than arbitrary cut-off times, such as 3 or 6 months. Temporal pain labels, however, provide no information about the biological nature of the pain itself, which is often of critical importance.

*Nociceptive and Neuropathic Pain:* A more useful nomenclature classifies pain on the basis of its patho-physiological process. Nociceptive pain is caused by the activation of nociceptors, and is generally, though not always, short-lived and is associated with the presence of an underlying medical condition. It is a “normal” process; a physiological response to an injurious stimulus. Nociceptive pain is a symptom. Neuropathic pain, on the other hand, results either from an injury to the nervous system or from inadequately-treated nociceptive pain. It is an abnormal response to a stimulus; a pathological process. It is a neuro-biological disease. Neuropathic pain is caused by abnormal neuronal firing in the absence of active tissue damage. It may be continuous or episodic and varies widely in how it is perceived. Neuropathic pain is complex and can be difficult to diagnose and to manage because available treatment options are limited.

A key aspect of both nociceptive and neuropathic pain is the phenomenon of sensitization, which is a state of hyper-excitability in either peripheral nociceptors or neurons in the central nervous system. Sensitization may lead to either hyperalgia or allodynia. Sensitization may arise from intense, repeated or prolonged stimulation of nociceptors, or from the influence of compounds released by the body in response to tissue damage or inflammation. Importantly, many patients – particularly those with persistent pain --- present with “compound” pain that has both nociceptive and neuropathic components, a situation which complicates assessment and treatment.

Differentiating between nociceptive and neuropathic pain is critical because the two respond differently to pain treatments. Neuropathic pain, for example, typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory drug (NSAID) agents. Other classes of medications, such as anti-epileptics, antidepressants or local anesthetics, may provide more effective relief for neuropathic pain.

*Cancer and Non-Cancer Pain:* Pain associated with cancer is sometimes given a separate classification, although it is not distinct from a patho-physiological perspective. Cancer-related pain includes pain caused by the disease itself and/or painful diagnostic or therapeutic procedures [and the sequelae of those processes]. The treatment of cancer-related pain may be influenced by the life expectancy of the patient, by co-morbidities and by the fact that such pain may be of exceptional severity and duration. A focus of recent attention by the public, regulators, legislators, and physicians has been chronic pain that is not associated with cancer. A key feature of such pain, which may be caused by conditions such as musculoskeletal injury, lower back trauma and dysfunctional wound healing, is that the severity of pain may not correspond well to identifiable levels of tissue damage.

*Tolerance, Dependence and Addiction:* Related to the nomenclature of pain itself is continuing confusion not only among the public, but also in the medical community, about terms used to describe the effects of drugs on the brain and on behavior. To help clarify and standardize understanding, the American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) have recommended the following definitions:

*Tolerance:* A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drugs' effects over time.

*Physical Dependence:* A state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug and/or administration of an antagonist.

*Addiction:* A primary, chronic, neurobiological disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving.

*Pain as an Illness:* Finally, it may be helpful to point out that pain can be regarded as an illness as well as a symptom or a disease. "Illness" defines the impact a disease has on an organism and is characterized by epiphenomena or co-morbidities with bio-psycho-social dimensions. Effective care of any illness, therefore, requires attention to all of these dimensions. Neuropathic pain, end-of-life pain and chronic pain should all be viewed as illnesses.

## **SPECIAL PATIENT POPULATIONS**

All patients may experience pain. Below are treatment considerations for differing patient populations or scenarios. As previously addressed, these guidelines are intended to particularly address the use of opioids in the long-term treatment of chronic, non-cancer pain. However, since many of the recommendations cited in these guidelines might be appropriate for other types of pain, other scenarios are listed below to provide additional guidance in prescribing opioids, when appropriate.

### *Acute Pain*<sup>4</sup>

Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies likely will not provide adequate pain relief. When opioid medications are prescribed for treatment of acute pain, the number dispensed should be for a short duration and no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

<sup>4</sup> Utah Department of Health (Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, 2009).

Long (and intermediate) duration-of-action opioids or extended-release/long-acting opioids (ER/LA) should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely, if ever, indicated for treatment of acute pain. The use of opioids should be re-evaluated carefully, including the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

**It is important to emphasize that numerous (but not all) recommendations cited in these guidelines may not be relevant for the physician treating a patient for acute pain.** For example, a physician treating a patient who presents to an emergency department or primary care physician with a medical condition manifested by objective signs (e.g., a fractured ulna or kidney stones discernible with imaging studies) would not necessarily need to undertake an opioid trial, perform a psychological assessment, utilize a pain management agreement, confer with the Prescription Drug Monitoring Program database, order a drug toxicology screen, etc.

#### *Emergency Departments*

Treating patients in an emergency department (ED) or urgent care clinic presents unique challenges in that, oftentimes, there is limited ability to procure adequate patient history and the primary physician is not available. Drug seeking patients may take advantage of this in order to secure controlled substances.

The American College of Emergency Physicians (ACEP) Clinical Policy - Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department (Appendix 1) - identifies acute low back pain as a common presenting complaint in the ED. Opioids are frequently prescribed, expected or requested for such presentations. Consequently, ACEP clinical policy recommends:

- (1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether non-opioid analgesics and non-pharmacologic therapies will be adequate for initial pain management.
- (2) Given a lack of demonstrated evidence of superior efficacy of either opioid or non-opioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.
- (3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (e.g., <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

For patients presenting to the ED with an acute exacerbation of non-cancer chronic pain, ACEP recommends the following:

- (1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic non-cancer pain seen in the ED.
- (2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., < 1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

- (3) The physician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs.

ACEP recommends that the use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

#### *End-of-Life Pain*<sup>5</sup>

Pain management at the end of life seeks to improve or maintain a patient's overall quality of life in addition to relieving suffering. This focus is important because sometimes a patient may have priorities that compete with, or supersede, the relief of pain. For some patients, mental alertness sufficient to allow lucid interactions with loved ones may be more important than physical comfort. Optimal pain management, in such cases, may mean lower doses of an analgesic and the experience, by the patient, of higher levels of pain.

Fear of inducing severe or even fatal respiratory depression may lead to the clinician<sup>6</sup> under-prescribing and reluctance by patients to take an opioid medication. Despite this fear, studies have revealed no correlation between opioid dose, timing of opioid administration and time of death in patients using opioids in the context of terminal illness. A consult with a specialist in palliative medicine in these situations may be advisable.

#### *Cancer Pain*

Pain is one of the most common symptoms of cancer, as well as being one of the most feared cancer symptoms. Opioid pain medications are the mainstay of cancer pain management, and are appropriate to consider for cancer patients with moderate to severe pain, regardless of the known or suspected pain mechanism. However, some cancer survivors with moderate-to-severe pain may additionally or alternatively benefit from the use of non-opioid treatments, and opioids may not be necessary. Other treatments such as surgeries, radiation therapy, and other procedures may provide sufficient pain relief so that opioids are not necessary.

ER/LA opioid formulations may lessen the inconvenience associated with the use of short-acting opioids. Patient-controlled analgesia using an ambulatory infusion device may provide optimal patient control and effective analgesia. The full range of adjuvant medications should be considered for patients with cancer pain, with the caveat that such patients are often on already complicated pharmacological regimens, which raises the risk of adverse reactions associated with polypharmacy.<sup>7</sup>

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<sup>5</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

<sup>6</sup> The term "clinician" throughout the document means "physician."

<sup>7</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

### *Older Adults*

With appropriate precautions opioid therapy for elderly patients can be efficacious. It is important to begin with lower starting doses, slower titration, longer dosing intervals, and more frequent monitoring. Tapering of benzodiazepines is important to reduce the potential for respiratory depression.

For additional information, see [Appendix 2](#).

### *Pediatric Patients*

Extreme caution should be used in prescribing opioids for pediatric patients. A trial of opioid therapy may be considered with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed or are unlikely to be effective for acute pain. Additionally, close monitoring and consultation should be undertaken.

For additional information, see [Appendix 3](#).

### *Pregnant Women*

Clinicians should encourage minimal or no use of opioids during pregnancy unless the potential benefits clearly outweigh risks. Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible.

Additional information on the appropriate use of opioids for pregnant patients is available from the American Congress of Obstetricians and Gynecologists (ACOG) committee opinion titled [\*Opioid Abuse, Dependence, and Addiction in Pregnancy\*](#).

### *Patients Covered by Workers' Compensation<sup>8</sup>*

This population of patients presents its own unique circumstances. Injured workers are generally sent to an occupational medicine facility for treatment. Ideally, the injured worker recovers and returns to work in full capacity. If recovery or healing does not occur as expected, early triage and appropriate, timely treatment is essential to restore function and facilitate a return to work.

The use of opioids in this population of patients can be problematic. Some evidence suggests that early treatment with opioids may actually delay recovery and a return to work. Conflicts of motivation may also exist in patients on workers' compensation, such as when a person may not want to return to an unsatisfying, difficult or hazardous job. Clinicians are advised to apply the same careful methods of assessment, creation of treatment plans and monitoring used for other pain patients but with the added consideration of the psycho-social dynamics inherent in the workers' compensation system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

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<sup>8</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

For additional information on treating patients covered by Workers' Compensation please see State of California Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries.

#### *Patients with History of Substance Use Disorder<sup>9</sup>*

Use of opioids for patients with a history of substance use disorder is challenging because such patients are more vulnerable to drug misuse, abuse and addiction. In patients who are actively using illicit drugs, the potential benefits of opioid therapy are likely to be outweighed by potential risks, and such therapy should not be prescribed outside of highly controlled settings (such as an opioid treatment program with directly observed therapy). In other patients, the potential benefits of opioid therapy may outweigh potential risks. Although evidence is lacking on best methods for managing such patients, potential risks may be minimized by more frequent and intense monitoring compared with lower risk patients, authorization of limited prescription quantities and consultation or co-management with a specialist in addiction medicine. Clinicians should use the [Controlled Substance Utilization Review and Evaluation System (CURES)/Prescription Drug Monitoring Program (PDMP)] CURES/PDMP to identify patients who obtain drugs from multiple sources.

If either the patient's medical history, self-report or scores on screening assessment tools such as the Opioid Risk Tool (Appendix 4) suggest an above-average risk of substance abuse, clinicians should consider the following steps in proceeding with a pain management strategy:

- Exhaust all non-opioid pain management methodologies prior to considering opioid therapy;
- Consult with a specialist in addiction medicine;
- Create a written treatment plan and patient agreement and review carefully with the patient, obtaining their signed informed consent;
- Closely monitor and assess pain, functioning and aberrant behaviors;
- Regularly check with a PDMP for compliance with prescribed amounts of opioids (using cross-state PDMP systems whenever they are available);
- While the patient is on long-term opioid therapy, implement urine drug testing, if possible; or
- If misuse or abuse of opioid analgesics is suspected or confirmed, initiate a non-confrontational in-person meeting, use a non-judgmental approach to asking questions, present options for referral, opioid taper/discontinuation or switching to non-opioid treatments, and avoid "abandoning" the patient or abruptly stopping opioid prescriptions.

#### *Psychiatric Patients*

A higher risk for deleterious side effects exists for patients with psychiatric diagnoses who are receiving opioid treatment. Opioids should only be prescribed for well-defined

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<sup>9</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

somatic or neuropathic pain conditions. Physicians should titrate slowly, closely monitor the patient and seek consultation from the appropriate specialist.

#### *Patients Prescribed Benzodiazepines*

Patients taking benzodiazepines and opioids are at an increased risk for respiratory depression, particularly elderly patients. Physicians should consider a trial of benzodiazepine tapering in patients concomitantly using opioids or other respiratory depressant medications. If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. For additional information, see [Benzodiazepines: How They Work and How to Withdraw](#).

#### *Patients Prescribed Methadone or Buprenorphine for Treatment of a Substance Use Disorder*

Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief from acute and/or chronic pain, beyond that provided by their maintenance medication. For more information on pain relief for persons on methadone or buprenorphine, see [Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy](#).

### **PATIENT EVALUATION AND RISK STRATIFICATION**

When considering long-term use of opioids for chronic, non-cancer pain, given the potential risks of opioid analgesics, careful and thorough patient assessment is critical. Risk stratification is one of the most important things a physician can do to mitigate potentially adverse consequences of opioid prescribing. The nature and extent of the clinical assessment depends on the type of pain and the context in which it occurs. This includes but is not limited to:

- Completing a medical history and physical examination ([Appendix 5](#)).
- Performing a psychological evaluation.
  - Psychological assessment should include risk of addictive disorders. Screening tools that can be considered for use include:
    - CAGE-AID ([Appendix 6](#));
    - PHQ-9 ([Appendix 7](#));
    - Opioid Risk Tool (ORT) ([Appendix 4](#)); and
    - SOAPP®-R ([Appendix 8](#)).
    - Note: Although the above-listed assessment tools are well-established with proven effectiveness, physicians must be aware that seasoned diverters know the right answers to these tools so they look "normal."
- Establishing a diagnosis and medical necessity (review past medical records, laboratory studies, imaging studies, etc. and order new ones, if necessary or if previous studies are outdated). Screening tools that can be considered for use include:
  - Pain Intensity and Interference (pain scale) ([Appendix 9](#)); and
  - [Sheehan Disability Scale](#).
- Exploring non-opioid therapeutic options.

Opioid medications may not be the appropriate first line of treatment for a patient with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. Resources that can be consulted include:

- Therapeutic Options for Pain Management (Appendix 10); and
- Non-Opioid Pain Management Tool (Appendix 11).
- Evaluating both potential benefits and potential risks of opioid therapy.
- Being cognizant of aberrant or drug seeking behaviors.
- As a universal precaution, undertaking urine drug testing.
- Reviewing the CURES/PDMP report for the patient. This allows a physician to check to see if a patient is receiving controlled substances from other prescribers in California (assuming the prescription is being filled at a California pharmacy).

### **CONSULTATION**

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, or an addiction or mental health specialist as needed. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available.

Physicians who prescribe long-term opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed.

### **TREATMENT PLAN AND OBJECTIVES**

When considering long-term use of opioids for chronic, non-cancer pain, the physician and the patient should develop treatment goals together. The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Pain relief is important, but it is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. Effective pain relief improves functioning, whereas addiction decreases functionality. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including

medications other than opioids) and non-pharmacologic. It also should specify measurable goals and objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function.

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. The treatment plan should also include an “exit strategy” for discontinuing opioid therapy in the event the tapering or termination of opioid therapy becomes necessary.

### **PATIENT CONSENT**

When considering long-term use of opioids, or in other medically appropriate situations, the physician should discuss the risks and benefits of the treatment plan with the patient, with persons designated by the patient, or with the patient’s conservator if the patient is without medical decision-making capacity. If opioids are prescribed, the patient (and possibly family members, if appropriate) should be counseled on safe ways to store and dispose of medications. For convenience, patient consent and a pain management agreement can be combined into one document.

Patient consent typically addresses:

- The potential risks and anticipated benefits of long-term opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as nausea, opioid-induced constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Gegmann et al., 2008) and cognitive impairment.
- The likelihood that some medications will cause tolerance and physical dependence to develop.
- The risk of drug interactions and over-sedation.
- The risk of respiratory depression.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.

### **PAIN MANAGEMENT AGREEMENT**

Use of a pain management agreement is recommended for patients:

- On short-acting opioids at the time of third visit within two months;
- On long-acting opioids; or
- Expected to require more than three months of opioids.

Pain management agreements typically outline the joint responsibilities of the physician and the patient and should include:

- The physician’s prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician’s policy on early refills and replacement of lost or stolen medications.

- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication to prevent misuse by other household members).
- The patient's agreement to share information with family members and other close contacts on how to recognize and respond to an opiate overdose, including administering an opioid antagonist, such as naloxone, if necessary. (Appendix 12)
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice and one pharmacy.
- The patient's agreement to periodic drug testing (blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills, if appropriate and in accordance with the patient's pain management agreement.

Samples of pain management agreements:

- Patient Pain Medication Agreement and Consent (Appendix 13)
- Treatment Plan Using Prescription Opioids (Appendix 14)

### **COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE**

Empirical evidence has shown that lay persons can be trained to recognize the signs of an opiate overdose and to safely administer naloxone, an opiate antagonist. Programs that have trained lay persons in naloxone administration have reported more than 10,000 overdose reversals.<sup>10</sup>

It is important to educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

- Snoring heavily and cannot be awakened.
- Periods of ataxic (irregular) or other sleep-disordered breathing.
- Having trouble breathing.
- Exhibiting extreme drowsiness and slow breathing.
- Having slow, shallow breathing with little chest movement or no breathing.
- Having an increased or decreased heartbeat.
- Feeling faint, very dizzy, confused or has heart palpitations.
- Blue skin/lips.
- Non-responsiveness to painful stimulation.

<sup>10</sup> Centers for Disease Control and Prevention. Community-based opioid overdose prevention programs providing naloxone-United States, 2010. Morbidity and mortality weekly report, February 17, 2012 / 61(06);101-105

Effective January 1, 2015, California pharmacists will be able to furnish an opioid overdose reversal drug in accordance with standardized procedures or protocols, naloxone, to family members of patients at risk for overdose, those who might be in contact with an individual at risk for overdose, or anyone who requests the drug without a prescription.

SAMHSA's Opiate Overdose Toolkit and Prescribe to Prevent contain numerous documents relating to overdose prevention and management.

### INITIATING OPIOID TRIAL

Safer alternative treatments should be considered before initiating opioid therapy for chronic pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 45 days) and with specific evaluation points. The *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*<sup>11</sup> reveals that "[o]ver half of persons receiving 90 days of continuous opioid therapy remain on opioids years later. Factors most strongly associated with continuation were intermittent prior opioid exposure, daily opioid dose  $\geq$  120 mg MED, and possible opioid misuse. Since high dose and opioid misuse have been shown to increase the risk of adverse outcomes, special caution is warranted when prescribing more than 90 days of opioid therapy in these patients."

The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety.

According to the California Medical Association:<sup>12</sup>

Oral administration, especially for the treatment of chronic pain, is generally preferred because it is convenient, flexible and associated with stable drug levels. Intravenous administration provides rapid pain relief and, along with rectal, sublingual and subcutaneous administration, may be useful in patients who cannot take medications by mouth. Continuous infusions produce consistent drug blood levels but are expensive, require frequent professional monitoring and may limit patient mobility.

Transdermal administration is a convenient alternate means of continuous drug delivery that does not involve needles or pumps. Patient-controlled analgesia (PCA) allows patients to self-administer pain medications and may be useful if analgesia is required for 12 hours or more and mobility is not required. Intrathecal delivery of opioids is a viable option for patients with chronic pain who have not responded to other treatment options, or for whom the required doses result in unacceptable side-effects. Patients with intrathecal delivery systems typically require ongoing ambulatory monitoring and supportive care.

<sup>11</sup> Journal of General Internal Medicine article (December 2011, Volume 26, Issue 12, pp 1450-1457).

<sup>12</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Patients on a steady dose of an opioid medication may experience pain that breaks through the analgesic effects of the steady-state drug. Paper or electronic pain diaries may help patients track these breakthrough episodes and spot correlations between the episodes and variables in their lives. A short-acting opioid is typically prescribed for treatment by patients with breakthrough pain.

Continuation of opioid therapy after an appropriate trial should be based on outcomes such as: making progress toward functional goals; presence and nature of side effects; pain status; and a lack of evidence of medication misuse, abuse, or diversion. Patients with no, or modest, previous opioid exposure should be started at the lowest appropriate initial dosage of a short-acting opioid and titrated upward to decrease the risk of adverse effects. The selection of a starting dose and manner of titration are clinical decisions made on a case-by-case basis because of the many variables involved. Some patients, such as frail older persons or those with co-morbidities, may require an even more cautious therapy initiation. Short-acting opioids are usually safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of overdose from drug accumulation. The general approach is to "start low and go slow."

Since opioids are known in some circumstances to worsen pain (hyperalgesia), instances of ongoing pain may suggest opioid insensitivity (or an inadequate dose). Careful assessment must be undertaken. If hyperalgesia is suspected, a dose reduction, opioid rotation or tapering to cessation could be considered.

#### *Dosing Recommendations For Opioid Naïve Patients*

There is a plethora of data available regarding recommended dosages for various analgesics. Because this is continuously evolving, physicians are encouraged to review the Food and Drug Administration's website and other relevant information sources.

#### *Morphine Equivalent Dose (MED)*

There are differing opinions among reputable experts and organizations as to what MED should trigger a consultation. The Board recommends that physicians proceed cautiously (yellow flag warning) once the MED reaches 80 mg/day. Referral to an appropriate specialist should be considered when higher doses are contemplated. There is no absolute safe ceiling dose of opioids, however, and caution and monitoring are appropriate for applications of these medications.

The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

### **ONGOING PATIENT ASSESSMENT**

When a trial of an opioid medication is successful and the physician and patient decide to continue opioid therapy, regular review and monitoring should be undertaken for the duration of treatment.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale or other validated assessment tools, may be helpful and time effective.

Consider the 5-As method for chronic pain management assessment:

Analgesia: the patient is experiencing a reduction in pain.

Activity: the patient is demonstrating an improvement in level of function.

Adverse: the patient is not experiencing side effects.

Aberrance: the patient is complying with the pain management agreement and there are no signs of medication abuse or diversion.

Affect: the patient's behavior and mood are appropriate.

"Opioid rotation," the switching from one opioid to another in order to better balance analgesia and side effects, may be used if pain relief is inadequate, if side effects are bothersome or unacceptable, or if an alternative route of administration is suggested. Opioid rotation must be done with great care, particularly when converting from an immediate-release formulation to an extended-release/long-acting (ER/LA) product. Equianalgesic charts, conversion tables and calculators must be used cautiously with titration and appropriate monitoring. Patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind, hence physicians may want to use initially lower-than-calculated doses of the switched-to opioid.

## **COMPLIANCE MONITORING**

Physicians who prescribe opioids or other controlled substances for pain should ensure the provisions of a pain management agreement are being heeded. Strategies for monitoring compliance may include:

### *CURES/PDMP Report*

The CURES/PDMP report can be useful in establishing whether or not an individual is receiving controlled substances from multiple prescribers. The CURES/PDMP report should be requested frequently for patients who are being treated for pain as well as addiction.

### *Drug Testing*

A patient's report of medication use is not always reliable; therefore, drug testing can be an important monitoring tool.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately. For example,

when a drug test is ordered, it is important to specify that it include the opioid being prescribed. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist. Urine toxicology tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies and interpreting laboratory data. Laboratories vary in their testing methodologies, thresholds and standards. Results from drug screens may involve diverse drug classes and interpreting them requires clinical understanding well beyond opioids.

“Variability may result from differences between laboratories. Some labs, for example, only report values above a certain preset threshold. So, a patient might have a measurable level of drug, but since it does not exceed the given threshold, it is reported as negative finding. This might lead the physician to suspect that a prescribed drug, which should be present at the time of testing, is absent.”<sup>13</sup>

“Limitations to Urine Drug Testing (UDT): There is currently no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug. A recent systematic review of the use of drug treatment agreements and urine drug testing to discourage misuse when opioids are prescribed for chronic non-cancer pain, found weak, heterogeneous evidence that these strategies were associated with less misuse. Limited research did find that UDT was a valuable tool to detect use of non-prescribed drugs and confirm adherence to prescribed medications beyond that identified by patient self-report or impression of the treating physician.”<sup>14</sup> “Consequently, additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, may be deemed necessary to monitor and treat patients receiving chronic opioid treatment and is considered part of a medically necessary treatment and monitoring program.”<sup>15</sup>

It is important to be aware of cost barriers related to a patient's ability to pay for the testing. There are numerous Clinical Laboratory Improvement Amendments waived office drug testing kits which are inexpensive and which physicians may wish to consider for use for initial drug testing. However, unexpected results from office-based testing should be confirmed by the more-sensitive laboratory testing before the patient's plan of care is changed.

#### *Pill Counting*

Periodic pill counting can be a useful strategy to confirm medication adherence and to minimize diversion (selling, sharing or giving away medications).

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<sup>13</sup> Responsible Opioid Prescribing, A Clinician's Guide, Second Edition, 2012, Scott Fishman, M.D.; Federation of State Medical Boards (FSMB), FSMB Foundation, and University of Nebraska Medical Center.

<sup>14</sup> State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part D: Comparison Of Recommendations From Existing Opioid Guidelines.

<sup>15</sup> State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part B Recommendations.

The physician must decide whether or not to revise or augment a pain management agreement and/or treatment plan if the patient's progress is unsatisfactory. If it is suspected that a patient may be abusing or diverting prescribed medications, or using "street" drugs, a careful re-assessment of the treatment plan must be undertaken. A patient's failure to adhere to a pain management agreement is not necessarily proof of abuse or diversion. Failure to comply may be the consequence of inadequate pain relief, confusion regarding the prescription, a language barrier or economic concerns. A physician should arrange for an in-person meeting in order to have a non-judgmental conversation to clarify his or her concerns. If abuse is confirmed, minimally, consultation with an addiction medicine specialist or mental health specialist trained in substance abuse disorders and/or referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) should be immediately facilitated. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firmer, immediate response. The degree to which the patient has breached the pain agreement and/or the presence of criminal activity should govern the physician's response. Although an immediate face-to-face meeting with the patient to re-evaluate the treatment plan may be appropriate, in some instances it may be necessary to taper opioid therapy and/or terminate the physician patient relationship. In situations where the patient has engaged in prescription forgery, prescription theft or assaultive behaviors directed towards physician or staff, the physician is strongly encouraged to contact the police/Drug Enforcement Agency (DEA). For other criminal behaviors, the physician is encouraged to contact legal counsel to determine whether it is appropriate to report to law enforcement. Failing to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death.

### **DISCONTINUING OPIOID THERAPY**

Discontinuing or tapering of opioid therapy may be required for many reasons and ideally, an "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment. Reasons may include:

- Resolution or healing of the painful condition;
- Intolerable side effects;
- Failure to achieve anticipated pain relief or functional improvement (although ensure that this failure is not the result of inadequate treatment);
- Evidence of non-medical or inappropriate use;
- Failure to comply with monitoring, such as urine drug screening (although ensure that this failure is not the result of a cost issue);
- Failure to comply with pain management agreement;

- Exhibition of drug-seeking behaviors (although ensure this behavior is not the result of inadequate treatment) or diversion, such as:
  - Selling prescription drugs;
  - Forging prescriptions;
  - Stealing or borrowing drugs;
  - Aggressive demand for opioids;
  - Injecting oral/topical opioids;
  - Unsanctioned use of opioids;
  - Unsanctioned dose escalation;
  - Concurrent use of illicit drugs;
  - Getting opioids from multiple prescribers and/or multiple pharmacies; or
  - Recurring emergency department visits for chronic pain management.

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely-structured tapering regimen. Opioid withdrawal symptoms are uncomfortable, but are generally not life threatening. Opioids can be stopped abruptly when the risks outweigh the benefits. This is not true for benzodiazepine withdrawals, which can be life threatening. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist. "Approaches to weaning range from a slow 10% reduction per week to a more aggressive 25 to 50% reduction every few days. In general, a slower taper will produce fewer unpleasant symptoms of withdrawal."<sup>16</sup> For strategies on tapering and weaning, see [Appendix 15](#). The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate.

If complete termination of care is necessary (as opposed to termination of a specific treatment modality), physicians should treat the patient until the patient has had a reasonable time to find an alternative source of care, and ensure that the patient has adequate medications, if appropriate, to avoid unnecessary risk from withdrawal symptoms. Physicians can be held accountable for patient abandonment if medical care is discontinued without adequate provision for subsequent care. If a patient is known to be abusing a medication, initiating a detoxification protocol may be appropriate. Consultation with an attorney and/or one's malpractice insurance carrier may be prudent in such cases. Physicians may want to also consult health plan contracts to ensure compliance. The Board also provides guidance on how to terminate/sever the patient relationship.

If a patient is dismissed for not honoring treatment agreements, consider referral to addiction resources. This can also include a 12-step program.

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<sup>16</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

## **MEDICAL RECORDS**

Every physician must maintain adequate and accurate medical records. The content of a patient's medical record may vary considerably, depending on numerous factors. For a physician treating a patient with opioids for chronic, non-cancer pain, an adequate medical record includes, but is not limited to, the documentation of:

- the patient's medical history;
- results of the physical examination and all laboratory tests ordered by the physician;
- patient consent;
- pain management agreement;
- results of the risk assessment, including results of any screening instruments used;
- description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity);
- instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement;
- notes on evaluations by, and consultations with, specialists;
- any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors (these may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers);
- authorization for release of information to other treatment providers as appropriate and/or legally required; and
- results of CURES/PDMP data searches.

The medical record should include all prescription orders for opioid analgesics and other controlled substances, whether written, telephoned or electronic. In addition, written instructions for the use of all medications should be given to the patient and documented in the record. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed, if the pharmacy that the patient will use is known. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review.

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient.

## **SUPERVISING ALLIED HEALTH PROFESSIONALS**

Physicians who supervise physician assistants or nurse practitioners who prescribe opioids should be aware of the specific regulations and requirements governing them and those whom they supervise.

## COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS

### California laws:

- California laws regarding controlled substances
- Guide to the Laws Governing the Practice of Medicine

### Federal laws:

- Title 21 United States Code (USC) Controlled Substances Act

### Other information:

- Pharmacist corresponding responsibilities

## Appendix 1 - Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

### PAIN MANAGEMENT/CLINICAL POLICY

## Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

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**ABSTRACT**

This clinical policy deals with critical issues in prescribing of opioids for adult patients treated in the emergency department (ED). This guideline is the result of the efforts of the American College of Emergency Physicians, in consultation with the Centers for Disease Control and Prevention, and the Food and Drug Administration. The critical questions addressed in this clinical policy are: (1) In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse? (2) In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications? (3) In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids? (4) In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

**INTRODUCTION**

Pain is a major symptom of many patients presenting to the emergency department (ED), with up to 42% of ED visits being related to painful conditions.<sup>1</sup> Pain management has received increased emphasis in the past decade, including The Joint Commission's focus on patient analgesia<sup>2</sup> and increasing institutional emphasis placed on patient satisfaction surveys covering pain management. Much literature, including the most recent Institute of Medicine report on this topic, has stressed that health care providers have not done as well as possible in the area of pain management.<sup>3</sup> A possible unintended consequence of these efforts is the increase in prescription drug abuse, especially opioid abuse, the fastest-growing drug abuse problem in the United States.<sup>4</sup>

As part of this issue, there has been a startling increase in unintentional drug overdoses and related deaths since the late 1990s.<sup>5,6</sup> Reported overdose deaths involving opioid analgesics increased from 4,030 in 1999 to 14,800 in 2008.<sup>7,8</sup> Data from 2008 reveal that drug overdoses were the second leading cause of injury death in the United States, after motor vehicle crashes.<sup>9</sup> Currently, deaths from opioid analgesics are significantly greater in number than those from cocaine and heroin combined.<sup>8</sup>

The efforts of clinicians to improve their treatment of pain, along with pharmaceutical industry marketing, have been factors in contributing to a significant increase in the sale and distribution of opioids in the United States. For example, the sales of opioid analgesics to hospitals, pharmacies, and practitioners quadrupled between 1999 and 2010.<sup>3</sup> Drug sales and distribution data of opioids show an increase from 180 mg morphine equivalents per person in the United States in 1997 to 710 mg per person in 2010.<sup>8,10</sup> This is the equivalent of 7.1

kg of opioid medication per 10,000 population, or enough to supply every American adult with 5 mg of hydrocodone every 4 hours for a month.<sup>8</sup>

The dilemma of treating pain appropriately while avoiding adverse events is further complicated by insufficient data supporting the long-term use of opioids in the treatment of chronic noncancer pain. Although selective use of opioids in the treatment of acute pain is traditionally accepted, the treatment of chronic noncancer pain is more complex. Many authors have begun to question the routine long-term use of opioids for the treatment of chronic noncancer pain.<sup>11-13</sup> Multiple practice guidelines have been developed to address this issue.<sup>14-19</sup> However, most recommendations in this area are of a consensus nature, being based on experiential or low-quality evidence.

Data from 2009 show that there were more than 201.9 million opioid prescriptions dispensed in the United States during that year.<sup>20</sup> It is difficult to obtain reliable data concerning the degree to which this is an emergency medicine issue, but during 2009, in the 10- to 19-year-old and 20- to 29-year-old patient groups, emergency medicine ranked third among all specialties in terms of number of opioid prescriptions, writing approximately 12% of the total prescriptions in each age group. In the 30- to 39-year-old group, emergency medicine ranked fourth.<sup>20</sup> Although these data do not deal with total doses dispensed by specialty, it is commonly postulated that the population served in EDs as a whole is at high risk for opioid abuse.<sup>21</sup>

The significant increase in opioid-related deaths has raised the concern of many.<sup>5,6,8</sup> This problem has also been observed in the pediatric population.<sup>22-24</sup> Action at the national level includes the recent proposal from the Food and Drug Administration for the establishment of physician education programs for the prescribing of long-acting and extended-release opioids as part of their national opioid risk evaluation and mitigation strategy (the REMS program).<sup>25</sup> State efforts to address this issue have included the development of statewide opioid prescribing guidelines, such as those developed by the Utah Department of Health<sup>17</sup> and statewide ED opioid prescribing guidelines, such as those developed in Washington State by the Washington chapter of the American College of Emergency Physicians (ACEP) working with other state organizations.<sup>16</sup> Some individual EDs and emergency physician groups have also promulgated opioid prescribing guidelines. Some of these policies also deal with the necessity of patient education about the safe use and proper disposal of opioid medications. Early data indicate that, in some cases, these guidelines may decrease prescription opioid overdose.<sup>26</sup> Anecdotal experience suggests that public policies such as these may change patient perceptions of appropriate prescribing and mitigate complaints arising from more stringent prescribing practices. ACEP has approved related policy statements about optimizing the treatment of pain in patients with acute presentations and the implementation of electronic prescription drug monitoring programs.<sup>27,28</sup>

This clinical policy addresses several issues believed to be important in the prescribing of opioids by emergency physicians for adult patients treated and released from the ED for whom opioids may be an appropriate treatment modality. Although relieving pain and reducing suffering are primary emergency physician responsibilities, there is a concurrent duty to limit the personal and societal harm that can result from prescription drug misuse and abuse. Because long-acting or extended-release opioids are not indicated for the treatment of acute pain, the aim of this clinical policy is to provide evidence-based recommendations for prescribing short-acting opioids for adult ED patients with painful acute or chronic conditions while attempting to address the increasing frequency of adverse events, abuse, and overdose of prescribed opioid analgesics.

## METHODOLOGY

This clinical policy was created after careful review and critical analysis of the medical literature. The critical questions were formulated in the PICO (patient, intervention, comparison, outcome)<sup>29</sup> format to strengthen the clarity and scientific rigor of the questions. Searches of MEDLINE, MEDLINE InProcess, and the Cochrane Library were performed. All searches were limited to English-language sources, human studies, adults, and years 2000 to 2011. Specific key words/phrases and years used in the searches are identified under each critical question. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members were included.

This policy is a product of the ACEP clinical policy development process, including expert review, and is based on the literature; when literature was not available, consensus of panel members was used. Expert review comments were received from emergency physicians, toxicologists, pain and addiction medicine specialists, pharmacologists, occupational medicine specialists, and individual members of the American Academy of Clinical Toxicology, American Academy of Family Physicians, American Academy of Pain Medicine, American Chronic Pain Association, American College of Occupational and Environmental Medicine, American College of Osteopathic Emergency Physicians, American College of Physicians, American Pain Society, American Society of Health-System Pharmacists, American Society of Interventional Pain Physicians, Emergency Medicine Resident's Association, and Emergency Nurses Association. Their responses were used to further refine and enhance this policy; however, their responses do not imply endorsement of this clinical policy. Clinical policies are scheduled for revision every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly. The Centers for Disease Control and Prevention was the funding source for this clinical policy.

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members for quality and strength of evidence. The articles were classified into 3 classes of

evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic studies, respectively (Appendix A). Articles were then graded on dimensions related to the study's methodological features: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (eg, selection, detection, transfer), external validity (ie, generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula, taking into account the design and study quality (Appendix B). Articles with fatal flaws or that were not relevant to the critical question were given an "X" grade and were not used in formulating recommendations for this policy. Evidence grading was done with respect to the specific data being extracted and the specific critical question being reviewed. Thus, the level of evidence for any one study may have varied according to the question, and it is possible for a single article to receive different levels of grading as different critical questions were answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of this policy. Evidence grading sheets may be viewed at <http://www.acep.org/clinicalpolicies/?pg=1>.

Clinical findings and strength of recommendations about patient management were then made according to the following criteria:

**Level A recommendations.** Generally accepted principles for patient management that reflect a high degree of clinical certainty (ie, based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

**Level B recommendations.** Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (ie, based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

**Level C recommendations.** Other strategies for patient management that are based on Class III studies, or in the absence of any adequate published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

This policy is not intended to be a complete manual on the evaluation and management of adult ED patients with painful conditions where prescriptions for opioids are being considered, but rather is a focused examination of critical issues that have

particular relevance to the current practice of emergency medicine.

The goal of the ACEP Opioid Guideline Panel is to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain enough quality information to answer a critical question, the members of the ACEP Opioid Guideline Panel believe that it is equally important to alert emergency physicians to this fact.

Recommendations offered in this policy are not intended to represent the only management options that the emergency physician should consider. ACEP clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

**Scope of Application.** This guideline is intended for physicians working in hospital-based EDs.

**Inclusion Criteria.** This guideline is intended for adult patients presenting to the ED with acute noncancer pain or an acute exacerbation of chronic noncancer pain.

**Exclusion Criteria.** This guideline is not intended to address the long-term care of patients with cancer or chronic noncancer pain.

## CRITICAL QUESTIONS

1. In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse?

### Recommendations

**Level A recommendations.** None specified.

**Level B recommendations.** None specified.

**Level C recommendations.** The use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

Key words/phrases for literature searches: opioid, drug prescriptions, drug monitoring, drug utilization review, substance abuse detection, drug-seeking behavior, drug and narcotic control, substance-related disorders, physician's practice patterns, program evaluation, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Emergency physicians must balance oligoanalgesia (undertreatment or ineffectual treatment of pain) with concerns about drug diversion\* and doctor shopping.<sup>†30-33</sup> Therefore, the

\*Drug diversion: The diversion of drugs for nonmedical use through routes that do not involve the direct prescription of the drug by a provider. Diverted drugs might be provided by family or friends, purchased on the street market, or obtained through fraudulent prescription. Epidemiologic data suggest that most opioids used nonmedically are obtained through these means.

development of mechanisms to address these issues is justified. The expanded use of prescription drug monitoring programs to curb prescription opioid misuse was recommended in the 2011 Prescription Drug Abuse Prevention Plan released by the White House Office of National Drug Control Policy.<sup>34</sup> Prescription drug monitoring programs are state-based monitoring programs for certain controlled substances that are prescribed by licensed practitioners and dispensed by pharmacies. Although existing in various forms for more than 3 decades, the first effort to standardize prescription drug monitoring practice was the passage in 2005 of the National All Schedules Prescription Electronic Reporting Act (NASPER). Unfortunately, this federal legislative mandate that intended to harmonize prescription drug monitoring programs across the various states has yet to be fully funded.

Prescription drug monitoring programs ideally serve multiple functions, including identifying patients who engage in doctor shopping, and patients, providers, or pharmacies who engage in diversion of controlled substances and providing information about prescribing trends for surveillance and evaluation purposes. Such information may serve to benefit the patients, the health care system, epidemiologists, policymakers, regulatory agencies, and law enforcement.<sup>35</sup> Certain large health care systems, particularly closed prescribing systems such as the Veterans Administration and health maintenance organizations, maintain databases that allow prescribers to view recent prescriptions of enrolled clients or patients. Forty-one states have operational prescription drug monitoring programs of various complexity and capability, with an additional 7 states having prescription drug monitoring program legislation in place but with programs that are not yet operational.<sup>36</sup> Most states allow health care providers and pharmacists to access the programs for patients under their care. Other groups such as law enforcement and regulatory boards may also have access. One program tracks only schedule II drug prescriptions, whereas most track drug prescriptions of schedule II to IV or II to V drugs.

Despite prescription drug monitoring programs providing an intuitive perception of benefit for the medical community, there are limited data to indicate any benefit of these programs for improving patient outcomes or reducing the misuse of prescription drugs.<sup>37</sup> In part, this relates to the limited optimization of and standardization between the programs and the lack of a mechanism to allow interstate communication.<sup>35</sup>

†Doctor shopping: The practice of obtaining prescriptions for controlled substances from multiple providers, which is regarded as a possible indication of abuse or diversion. There is no rigorous definition, and various authors have defined it in different ways, from 2 or more prescribers within 30 days, greater than 4 during 1 year, and greater than 5 during 1 year.<sup>30-32</sup> It has also been defined as the amount of drug obtained through doctor shopping compared with the amount intended to be prescribed.<sup>33</sup> The use of "pill mills," in which a prescriber provides ready access to prescriptions or pills, can be considered a form of doctor shopping.

One study has demonstrated that compared with states without a prescription monitoring program, those with such a program had a slower rate of increase in opioid misuse.<sup>38</sup>

In an attempt to quantify the effect of a prescription drug monitoring program, Baehren et al<sup>39</sup> conducted a prospective study (Class III) of 18 providers who cared for a convenience sample of adult patients with pain in a single Ohio ED. After the clinical assessment of a patient, the researchers queried the providers about 3 patient-specific issues: (1) the likelihood of querying the state's prescription drug monitoring program, called Ohio Automated Rx Reporting System; (2) the likelihood of providing an opioid prescription at discharge; and (3) if yes, which opioid and what quantity. They were then provided with a printout of the patient data from the prescription drug monitoring program and asked to reassess the same questions. Of the 179 patients with complete data, information from the Ohio Automated Rx Reporting System altered prescribing practice in 74 of 179 (41%). The majority (61%) of these patients received fewer or no opioids, whereas 39% received more. The change in management was attributed to the number of previous prescriptions, 30 of 74 (41%); number of previous prescribers, 23 of 74 (31%); number of pharmacies used, 19 of 74 (26%); and number of addresses listed, 12 of 74 (16%). A limitation of this study was that 4 prescribers accounted for almost two thirds of the total patient encounters. In this study, knowledge of the information provided by a prescription drug monitoring program had an important impact on the prescription practices for controlled substances in an ED, although the actual effect of prescription drug monitoring program data on patient outcomes in this study is unknown.

Although not specifically evaluating the benefit of prescription drug monitoring programs on identifying high-risk patients, Hall et al,<sup>32</sup> in a Class III study, reviewed characteristics of decedents who died of prescription drugs in West Virginia and reported that opioid analgesics accounted for 93% of deaths. Cross-referencing the medical examiner's detailed analysis of the cause of death with the West Virginia prescription monitoring program, the authors determined the prescription history of the drug associated with each fatality. Patients who had received controlled drugs from 5 or more prescribers in the year before death were defined as engaging in "doctor shopping," whereas those whose death was not associated with a valid prescription were considered to have obtained their drugs through "diversion." Of the 295 deaths that were reviewed, the mean age of patients who died was 39 years, and 92% were between ages 18 and 54 years. Diversion was associated with 186 (63%) of the fatalities, and doctor shopping was associated with 63 (21%) of the fatalities. Of the 295 total decedents, 279 (95%) had at least 1 indicator of substance abuse, and these differed according to whether the drug was obtained through diversion or doctor shopping. Deaths involving diversion were associated with a history of substance abuse (82.3% versus 71.6%; odds ratio [OR] 1.8; 95% confidence interval [CI] 1.0 to 3.4), nonmedical route of

pharmaceutical administration (26.3% versus 15.6%; OR 1.9; 95% CI 1.0 to 3.8), and a contributory illicit drug (19.4% versus 10.1%; OR 2.1; 95% CI 1.0 to 4.9). Patients with evidence of doctor shopping were significantly more likely to have had a previous overdose (30.2% versus 13.4%; OR 2.8; 95% CI 1.4 to 5.6) and significantly less likely to have used contributory alcohol (7.9% versus 19.8%; OR 0.3; 95% CI 0.1 to 0.9). Few patients (8.1%) were involved in both doctor shopping and diversion. The study suggests that the information provided by a prescription drug monitoring program, with correct interpretation and action based on that knowledge, might have prevented some inappropriate prescribing and poor outcomes in this patient population.

In another Class III study, Pradel et al<sup>33</sup> monitored prescribing trends for buprenorphine in a select area of France, using a prescription drug database during a multiple-year period. During this time, a prescription drug monitoring program was implemented, allowing a before-after comparison of the buprenorphine prescribing pattern for more than 2,600 patients. The doctor shopping drug quantity, which was defined as the total drug quantity received by the patient minus the quantity prescribed by an individual provider, increased from 631 g in the first 6 months of 2000 to a peak of 1,151 g in the first 6 months of 2004, equivalent to 143,750 days of treatment at 8 mg/day. The doctor shopping ratio, determined as the ratio of the quantity delivered to the quantity prescribed, increased steadily from early 2000 (14.9% of the grams of drug prescribed) to a peak value in the first 6 months of 2004 (21.7%). After implementation of the prescription drug monitoring program in early 2004, this value decreased rapidly, in fewer than 2 years reaching the value observed in 2000. The points of inflection of the doctor shopping curves (quantity and ratio) coincided with the implementation of the prescription drug monitoring program, suggesting an immediate benefit of this program. The prescribed quantity did not change after the implementation, indicating that access to treatment may not have changed. Eighty percent of the total doctor shopping quantity of buprenorphine was obtained by approximately 200 (8%) of the total patients. However, it is difficult to make any inferences about the effect of a decrease in doctor shopping, given the fractional amount of total prescribing accounted for by this practice.<sup>33</sup> The authors suggested that the doubling in the street price of buprenorphine after the prescription drug monitoring program implementation was an indicator of success.

An observational study of opioid-related deaths by Paulozzi et al<sup>37</sup> highlights some important considerations in the assessment of the effectiveness of prescription drug monitoring programs. The authors assessed the mortality rate from 1999 to 2005 from schedule II and III prescription opioids in the United States and compared states that had prescription drug monitoring programs with those that did not. They further divided states with prescription drug monitoring programs into those that proactively informed prescribers, generally by mail, of potential

misuse and those that did not. This study found no difference in the mortality rates over time for states with and without a prescription drug monitoring program, nor did states with proactive prescription drug monitoring programs perform better than those with programs that were not proactive. There was a nonsignificantly lower rate of consumption of schedule II opioids and a significantly higher rate of consumption of hydrocodone (schedule III) in states that had a prescription drug monitoring program. A major limitation of this study is that the variability in the prescription drug monitoring program structure, including the ability of health care providers to access the database, was not considered. Current applicability is somewhat limited by substantial changes in the manner in which prescription drug monitoring programs function since the study was conducted, including the extent of physician access and the definition of patient inclusion criteria. Because of the practical limitation of the delay in informing the prescriber of a patient's potential drug misuse, the proactive notification aspect of these programs would have minimal effect on emergency medical practice in states that cannot provide prescription drug monitoring program data in real time.

In conclusion, there are no studies that directly evaluate the effect of real-time, voluntary access to a prescription drug monitoring program on prescribing practices of emergency physicians. In addition, the broader effect of such access on diversion, abuse, doctor shopping, mortality, and the possibility of pain undertreatment remains undefined. Prescription drug monitoring programs have many limitations in their current format, including complex access issues, limitations on access permission, thresholds for patient listing, timeliness, interstate communication, and whether the data are presented to the physician automatically or require physician effort to retrieve. Furthermore, the recent addition of prescription drug monitoring programs in several states and continuing changes in the structure or function of existing programs limit the direct application of even recently published research. Legislation designed to improve prescription drug monitoring program operation (eg, NASPER) has stalled or remained underfunded, and concerns over patient confidentiality have often trumped public health concerns. Until an interstate, frequently updated, multiple-drug-schedule, easily accessible, widely used prescription drug monitoring system is implemented, the likelihood of success is limited.<sup>35</sup>

## 2. In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications?

### Recommendations

**Level A recommendations.** None specified.

**Level B recommendations.** None specified.

**Level C recommendations.** (1) For the patient being discharged from the ED with acute low back pain, the

emergency physician should ascertain whether nonopioid analgesics and nonpharmacologic therapies will be adequate for initial pain management.

(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or nonopioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.

(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

**Key words/phrases for literature searches:** acute low back pain, opioid, and variations and combinations of the key words/phrases.

Acute low back pain is a common ED presenting complaint. Opioids are frequently prescribed, expected, or requested for such presentations.<sup>40,41</sup> In a recent study, it was estimated that low back pain-related disorders result in approximately 2.6 million annual ED visits in the United States. Of medications either administered in the ED or prescribed at discharge, the most frequently used classes were opioids (61.7%; 95% CI 59.2% to 64.2%), nonsteroidal anti-inflammatory drugs (NSAIDs) (49.6%; 95% CI 46.7% to 52.3%), and muscle relaxants (42.8%; 95% CI 40.2% to 45.4%).<sup>41</sup> The opioid analgesics most commonly prescribed for low back pain, hydrocodone and oxycodone products, are also those most prevalent in a Government Accountability Office study of frequently abused drugs.<sup>42</sup> Low back pain as a presenting complaint was also observed in a recent study to be associated with patients at higher risk for opioid abuse.<sup>43</sup> Low back pain, although a common acute presentation, is also often persistent and recurrent, with 33% of patients continuing to complain of moderate-intensity pain and 15% of severe pain at 1 year from initial presentation. Symptoms recur in 50% to 80% of people within the first year.<sup>44</sup> In one study, 19% reported opioid use at a 3-month follow-up.<sup>40</sup> Emergency physicians, as a specialty, are among the higher prescribers of opioid pain relievers for patients aged 10 to 40 years.<sup>20</sup> Recent data show simultaneous increases in overall opioid sales rates and prescription opioid-related deaths and addiction rates and suggest that widespread use of opioids has adverse consequences for patients and communities.<sup>8</sup>

There is a paucity of literature that addresses the use of opioids after ED discharge for acute low back pain versus the use of NSAIDs or the combination of NSAIDs and muscle relaxants. Two meta-analyses published in the last 5 years identified relatively few valid studies that address the use of opioids for low back pain.<sup>45,46</sup>

In a Class III 2008 Cochrane review, NSAIDs were compared with opioids and muscle relaxants for the treatment of low back pain.<sup>46</sup> Three studies were reviewed that compared opioids (2 of which are no longer in use) with NSAIDs for treatment of acute low back pain, including 1 study considered by the Cochrane reviewers to be of higher quality.<sup>47</sup> None of

the individual studies found statistically significant differences in pain relief. A Class III review by McIntosh and Hall<sup>45</sup> of clinical evidence for treatment of acute low back pain similarly found no evidence for superiority of opioids over other therapies and no direct information to demonstrate that opioids were better than no active therapy; however, the authors concluded that the opioid-related studies were too small to detect any clinically important differences.

A Class III Cochrane review of NSAID treatment for acute low back pain evaluated 65 studies (including more than 11,000 patients) of mixed methodological quality that compared various NSAIDs with placebo, other drugs, other therapies, and other NSAIDs.<sup>46</sup> The review authors concluded that NSAIDs are slightly effective for short-term symptomatic relief in patients with acute and chronic low back pain without sciatica (pain and tingling radiating down the leg). In patients with acute sciatica, no difference in effect between NSAIDs and placebo was found but moderate efficacy was found for opioids. The systematic review also reported that NSAIDs are no more effective than other drugs (acetaminophen, opioids, and muscle relaxants). Placebo and acetaminophen had fewer adverse effects than NSAIDs, and NSAIDs had fewer adverse effects than muscle relaxants or opioids.

A 2003 Cochrane review of muscle relaxants for low back pain (Class X because it did not address the role of opioids) found that muscle relaxants were effective for short-term symptomatic relief in patients with acute and chronic low back pain.<sup>48</sup> However, muscle relaxants were associated with a high incidence of adverse effects. This study cited strong evidence in 4 trials involving a total of 294 people that oral nonbenzodiazepine muscle relaxants are more effective than placebo in patients with acute low back pain for short-term pain relief, global efficacy, and improvement of physical outcomes.

Although no superiority has been demonstrated for opioids over other therapies for treatment of acute low back pain, groups have recommended against use of opioids as first-line therapy for treatment of this problem.<sup>49,50</sup> A guideline for diagnosis and treatment of low back pain endorsed by the American College of Physicians and the American Pain Society recommends opioids only for severe, disabling pain that is not controlled or not likely to be controlled with acetaminophen or NSAIDs.<sup>49</sup> In their 2007 guidelines, the American College of Occupational and Environmental Medicine stated that routine use of opioids for acute, subacute, or chronic low back pain is not recommended.<sup>50</sup>

Several observational non-ED studies also suggest caution with regard to opioid prescribing for back pain. Franklin et al,<sup>51</sup> in a retrospective study (Class X because of the non-ED patient population), found that workers with acute low back injury and worker's compensation claims who were treated with prescription opioids within 6 weeks of acute injury for more than 7 days had a significantly higher risk for long-term disability. In a subsequent Class III population-based prospective study of opioid use among injured Washington

State workers with low back pain, Franklin et al<sup>52</sup> observed a strong association between the amount of prescribed opioids received early after injury and long-term use of prescription opioids. A retrospective study of 98 workers with acute low back pain and subsequent disability claims by Mahmud et al<sup>53</sup> found that patients whose treatment of new work-related low back pain involved opioid use for 7 days or more were more likely to have long-term disability (relative risk 2.58; 95% CI 1.22 to 5.47); however, the direct applicability of this study (Class X) was limited because most patients were not seen in the ED. In another study that addressed associations of long-term outcome with opioid therapy for nonspecific low back pain, Volinn et al<sup>54</sup> found that the odds of chronic work loss were 11 to 14 times greater for claimants treated with schedule II ("strong") opioids compared with those not treated with opioids at all. They further observed that the strong associations between schedule II use and long-term disability suggest that for most workers, opioid therapy did not arrest the cycle of work loss and pain. Although this study was also graded as Class X because of the population selected and failure to directly address acute or immediate benefit, the results highlight potential problems of treating acute low back pain with opioids.<sup>54</sup> Unfortunately, causation cannot be directly inferred from these studies because of possible confounding.

In summary, although opioids currently offer the most potent form of pain relief, there is essentially no published evidence that the prescription of opioid analgesics for acute low back pain provides benefit over other available medications or vice versa. Several observational studies suggest associations of both prescription of "strong" opioids or longer prescription duration (greater than 7 days) and early opioid prescribing with worsened functional outcomes. Additionally, as noted, the overall increased rate of opioid sales has been strongly associated with adverse effects in the community (overdose, addiction, aberrant use, and death).<sup>8</sup> Therefore, it can be recommended that opioids not be routinely prescribed for acute low back pain but reserved for select ED patients with more severe pain (eg, sciatica) or pain refractory to other drug and treatment modalities. Prescriptions for opioids should always be provided for limited amounts and for a limited period. Extra caution (such as use of prescription drug monitoring programs and seeking of collateral patient information such as patient visit history) may be indicated for patients identified as possibly having an increased risk for substance dependence or abuse.

### **3. In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids?**

#### **Recommendations**

*Level A recommendations.* None specified.

*Level B recommendations.* For the short-term relief of acute musculoskeletal pain, emergency physicians may prescribe short-acting opioids such as oxycodone or hydrocodone

products while considering the benefits and risks for the individual patient.

**Level C recommendations.** Research evidence to support superior pain relief for short-acting schedule II over schedule III opioids is inadequate.

Key words/phrases for literature searches: opioids, schedule II narcotics, schedule III narcotics, acute pain, acute disease, emergency service, and variations and combinations of the key words/phrases.

Schedules II and III are classifications established by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and determined by the Drug Enforcement Administration. Among other criteria, classification decisions for specific drugs are based on judgments about the potential for their abuse. Schedule II opioids include morphine (eg, MS Contin), oxymorphone (eg, Opana), oxycodone (eg, Roxicodone) and oxycodone combination products (eg, Percocet, Percodan), as well as hydromorphone (eg, Dilaudid) and fentanyl (eg, Duragesic patch, Actiq). Schedule III opioids include combination products, such as hydrocodone (15 mg or less) combined with acetaminophen (eg, Vicodin, Lortab) or ibuprofen (eg, Vicoprofen), as well as some of the codeine combination products.<sup>55</sup> Schedule classifications for opioids may change over time in response to a number of factors, including their perceived risk of abuse. Calls to reclassify hydrocodone combination products (eg, Vicodin, Lortab) from schedule III to schedule II have increased in recent years in response to increasing levels of abuse of these substances.

These recommendations address only new-onset acute pain. Long-acting or extended-released schedule II products such as oxycodone ER (OxyContin), methadone, fentanyl patches, or morphine extended-release (MS Contin) are indicated for chronic pain and should not be used for acute pain.<sup>56</sup> Long-acting and extended-release opioids are for use in opioid-tolerant patients only and are not intended for use as an "as-needed" analgesic. In addition, the immediate-release oral transmucosal formulations of fentanyl are indicated only for breakthrough pain relief in cancer patients who are already taking sustained-release medications and are opioid tolerant. These formulations should not be used for acute new-onset pain.

As part of the decision to prescribe opioids for new onset of acute pain, the care provider can select between short-acting schedule II or III agents (Table). In general, equianalgesic doses of opioids are equally efficacious in relieving pain. Therefore, *a priori*, there is no reason to consider an equianalgesic dose of a short-acting schedule II opioid more effective in providing pain relief than a short-acting schedule III opioid. However, some studies have compared schedule II and III opioids combined with nonopioid analgesics with one another. Two prospective randomized controlled trials have compared the efficacy of short-acting oxycodone, a schedule II drug, with hydrocodone combination products (schedule III) and found them to be equal.<sup>57,58</sup> In 2005, Marco et al<sup>57</sup> compared single doses of

**Table.** Short-acting oral opioid formulations. Dose and interval are recommended starting dosing ranges.

Medication	Initial Dose/Interval	Schedule
Codeine/APAP	30-60 mg* PO Q4-6h PRN	III
Codeine	30-60 mg PO Q4-6h PRN	II
Hydrocodone/APAP	5-15 mg* PO Q4-6h PRN	III
Hydromorphone	2-4 mg PO Q4-6h PRN	II
Morphine	15-30 mg PO Q4-6h PRN	II
Oxycodone/APAP	5-15 mg* PO Q4-6h PRN	II
Oxycodone	5-15 mg PO Q4-6h PRN	II
Oxymorphone	10-20 mg PO Q4-6h PRN	II

APAP, acetaminophen; h, hour; mg, milligram; PO, by mouth; PRN, as needed; Q, every.

\*Listed dose is of the opioid component. Note that the acetaminophen component is now limited to 325 mg or less per pill.

oxycodone 5 mg with hydrocodone 5 mg (both combined with 325 mg acetaminophen). In this single-site Class II study of 67 adolescent and adult subjects with acute fractures, no differences in analgesic efficacy were observed at 30 or 60 minutes. Constipation rates were higher for hydrocodone. In a 2002 Class I study, Palangio et al<sup>58</sup> compared oxycodone 5 mg combined with acetaminophen 325 mg (schedule II) with hydrocodone 7.5 mg combined with ibuprofen 200 mg (schedule III) in a prospective, multicenter, multidose, randomized controlled trial of 147 adults with acute or recurrent low back pain. During an 8-day study period, no differences were found in pain relief, doses taken, global evaluations of efficacy, health status, or pain interference with work. As noted above, equianalgesic doses of opioids have similar efficacy in the treatment of acute pain, no matter their Drug Enforcement Administration classification. Given this understanding, it was not unexpected that 2 randomized controlled trials comparing schedule II with III agents found no differences in analgesic efficacy.

**4. In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?**

**Recommendations**

**Level A recommendations.** None specified.

**Level B recommendations.** None specified.

**Level C recommendations.** (1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic noncancer pain seen in the ED.

(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

(3) The clinician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and

consider past prescription patterns from information sources such as prescription drug monitoring programs.

Key words/phrases for literature searches: opioid, patient discharge, pain, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Patients with chronic noncancer pain, either already taking opioids or not, commonly present to the ED for treatment of acute exacerbation of their pain. There have been no studies that evaluate the efficacy or potential harms of prescribing opioids specifically for these patients on discharge from the ED. Thus, given the paucity of evidence, this critical question cannot be definitively answered. Despite the biological plausibility that treating any acute exacerbation of pain with parenteral or oral opioids should decrease pain intensity, no studies were found to support this hypothesis.

Only 2 randomized controlled trials were identified that addressed the use of short-acting opioids for the treatment of breakthrough pain in patients taking opioids for chronic noncancer pain; transmucosal fentanyl was the intervention for both trials.<sup>59,60</sup> Because of methodological problems, valid estimates for efficacy of the intervention could not be determined, but adverse event rates among both treated populations were common and similar (range 63% to 65%) (Class III).

A systematic review of nonrandomized studies by Devulder et al<sup>61</sup> examined the effect of rescue medications on overall analgesic efficacy and adverse events. They examined 48 studies of patients treated with long-acting opioids for chronic noncancer pain and compared the analgesic efficacy and adverse events among those that allowed short-acting opioid rescue medications for breakthrough pain with those that did not allow such rescue medications. Although graded Class X because of lack of randomized studies and the limitation of harms studied to adverse effects only, no significant difference in the analgesic efficacy between the rescue and nonrescue studies was found. There was also no difference between these 2 groups in the incidence of nausea, constipation, or somnolence. Kalso et al,<sup>62</sup> in a Class III systematic review, found that 80% of patients receiving opioids for chronic noncancer pain had at least 1 adverse event, including nausea (32%), constipation (41%), and somnolence (29%).

Studies of the use of opioids for chronic pain indicate that adverse effects of these drugs are common. Several studies assessed the adverse effects with the use of tramadol with acetaminophen in the treatment of patients with chronic low back pain.<sup>63-65</sup> All of the studies had high dropout rates and reported adverse event rates of nausea, dizziness, and somnolence between 8% and 17%. Allan et al,<sup>66</sup> in a nonblinded Class III study comparing transdermal fentanyl versus oral morphine, found a constipation rate of 48% in the morphine-treated patients compared with a rate of 31% in the fentanyl-treated patients. Constipation was also the major adverse effect in a Class III study by Hale et al<sup>67</sup> comparing oxycodone extended release, oxycodone controlled release,

and placebo. Furlan et al,<sup>68</sup> in a Class II meta-analysis of 41 randomized studies of opioid use in the treatment of chronic noncancer pain, found that constipation and nausea were the only significant adverse effects. Holmes et al,<sup>69</sup> however, in a Class III study, assessed an opioid screening instrument, the Pain Medication Questionnaire, in chronic noncancer pain patients and found that those patients with a higher score were more likely to have a substance abuse problem or request early refills of their opioid prescription. In a retrospective Class III cohort study, Jensen et al<sup>70</sup> conducted a 10-year follow-up on patients discharged from a pain clinic and found that chronic opioid treatment may put patients at risk for chronic depression. Unfortunately, near-universal shortcomings of these studies include the exclusion of patients with a history of substance abuse, other significant medical problems, or psychiatric disease, and lack of follow-up to detect long-term effects such as aberrant drug-related behaviors, addiction, or overdose. Therefore, studies such as these can be confounded, making the ability to draw conclusions about causality difficult.

Questions of opioid effectiveness involve the assessment of reduction in pain and improvement in function for the patient, potential patient adverse effects, and the potential harm to the community (eg, opioid diversion and abuse) from the drugs prescribed. Hall et al,<sup>32</sup> in a Class III retrospective analysis of 295 unintentional prescription overdose deaths, found that 93% were due to opioids, 63% represented pharmaceutical drug diversion, 21% of the patients had engaged in doctor shopping, and 95% of the patients had a history of substance abuse. Although no studies have addressed the effects related to dose and duration of prescribed opioids in this specific patient population, 2 general studies have shown a correlation between high daily opioid dose and overdose death.<sup>71,72</sup>

Patient assessment tools such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), Opioid Risk Tool (ORT), Diagnosis, Intractability, Risk, and Efficacy (DIRE), and others to assess the risk of prescription opioid misuse and abuse have yet to be fully validated in the ED in terms of sensitivity, specificity, and utility.<sup>73</sup> Many, however, believe that use of these tools, as imperfect as they are, represents a beginning in the ability to better quantify potential risks related to opioid prescribing for outpatients.

Many patients undergoing treatment for chronic noncancer pain have pain contracts/treatment agreements with their primary care providers. These should be honored if possible in treating any acute exacerbation of their pain.<sup>74,75</sup> As discussed in critical question 1, use of prescription drug monitoring programs may also assist the emergency physician in making appropriate clinical decisions about the use of outpatient opioid prescriptions for these patients.

## FUTURE RESEARCH

Provider pain management practices related to opioids are highly variable. In part, this variability reflects the lack of evidence to guide many of these therapeutic decisions.<sup>76</sup>

Although there is high-quality research assessing the treatment of acute pain with opioid analgesics during the ED encounter, there is a paucity of studies assessing the benefits of prescribing opioids for discharged ED patients with acute pain and chronic noncancer pain, especially in comparison to other analgesic drugs and pain treatment modalities. Therefore, clinical decisions and practice recommendations must rely on practice experience and consensus rather than research evidence.

ED populations typically include patients with unmet substance abuse treatment needs and psychiatric comorbidities, and many of these patients present with acute pain.<sup>77</sup> In almost all pain studies, these patients are excluded, leaving clinicians with little evidence-based guidance for their pain management. There are also significant research gaps in clearly understanding the long-term harms of opioids, including drug abuse and addiction, aberrant drug-related behaviors, and diversion. As mentioned above, further research and validation is needed on ED patient abuse and addiction-related assessment tools. Additional studies to characterize individual patient-related risks for opioid abuse are also greatly needed.

Although there has been recent widespread adoption of prescription monitoring programs, there remains a dearth of evidence about the effectiveness of these programs in altering physician prescribing patterns or diminishing the adverse effects of opioids in the community. For research in this area to advance, further refinement of prescribing metrics (quantity, duration, and frequency) and public health measures is required. Comparison of the functionality and effectiveness of the various state prescription drug monitoring program models may provide additional insight into developing best practices that could be adopted nationally, including the sharing of data between states. Important distinctions among the states, such as immediate online prescriber access to the prescription monitoring program, should be examined for their relative contributions. However, this type of analysis must consider baseline variability among states for prescription opioid misuse (versus heroin or methadone, for example) and other state-specific issues (such as prescription-writing regulations).

With respect to the treatment of acute low back pain in the ED, there is a need for quality studies comparing the effectiveness of the more commonly prescribed opioids (hydrocodone and oxycodone congeners and other semisynthetic opioids) and nonopioid therapies, with attention to confounding variables such as depression or other psychopathology. Further study is needed to validate or refute the reported associations of early or potent opioid prescribing with increased rates of disability.<sup>51</sup> Given the frequency of acute low back pain as an ED presentation and its association with perceived drug-seeking behavior,<sup>78</sup> and with apparent higher risk for misuse,<sup>43</sup> more attention needs to be paid to discriminatory historical or physical factors that may be predictive of drug-seeking or abuse to allow better matching of treatment modality for individual patients.

Future studies should include additional multiple-dose analgesic protocols to better understand the postdischarge experience of patients with acute pain and what would constitute optimum patient follow-up provisions. Investigators should include clinically relevant study periods (days to weeks), which vary by diagnosis; thus, trials should be stratified by specific presenting complaints, pain site, discharge diagnosis, and classification of pain type, ie, nociceptive, neuropathic, and visceral pain. In addition to measuring pain and adverse effects, functional outcomes, such as return to work or pain-related quality-of-life measures, should be included.<sup>79</sup> Straightforward observational studies are needed to determine the relative duration of different acute pain presentations, thus informing decisions to prescribe an appropriate number of opioid doses per prescription. Current prescribing practice often involves a "one size fits all" pattern that is encouraged by electronic prescribing software. Prescribing practices that ignore variable durations of acute pain syndromes will predictably result in undertreatment for some patients and overtreatment for others. The latter increases the likelihood that unused opioids will be diverted into nonmedical use in communities at risk.

Additional research should include evaluation of the appropriateness of patient satisfaction as a quality metric as related to patient expectations of opioids and the prevalence of providers reporting pressure through low patient satisfaction scores or administrative complaints to provide opioids when the providers believe these drugs are not medically indicated. This issue may gain increased importance with the institution of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which may tie some reimbursement to patient satisfaction scores. Additional work is needed to investigate what constitutes an appropriate educational curriculum in both medical school and residency for physician education concerning safe, appropriate, and judicious use of opioids.

Research addressing the treatment of chronic noncancer pain would be enhanced by the use of accepted case definitions, standardized definitions of adverse events, and validated pain measurements. Case definitions should use a similar definition of chronic, nociceptive (musculoskeletal or visceral) versus neuropathic pain, or pain by disease type (headache, low back pain, etc). Research reporting also requires more refined descriptions of opioid potency and routes of administration.

Although opioids represent a treatment modality that has long been used in patient care, it is clear by the paucity of definitive answers to the questions posed in this document and the significant number of future research issues that much work remains to be done to clarify the best use of opioids in the care of patients.

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American Chronic Pain Association and has previously been a consultant to the pharmaceutical industry.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical questions.

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Evidentiary Table.

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hall et al <sup>32</sup>	2008	Retrospective, population based, observational study	Comparison of West Virginia medical examiner data with patient data from the state prescription monitoring program and opioid abuse treatment program records	Behaviors of those who died of a pharmaceutical overdose; diversion; doctor shopping; substance abuse history; type of drug	295 deaths; 67% male; 92% aged 18-54 y; 63% pharmaceutical diversion; 21% doctor shopping; 95% substance abuse history; 93% opioids	Actual source of opioids involved in death not known; single state; not validated definitions; retrospective	III
Pradel et al <sup>33</sup>	2009	Database	Review of prescription drug database (not prescription monitoring program) to identify amount of buprenorphine delivered, prescribed, and obtained by doctor shopping; extension of 2004 study, used multiple time period comparisons; evaluation of trends in doctor shopping over time	Determined prescribed quantity of buprenorphine, delivered quantity, and the doctor shopping quantity	Although there was some variation over time, the trend for prescribing stayed constant overall and doctor shopping decreased after 2004, associated with the change in the mechanism by which prescriptions are monitored	Reasons for multiple providers or overlapping or interrupted prescriptions unclear; did not examine risk factors for abuse	III
Baehren et al <sup>39</sup>	2010	Prospective, uncontrolled	Physicians prescribing analgesics for nonacute pain were asked details about the patient's prescription and then again after being informed of the prescription monitoring program search result for that patient	Change in prescription for the specific patient	179 enrolled; management changed in 41%; 61% received fewer opioids, 39% received more	Convenience sample; majority of data from 4 prescribers	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
McIntosh and Hall <sup>25</sup>	2011	Review of randomized controlled trials, systematic reviews, and observational studies found searching MEDLINE 1966-12/2009, EMBASE 1980 to 12/2009, and Cochrane database up to 12/2009; 49 studies met inclusion criteria	Multiple treatment modalities for acute low back pain, including oral drugs, local injections, and nondrug treatment	Clinical improvement of low back pain	NSAIDs shown to effectively improve symptoms compared with placebo, but use associated with gastrointestinal adverse effects; muscle relaxants may reduce pain and improve clinical assessment but are associated with adverse effects including drowsiness, dizziness, nausea	The studies examining the effects of analgesics such as acetaminophen or opioids were generally too small to detect any clinically important differences	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Roelofs et al. <sup>46</sup>	2008	Cochrane review: search of MEDLINE, EMBASE, and Cochrane central registry of controlled trials up to 7/2007; 65 trials qualified for review	NSAIDs and COX-2 inhibitors administered to treat low back pain	Clinical improvement of low back pain	Review authors found NSAIDs are not more effective than other drugs (acetaminophen, opioids, and muscle relaxants); placebo and acetaminophen had fewer adverse effects than NSAIDs, although the latter had fewer adverse effects than muscle relaxants and opioids; the new COX-2 NSAIDs do not seem to be more effective than traditional NSAIDs but are associated with fewer adverse effects, particularly stomach ulcers, although other literature has shown that some COX-2 NSAIDs are associated with increased cardiovascular risk	7 studies reported on acute low back pain. 5 of which, including 1 higher-quality study, did not find any statistical differences between NSAIDs and opioids or muscle relaxants; there is moderate evidence that NSAIDs are not more effective than other drugs for acute low back pain	III
Videman et al. <sup>47</sup>	1984	Double-blind parallel study	70 patients; comparative trial of meptazinol vs diflunisal for up to 3 wk	Patients examined at 1-wk intervals for task capability, range of motion, and subjective pain self-assessment	Both regimens produced marked improvement in most parameters, similar adverse effect profiles	No mention of patient randomization	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Franklin et al <sup>52</sup>	2009	Prospective cohort; Washington State workers with back injury; n=1,883	Prospective cohort of workers with back injuries interviewed at 18 days (medial) and 1 y after injury; pharmacy data obtained from computerized records; analyzed for demographic and covariates	Injury severity, pain, function, and quantities of opioids used	For long-term users total number of medications increased significantly ( $P=.01$ ) from the first to the fourth quarter; after adjustment for baseline pain, function, and injury severity, the strongest predictor of longer-term opioid prescriptions was total number of medications in the first quarter; receipt of $\geq 10$ mg/day medicine in first quarter more than tripled the odds of receiving opioids long term, and receipt of $\geq 40$ mg/day medicine in first quarter had 6-fold odds of receiving long-term opioids; amount of prescribed opioid received early after injury predicts long-term use	Addressed progression to long-term use according to initial treatment and continuation of same	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Marco et al <sup>57</sup>	2005	Single site; prospective; double blind; randomized controlled trial; concealment method described; ED patients with fractures	Single dose of oxycodone 5 mg/acetaminophen 325 mg schedule II vs hydrocodone 5 mg/acetaminophen 325 mg schedule III	Primary outcomes were numeric pain scores (0-10) at 30 and 60 min	88 subjects evaluated, 73 enrolled, 67 completed ED study period, 35 to oxycodone, 32 to hydrocodone; no baseline differences, no differences in outcomes at 30 min: -0.6 (95% CI -1.8 to 0.5); 60 min -0.5 (95% CI -2.0 to 1.0); adverse effects higher for constipation with hydrocodone (21% vs 0%; 95% CI 3% to 39%)	Small sample size powered to address acute pain during the first 30 to 60 min in the ED; study also assessed adverse effects during a longer period of time; excluded history of alcohol or opioid or other substance abuse; limited time period	II
Palangio et al <sup>38</sup>	2002	Prospective multicenter (18 sites), randomized controlled trial, sequential assignment by computer-generated randomization schedule	Hydrocodone 7.5 mg/ibuprofen 200 mg (schedule III) vs oxycodone 5 mg/acetaminophen 325 mg (schedule II)	Primary outcome was mean daily pain relief score at endpoint (day 8 or day of discontinuation), study period up to 8 days, intention-to-treat analysis	147 subjects enrolled (75 hydrocodone/ibuprofen, 72 oxycodone/acetaminophen), adults with acute or recurrent low back pain requiring opioids, 85% completed study in both groups, mean days to endpoint 6.5 vs 6.9 days, no baseline differences, no differences in pain relief, number of pills, global evaluations, SF-36, pain interference with work, adverse events	Excluded drug or alcohol abuse, concealment methods described	I

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Portenoy et al <sup>59</sup>	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic low back pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain in chronic low back pain; adverse effects in 65%; 34% during double-blind phase	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Simpson et al <sup>60</sup>	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain; adverse effects in 63%; 22% dropout	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Kalso et al <sup>62</sup>	2004	Systematic review	Randomized trials in chronic noncancer pain comparing potent opioids with placebo	Pain intensity outcomes	15 randomized trials were included; 11 studies compared oral opioids for 4 wk; pain intensity decrease was 30% compared with placebo; only 44% were taking opioids by mo 7 to 24; 80% of patients experienced at least 1 adverse event: constipation (41%), nausea (32%), somnolence (29%)	4-wk duration on average; differing causes of pain; open label in many of the studies; limited power calculations; concealment not maintained in some studies	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Peloso et al <sup>63</sup>	2004	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; 3-mo trial	336 patients randomized; improved mean final pain scores (47 vs 63; $P<.001$ ), adverse effects: nausea 12%, dizziness 11%, constipation 10%, somnolence 9%	35%-40% dropout rate; pharmaceutical-sponsored research	II
Ruoff et al <sup>64</sup>	2003	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; Roland Disability Questionnaire	318 patients randomized; tramadol improved pain VAS ( $P=.15$ ) and final Pain Relief Rating Scale ( $P<.001$ ); adverse effects: nausea 13%, somnolence 12%, constipation 11%, dizziness 8%	153 of 318 dropped out; pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Schnitzer et al <sup>65</sup>	2000	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Time to discontinuation because of inadequate pain relief; Short Form Magill Pain Questionnaire; Roland Disability Questionnaire	380 patients in open-label phase; 254 entered into blinded phase; time to therapeutic failure was greater in the placebo group ( $P<.0001$ ); other parameters showed improvement; adverse effects: nausea 17%, dizziness 15%, somnolence 14%, headache 12%	The dropout rate was the primary outcome; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Allan et al <sup>66</sup>	2005	Nonblinded, randomized comparison of 2 treatments in patients with chronic low back pain	Transdermal fentanyl vs sustained-release oral morphine; 680 total patients; dose titrated to effect; followed for 13 mo; outpatient setting; not applicable to ED	Pain relief (VAS scale); bowel function (validated questionnaire); quality of life (SF-36); disease, progression (3-point scale), days not working, adverse events all during 13 mo	Comparable pain relief, noninferior, VAS score for fentanyl (56) vs morphine (55); fentanyl had lower constipation rate: fentanyl (31%) vs morphine (48%)	Both groups had half of the participants drop out; vague definition of chronic low back pain; not blinded	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hale et al <sup>67</sup>	2005	Randomized trial, blinded	Comparison of oxymorphone extended-release vs oxycodone controlled-release vs placebo in patients with chronic low back pain who were taking a stable dose of opioids	VAS of pain score 4 h after morning dose; use of breakthrough pain medications; categorical pain intensity, pain intensity, global assessment, adverse events	Opioids were superior to placebo at reducing VAS for pain compared with placebo, oxymorphone or morphine (-27), oxycodone (-36); oxymorphone was comparable to oxycodone in pain efficacy and adverse effects; sedation and constipation were more common with opioids (35% vs 29% vs 11%)	Only 22 of 75 patients in the placebo group completed the study; included only patients receiving stable opioids and then randomized to opioids or placebo; baseline characteristics between groups not specified; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Furian et al <sup>68</sup>	2006	Meta-analysis	Study included randomized trials of any opioid for chronic noncancer pain (defined as pain for longer than 6 mo) vs placebo or some other nonopioid treatment	41 randomized studies with 6,019 patients evaluated for effectiveness and adverse effects; most (80%) had nociceptive pain	81% of the studies were believed to be of high quality; dropout rates were 33% in the opioid group and 38% in the placebo group; opioids improved pain and functional outcomes compared with placebo in nociceptive and neuropathic pain; strong opioids were superior to naproxen and nortriptyline for pain relief; weak opioids were not superior; constipation and nausea were the only significant adverse effects observed	Average duration of the study was 5 wk (range 1-16 wk); adequate random patient assignment in only 17 of 41 trials; 90% of trials were pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Holmes et al <sup>69</sup>	2006	Prospective cohort	Convenience sample of patients who were new at a pain clinic; Pain Medication Questionnaire was administered; patients were treated with interdisciplinary treatment and/or medications alone, depending on the results of an initial evaluation	Beck Depression Inventory; Confidential Pain questionnaire; SF-36; Million VAS; Oswestry Disability Questionnaire; Physician Risk Assessment; VAS	271 patients, divided into low-, medium-, and high-score pain medication questionnaire; high-score group was more likely to have a known substance use problem (OR 2.6), request early refills (OR 3.2), or drop out of treatment (OR 2.3)	Only 26% of patients completed the full treatment program; heterogeneous types of pain diagnosis; differing treatment plans	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Jensen et al <sup>70</sup>	2006	Retrospective review of cohort	Patients who were treated and discharged from a pain clinic 10 y ago; medical records were abstracted and questionnaires were sent to willing participants	Demographics, health care utilization, SF-36; Hospital Anxiety and Depression Scale; Coping Strategy Questionnaire; CAGE* test	160 patients; 60% of patients were still taking long-acting opioids; dose escalation was unusual; chronic users had lower health-related quality of life and higher occurrence of depression	160 of 279 possible patients participated; no control group	III

COX-2, cyclooxygenase-2; ED, emergency department; h, hour; mg, milligram; min, minute; mo, month; NSAID, nonsteroidal anti-inflammatory drug; OR, odds ratio; SF-36, Short-Form Health Survey; VAS, visual analog scale; vs, versus; wk, week; y, year.  
 \*CAGE (Cutting down, Annoyed, Guilty, Eye-opener) test is a method of screening for alcoholism.

**Appendix A.** Literature classification schema.\*

Design/Class	Therapy <sup>†</sup>	Diagnosis <sup>‡</sup>	Prognosis <sup>§</sup>
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)

\*Some designs (eg, surveys) will not fit this schema and should be assessed individually.

<sup>†</sup>Objective is to measure therapeutic efficacy comparing interventions.

<sup>‡</sup>Objective is to determine the sensitivity and specificity of diagnostic tests.

<sup>§</sup>Objective is to predict outcome, including mortality and morbidity.

**Appendix B.** Approach to downgrading strength of evidence.

Downgrading	Design/Class		
	1	2	3
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

## Appendix 2 - Older Adults

### Older Adults<sup>17</sup>

The prevalence of pain among older adults has been estimated between 25% and 50%. The prevalence of pain in nursing homes is even higher. Unfortunately, managing pain in older adults is challenging due to: underreporting of symptoms; presence of multiple medical conditions; polypharmacy; declines in liver and kidney function; problems with communication, mobility and safety; and cognitive and functional decline in general.

Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding, renal toxicities, and cognitive side-effects that have been observed with NSAIDs in older adults (although acetaminophen may pose a risk of liver damage). Opioids must be used with particular caution and clinicians should “start low, go slow” with initial doses and subsequent titration. Clinicians should consult the American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults for further information on the many medications that may not be recommended.

The various challenges of pain management in older adults, only sketched here, suggest that early referral and/or consultation with geriatric specialists or pain specialists may be advisable.

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<sup>17</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

## Appendix 3 - Pediatric Patients

### Pediatric Patients<sup>18</sup>

Children of all ages deserve compassionate and effective pain treatment. In fact, due to their more robust inflammatory response and immature central inhibitory influences, infants and young children actually may experience greater pain sensations and pain-related distress than adults. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that opioids have a place in the treatment armamentarium. Developmental differences, however, can make opioid dosing challenging, especially in the first several months of life. In the first week of a newborn's life, for example, the elimination half-life of morphine is more than twice as long as that in older children and adults, as a result of delayed clearance. For older children, dosing must be adjusted for body weight.

Although a thorough discussion of this topic is not possible in this document, the following are summary recommendations for pain management in children and teens from the American Pain Society and the American Academy of Pediatrics:

- Provide a calm environment for procedures that reduce distress-producing stimulation;
- Use age-appropriate pain assessment tools and techniques;
- Anticipate predictable painful experiences, intervene and monitor accordingly;
- Use a multimodal approach (pharmacologic, cognitive, behavioral and physical) to pain management and use a multidisciplinary approach when possible;
- Involve families and tailor interventions to the individual child; and
- Advocate for the effective use of pain medication for children to ensure compassionate and competent management of their pain.

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<sup>18</sup> California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

**Appendix 4 - Opioid Risk Tool (ORT)**

Date \_\_\_\_\_

Patient Name \_\_\_\_\_

**OPIOID RISK TOOL**

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder	[ ]	2	2
	Obsessive Compulsive Disorder			
	Bipolar			
	Schizophrenia			
	Depression	[ ]	1	1
<b>TOTAL</b>		[ ]		
<b>Total Score Risk Category</b>	<b>Low Risk 0 – 3</b>	<b>Moderate Risk 4 – 7</b>	<b>High Risk <math>\geq 8</math></b>	

## Appendix 5 - Patient Evaluation and Risk Stratification

### Patient Evaluation and Risk Stratification<sup>19</sup>

The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning.

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing?

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R] or the Opioid Risk Tool [ORT]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

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<sup>19</sup> Federation of State Medical Boards - Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers.

If possible, the patient evaluation should include information from family members and/or significant others. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community.

## Appendix 6 - CAGE-AID

### CAGE-AID Questionnaire

#### CAGE-AID Questionnaire

Patient Name \_\_\_\_\_ Date of Visit \_\_\_\_\_

When thinking about drug use, include illegal drug use and the use of prescription drug other than prescribed.

Questions:	YES	NO
1. Have you ever felt that you ought to cut down on your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have people annoyed you by criticizing your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you ever felt bad or guilty about your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?	<input type="checkbox"/>	<input type="checkbox"/>

#### Scoring

Regard one or more positive responses to the CAGE-AID as a positive screen.

#### Psychometric Properties

The CAGE-AID exhibited:	Sensitivity	Specificity
One or more Yes responses	0.79	0.77
Two or more Yes responses	0.70	0.85

(Brown 1995)

Appendix 7 - PHQ-9 Nine Symptom Checklist

PHQ-9 — Nine Symptom Checklist

Patient Name \_\_\_\_\_ Date \_\_\_\_\_

1. Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.
- a. Little interest or pleasure in doing things  
Not at all      Several days      More than half the days      Nearly every day
  - b. Feeling down, depressed, or hopeless  
Not at all      Several days      More than half the days      Nearly every day
  - c. Trouble falling asleep, staying asleep, or sleeping too much  
Not at all      Several days      More than half the days      Nearly every day
  - d. Feeling tired or having little energy  
Not at all      Several days      More than half the days      Nearly every day
  - e. Poor appetite or overeating  
Not at all      Several days      More than half the days      Nearly every day
  - f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down  
Not at all      Several days      More than half the days      Nearly every day
  - g. Trouble concentrating on things such as reading the newspaper or watching television  
Not at all      Several days      More than half the days      Nearly every day
  - h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual  
Not at all      Several days      More than half the days      Nearly every day
  - i. Thinking that you would be better off dead or that you want to hurt yourself in some way  
Not at all      Several days      More than half the days      Nearly every day
2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
- Not Difficult at All      Somewhat Difficult      Very Difficult      Extremely Difficult

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## PHQ-9 — Scoring Tally Sheet

Patient Name \_\_\_\_\_ Date \_\_\_\_\_

1. Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.

	Not at all 0	Several days 1	More than half the days 2	Nearly every day 3
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c. Trouble falling asleep, staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down				
g. Trouble concentrating on things such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual				
i. Thinking that you would be better off dead or that you want to hurt yourself in some way				
<b>Totals</b>				

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not Difficult At All 0	Somewhat Difficult 1	Very Difficult 2	Extremely Difficult 3

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## How to Score PHQ-9

### Scoring Method For Diagnosis

Major Depressive Syndrome is suggested if:

- Of the 9 items, 5 or more are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Minor Depressive Syndrome is suggested if:

- Of the 9 items, b, c, or d are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

### Scoring Method For Planning And Monitoring Treatment

Question One

- To score the first question, tally each response by the number value of each response:

Not at all = 0

Several days = 1

More than half the days = 2

Nearly every day = 3

- Add the numbers together to total the score.
- Interpret the score by using the guide listed below:

Score	Action
≤4	The score suggests the patient may not need depression treatment.
> 5-14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment.
≥15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment

Question Two

In question two the patient responses can be one of four: not difficult at all, somewhat difficult, very difficult, extremely difficult. The last two responses suggest that the patient's functionality is impaired. After treatment begins, the functional status is again measured to see if the patient is improving.

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How to Score PHQ-9

## Appendix 8 - SOAPP®-R

### Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is NOT intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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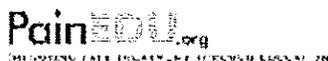
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SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	<input type="radio"/>				
2. How often have you felt a need for higher doses of medication to treat your pain?	<input type="radio"/>				
3. How often have you felt impatient with your doctors?	<input type="radio"/>				
4. How often have you felt that things are just too overwhelming that you can't handle them?	<input type="radio"/>				
5. How often is there tension in the home?	<input type="radio"/>				
6. How often have you counted pain pills to see how many are remaining?	<input type="radio"/>				
7. How often have you been concerned that people will judge you for taking pain medication?	<input type="radio"/>				
8. How often do you feel bored?	<input type="radio"/>				
9. How often have you taken more pain medication than you were supposed to?	<input type="radio"/>				
10. How often have you worried about being left alone?	<input type="radio"/>				
11. How often have you felt a craving for medication?	<input type="radio"/>				
12. How often have others expressed concern over your use of medication?	<input type="radio"/>				

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	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	<input type="radio"/>				
14. How often have others told you that you had a bad temper?	<input type="radio"/>				
15. How often have you felt consumed by the need to get pain medication?	<input type="radio"/>				
16. How often have you run out of pain medication early?	<input type="radio"/>				
17. How often have others kept you from getting what you deserve?	<input type="radio"/>				
18. How often, in your lifetime, have you had legal problems or been arrested?	<input type="radio"/>				
19. How often have you attended an AA or NA meeting?	<input type="radio"/>				
20. How often have you been in an argument that was so out of control that someone got hurt?	<input type="radio"/>				
21. How often have you been sexually abused?	<input type="radio"/>				
22. How often have others suggested that you have a drug or alcohol problem?	<input type="radio"/>				
23. How often have you had to borrow pain medications from your family or friends?	<input type="radio"/>				
24. How often have you been treated for an alcohol or drug problem?	<input type="radio"/>				

Please include any additional information you wish about the above answers.  
Thank you.

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## Scoring Instructions for the SOAPP<sup>®</sup>-R

All 24 questions contained in the SOAPP<sup>®</sup>-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

### What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Value for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive Likelihood Ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is 2.5 times (2.53 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 17 or above	.83	.85	.58	.88	2.38	.26
Score 18 or above	.81	.88	.57	.87	2.53	.29
Score 19 or above	.77	.75	.82	.86	3.03	.31

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***How does the SOAPP-R help determine appropriate treatment?***

The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

***Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater\*)***

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician's care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abuseable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

*\* Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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**Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21\*)**

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy.

*\* Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

**Who is at a low risk for opioid misuse? (SOAPP-R score < 9\*)**

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

*\*Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

SAMPLE

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MULTIPLE PAIN EVALUATION FOR PAIN MANAGEMENT

## Appendix 9 - Pain Intensity and Interference (pain scale)

### Pain Intensity and Interference (pain scale)<sup>20</sup>

Pain intensity and interference										
In the last month, on average, how would you rate your pain? Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"? [That is, your usual pain at times you were in pain.]										
No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
In the last month, how much has pain interfered with your daily activities? Use a scale from 0 to 10, where 0 is "no interference" and 10 is "unable to carry on any activities"?										
No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

**Interpretation of the Two Item Graded Chronic Pain Scale** – This two item version of the Graded Chronic Pain Scale is intended for brief and simple assessment of pain severity in primary care settings. Based on prior research, the interpretation of scores on these items is as follows:

Pain Rating Item	Mild	Moderate	Severe
Average/Usual Pain Intensity	1-4	5-6	7-10
Pain-related interference with activities	1-3	4-6	7-10

Although pain intensity and pain-related interference with activities are highly correlated and tend to change together, it is recommended that change over time be tracked for pain intensity and pain-related interference with activities separately when using these two items.

For an individual patient, a reduction in pain intensity and improvement in pain-related interference with activities of two points is considered moderate but clinically significant improvement.

Similar pain ratings have been widely used in the Brief Pain Inventory, the Multidimensional Pain Inventory, and the Pain Severity Scale of the SF-12.

There is extensive research on the reliability, validity and responsiveness to change of these pain severity ratings, which is summarized in the following reference:

Von Korff M. Chronic Pain Assessment in Epidemiologic and Health Services Research: Empirical Bases and New Directions. Handbook of Pain Assessment: Third Edition. Dennis C. Turk and Ronald Metzack, Editors. Guilford Press, New York., In press

<sup>20</sup> Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy (Washington State Agency Medical Directors' Group)

## **Appendix 10 - Therapeutic Options for Pain Management**

### Therapeutic Options for Pain Management<sup>21</sup>

In treating pain, clinicians can avail themselves of five basic modalities of pain-management tools:

1. Cognitive-behavioral approaches
2. Rehabilitative approaches
3. Complementary and alternative therapies
4. Interventional approaches
5. Pharmacotherapy

Not all of these options are necessary or appropriate for every patient, but clinical guidelines suggest that all options should be considered every time a health care provider decides to treat a patient with chronic pain. These options can be used alone or in combinations to maximize pain control and functional gains. Only one of these options involves medications and opioids are only one of many types of medications with potential analgesic utility. Which options are used in a given patient depends on factors such as the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses, patient life expectancy, cost and the local availability of the treatment option.

#### ***Cognitive-behavioral Approaches***

The brain plays a vitally important role in pain perception and in recovery from injury, illness or other conditions involving pain. Psychological therapies of all kinds, therefore, may be a key element in pain management. At the most basic level, such therapy involves patient education about disease states, treatment options or interventions, and methods of assessing and managing pain. Cognitive therapy techniques may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain. For example, some patients engage in an exaggeration of their condition called “catastrophizing” or they may have an overly passive attitude toward their recovery which leads them to inappropriately expect a physician to “fix” their pain with little or no work or responsibility on their part. Another way to frame this is to assess whether a patient has an internal or external “locus of control” relative to their pain. Someone with an external locus of control attributes the cause/relief of pain to external causes and they expect that the relief comes from someone else. Someone with an internal locus of control believes that they are responsible for their own well being; they own the experience of pain and recognize they have the ability and obligation to undertake remediation, with the help of others.

Some chronic pain patients have a strong external locus of control, and successful management of their pain hinges, in part, on the use of cognitive or other types of

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<sup>21</sup> California Medical Association (Prescribing Opioids: Care amid Controversy March 2014)

therapy to shift the locus from external to internal. Individual, group or family psychotherapy may be extremely helpful for addressing this and other psychological issues, depending on the specific needs of a patient.

In general, psychological interventions may be best suited for patients who express interest in such approaches, who feel anxious or fearful about their condition, or whose personal relationships are suffering as a result of chronic or recurrent pain. Unfortunately, the use of psychological approaches to pain management can be hampered by such barriers as provider time constraints, unsupportive provider reimbursement policies, lack of access to skilled and trained providers, or a lack of awareness on the part of patients and/or physicians about the utility of such approaches for improving pain relief and overall function.

### ***Rehabilitative Approaches***

In addition to relieving pain, a range of rehabilitative therapies can improve physical function, alter physiological responses to pain and help reduce fear and anxiety. Treatments used in physical rehabilitation include exercises to improve strength, endurance, and flexibility; gait and posture training; stretching; and education about ergonomics and body mechanics. Exercise programs that incorporate Tai Chi, swimming, yoga or core-training may also be useful. Other noninvasive physical treatments for pain include thermotherapy (application of heat), cryotherapy (application of cold), counter-irritation and electroanalgesia (e.g., transcutaneous electrical stimulation). Other types of rehabilitative therapies, such as occupational and social therapies, may be valuable for selected patients.

### ***Complementary and Alternative Therapies***

Complementary and alternative therapies (CAT) of various types are used by many patients in pain, both at home and in comprehensive pain clinics, hospitals or other facilities.<sup>27</sup> These therapies seek to reduce pain, induce relaxation and enhance a sense of control over the pain or the underlying disease. Meditation, acupuncture, relaxation, imagery, biofeedback and hypnosis are some of the therapies shown to be potentially helpful to some patients. CAT therapies can be combined with other pain treatment modalities and generally have few, if any, risks or attendant adverse effects. Such therapies can be an important and effective component of an integrated program of pain management.

### ***Interventional Approaches***

Although beyond the scope of this paper, a wide range of surgical and other interventional approaches to pain management exist, including trigger point injections, epidural injections, facet blocks, spinal cord stimulators, laminectomy, spinal fusion, deep brain implants and neuro-augmentative or neuroablative surgeries. Many of these approaches involve some significant risks, which must be weighed carefully against the potential benefits of the therapy.

## ***Pharmacotherapy***

Many types of medications can be used to alleviate pain, some that act directly on pain signals or receptors, and others that contribute indirectly to either reduce pain or improve function. For patients with persistent pain, medications may be used concurrently in an effort to target various aspects of the pain experience.

### *NSAIDs and Acetaminophen*

Non-steroidal anti-inflammatory drugs (NSAIDs), which include aspirin and other salicylic acid derivatives, and acetaminophen, are categorized as non-opioid pain relievers. They are used in the management of both acute and chronic pain such as that arising from injury, arthritis, dental procedures, swelling or surgical procedures. Although they are weaker analgesics than opioids, acetaminophen and NSAIDs do not produce tolerance, physical dependence or addiction. Acetaminophen and NSAIDs are also frequently added to an opioid regimen for their opioid-sparing effect. Since non-opioids and opioids relieve pain via different mechanisms, combination therapy can provide improved relief with fewer side effects.

These agents are not without risk, however. Adverse effects of NSAIDs as a class include gastrointestinal problems (e.g., stomach upset, ulcers, perforation, bleeding, liver dysfunction), bleeding (i.e., antiplatelet effects), kidney dysfunction, hypersensitivity reactions and cardiovascular concerns, particularly in the elderly. The threshold dose for acetaminophen liver toxicity has not been established, although the FDA recommends that the total adult daily dose should not exceed 4,000 mg in patients without liver disease (although the ceiling may be lower for older adults).

In 2009, the FDA required manufacturers of products containing acetaminophen to revise their product labeling to include warnings of the risk of severe liver damage associated with its use. In 2014, new FDA rules went into effect that set a maximum limit of 325 mg of acetaminophen in prescription combination products (e.g. Vicodin and Percocet) in an attempt to limit liver damage and other ill effects from the use of these products. Of note, aspirin (> 325 mg/d), ibuprofen, ketoprofen, naproxen and other non-cyclooxygenase-selective NSAIDs, are listed as “potentially inappropriate medications” for use in older adults in the American Geriatrics Society 2012 Beers Criteria because of the range of adverse effects they can have at higher doses.

Nonetheless, with careful monitoring, and in selected patients, NSAIDs and acetaminophen can be safe and effective for long-term management of persistent pain.

### *Opioids*

Opioids can be effective pain relievers because, at a molecular level, they resemble compounds, such as endorphins, which are produced naturally in the human central nervous system. Opioid analgesics work by binding to one or more of the three major types of opioid receptors in the brain and body: mu, kappa and delta receptors. The

most common opioid pain medications are called “mu agonists” because they bind to and activate mu opioid receptors. The binding of mu agonist opioids to receptors in various body regions results in both therapeutic effects (such as pain relief) and side effects (such as constipation).

Physical tolerance develops for some effects of opioids, but not others. For example, tolerance develops to respiratory suppressant effects within 5-7 days of continuous use, whereas tolerance to constipating effects is unlikely to occur. Tolerance to analgesia may develop early, requiring an escalation of dose, but tolerance may lessen once an effective dose is identified and administered regularly, as long as the associated pathology or condition remains stable.

Opioids, as a class, comprise many specific agents available in a wide range of formulations and routes of administration. Short-acting, orally-administered opioids typically have rapid onset of action (10-60 minutes) and a relatively short duration of action (2-4 hours). They are typically used for acute or intermittent pain, or breakthrough pain that occurs against a background of persistent low-level pain. Extended-release/long-acting (ER/LA) opioids have a relatively slow onset of action (typically between 30 and 90 minutes) and a relatively long duration of action (4 to 72 hours). The FDA states that such drugs are “indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

These agents achieve their extended activity in various ways. Some have intrinsic pharmacokinetic properties that make their effects more enduring than short-acting opioids, while others are modified to slow their absorption or to slow the release of the active ingredient. A given patient might be appropriate for ER/LA therapy only, short-acting only or a combination of an ER/LA opioid with a short-acting opioid. Note that patients may respond in very different ways to any given medication or combination of medications. One size does not fit all, and treatment is best optimized by titrating a given regimen on an individual basis. Combination products that join an opioid with a non-opioid analgesic entail the risk of increasing adverse effects from the non-opioid co-analgesic as doses are escalated, even if an increase of the opioid dose is appropriate.

In response to concerns about opioid misuse and abuse, abuse-deterrent and tamper-resistant opioid formulations have been developed. One class of deterrent formulation incorporates an opioid antagonist into a separate compartment within a capsule; crushing the capsule releases the antagonist and neutralizes the opioid effect. Another strategy is to modify the physical structure of tablets or incorporate compounds that make it difficult or impossible to liquefy, concentrate, or otherwise transform the tablets. Although abuse-deterrent opioid formulations do not prevent users from simply consuming too much of a medication, they may help reduce the public health burden of prescription opioid abuse.

Patients who receive opioids on a long-term basis to treat pain are considered to be receiving long-term opioid analgesic therapy, which is differentiated from opioid use by

patients who have an established opioid use disorder who use an opioid (e.g. methadone) as part of their treatment program.

### *Potential Adverse Effects of Opioids*

Although opioid analgesics (of all formulations) may provide effective relief from moderate-to-severe pain, they also entail the following significant risks:

- Overdose
- Misuse and diversion
- Addiction
- Physical dependence and tolerance
- Potentially grave interactions with other medications or substances
- Death

At the heart of much of the current controversy over the use of opioid analgesics for chronic pain are beliefs about the degree to which these pain medications are potentially addicting. Unfortunately, it is difficult to quantify the degree of addictive risk associated with opioid analgesics, either for an individual patient or the population of pain patients in general.

In this context, it is critical to differentiate addiction from tolerance and physical dependence which are common physiological responses to a wide range of medications and even to widely-consumed non-prescription drugs (e.g. caffeine). Physical dependence and tolerance alone are not synonymous with addiction. Addiction is a complex disease state that severely impairs health and overall functioning. Opioid analgesics may, indeed, be addicting, but they share this potential with a wide range of other drugs such as sedatives, alcohol, tobacco, stimulants and anti-anxiety medications.

Rigorous, long-term studies of both the potential effectiveness and potential addictive risks of opioid analgesics for patients who do not have co-existing substance-use disorders have not been conducted. The few surveys conducted in community practice settings estimate rates of prescription opioid abuse of between 4% to 26%. A 2011 study of a random sample of 705 patients undergoing long-term opioid therapy for non-cancer pain found a lifetime prevalence rate of opioid-use disorder of 35%.<sup>41</sup> The variability in results reflect differences in opioid treatment duration, the short-term nature of most studies and disparate study populations and measures used to assess abuse or addiction. Although precise quantification of the risks of abuse and addiction among patients prescribed opioids is not currently possible, the risks are large enough to underscore the importance of stratifying patients by risk and providing proper monitoring and screening when using opioid analgesic therapy.

**Particular caution should be exercised** when prescribing opioids to patients with conditions that may be complicated by adverse effects from opioids, including chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current

or past alcohol or substance misuse, mental illness, advanced age or patients with a history of kidney or liver dysfunction.

In addition, opioids generally should not be combined with other respiratory depressants, such as alcohol or sedative-hypnotics (benzodiazepines or barbiturates) unless these agents have been demonstrated to provide important clinical benefits, since unexpected opioid fatalities can occur in these combination situations at relatively low opioid doses.

In addition to the potential risks just described, opioids may induce a wide range of side effects including respiratory depression, sedation, mental clouding or confusion, hypogonadism, nausea, vomiting, constipation, itching and urinary retention. With the exception of constipation and hypogonadism, many of these side effects tend to diminish with time. Constipation requires prophylaxis that is prescribed at the time of treatment initiation and modified as needed in response to frequent monitoring. With the exception of constipation, uncomfortable or unpleasant side effects may potentially be reduced by switching to another opioid or route of administration (such side effects may also be alleviated with adjunctive medications). Although constipation is rarely a limiting side effect, other side effects may be intolerable. Because it is impossible to predict which side effects a patient may experience, it is appropriate to inquire about them on a regular basis.

Patients should be fully informed about the risk of respiratory depression with opioids, signs of respiratory depression and about steps to take in an emergency. Patients and their caregivers should be counseled to immediately call 911 or an emergency service if they observe any of these warning signs.

As of January 2014, a California physician may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. A physician may also issue a standing order for the administration of an opioid antagonist to a person at risk of an opioid-related overdose to a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose.

The potential of adverse effects and the lack of data about the addictive risks posed by opioids do not mean these medications should not be used. Common clinical experience and extensive literature document that some patients benefit from the use of opioids on a short or long term basis. Existing guidelines from many sources, including physician specialty societies (American Academy of Pain Medicine, The American Pain Society), various states (Washington, Colorado, Utah), other countries (Canada) and federal agencies (Department of Defense, Veterans Administration), reflect this potential clinical utility.

Recommendations from authoritative consensus documents have been summarized in concise, user-friendly formats such as: Responsible Opiate Prescribing: A Clinician's

Guide for the Federation of State Medical Boards; the 2013 Washington State Labor and Industries Guideline for Prescribing Opioids to Treat Pain in Injured Workers; and the Agency Medical Directors' Group 2010 Opioid Dosing Guideline for Chronic Non-Cancer Pain.

### *Methadone*

Particular care must be taken when prescribing methadone. Although known primarily as a drug used to help patients recovering from heroin addiction, methadone can be an effective opioid treatment for some pain conditions. Methadone is a focus of current debate because it is frequently involved in unintentional overdose deaths. These deaths have escalated as methadone has increasingly been used to treat chronic pain.

Methadone must be prescribed even more cautiously than other opioids and with full knowledge of its highly variable pharmacokinetics and pharmacodynamics. Of critical importance is the fact that methadone's analgesic half-life is much shorter than its elimination half-life. This can lead to an accumulation of the drug in the body. In addition, methadone is metabolized by a different group of liver enzymes than most other opioids, which can lead to unexpected drug interactions.

When rotating from another opioid to methadone, extreme caution must be used when referring to equianalgesic conversion tables. Consensus recommendations suggest a 75 to 90% decrement in the equianalgesic dose from conventional conversion tables when a switch is made from another opioid to methadone.

Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of mixing unauthorized substances, especially alcohol and other sedatives, with their medication. This should be explicitly stated in any controlled substance agreement that the patient receives, reads and signs before the initiation of treatment [...].

Although uncommon, potentially lethal cardiac arrhythmias can be induced by methadone. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to a history of heart disease or arrhythmias. An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease or cardiac risk factors or is taking agents that may interact with methadone. In addition, it is important that an ECG be repeated periodically, because QT interval prolongation has been demonstrated to be a function of methadone blood levels and/or in response to a variety of other medications.

### *Adjuvant Pain Medications*

Although opioid medications are powerful pain relievers, in the treatment of neuropathic pain and some other centralized pain disorders such as fibromyalgia, they are of limited effectiveness and are not preferred. Other

classes of medications, however, may provide relief for pain types or conditions that do not respond well to opioids. Some of these adjuvant medications exert a direct analgesic effect mediated by non-opioid receptors centrally or peripherally. Others have no direct analgesic qualities but may provide pain relief indirectly via central or peripheral affects.

Commonly-used non-opioid adjuvant analgesics include antiepileptic drugs (AEDs), tricyclic antidepressants (TCAs) and local anesthetics (LAs). AEDs, such as gabapentin and pregabalin, are used to treat neuropathic pain, especially shooting, stabbing or knife-like pain from peripheral nerve syndromes. TCAs and some newer types of antidepressants may be valuable in treating a variety of types of chronic and neuropathic pain, including post-herpetic neuralgia and diabetic neuropathy. LAs are used to manage both acute and chronic pain. Topical application provides localized analgesia for painful procedures or conditions with minimal systemic absorption or side effects. Topical LAs are also used to treat neuropathic pain. Epidural blocks with LAs, with or without opioids, play an important role in managing postoperative and obstetrical pain.

Appendix 11 - Non-Opioid Pain Management Tool

Non-Opioid Pain Management Tool by Jeremy Biggs MD MSPH

Area/Type of Pain	Treatment Options (Strongest Recommendations listed first)	When to initiate	Population	Duration/Indication of Treatment	Cautions/MISC
Back Pain <4 weeks	Directed Exercise Program 1, 2, 3, 4, 5, 6	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss 2	Immediately	All ages	Life long	Consider co morbidities
	Ice/Heat 2, 4, 6, 7	During the first 1-4 days	All ages	Most effective in first 1-3 days	Consider co morbidities
	Acetaminophen up to 4 g/day 1, 2, 4, 5, 8, 9	Immediately	Adults	Can be long term	Consider co morbidities
	Physical therapy 4, 6, 10, 11	After 3 weeks of conservative therapy	Adults	1-2 visits	Consider co morbidities
	NSAIDs 2, 4, 6, 9, 12	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers 4, 9, 13	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults, not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Back School 14, 15	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain.
	Tramadol/acetaminophen 2	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol 2	After initial acetaminophen trial	Adults	Can be long term	Consider co morbidities
	Manipulation 1, 4, 6, 16, 17, 18, 19	Most effective when used for pain <5 weeks of duration without radiculopathy	Adults	3-4 weeks of treatment has been studied. Up to 8 treatments.	Consider co morbidities, not shown to be better than other therapies. Not to be used with herniated disks
	Back Pain >4 weeks	Directed Exercise Program 1, 2, 3, 4, 5, 8, 18, 19	Immediately	Adults	Life Long
Yoga over/less (vinyoga) 20		Immediately	Adults	Life Long, studies for 12 weekly sessions	Has been shown to be as or more beneficial than exercise in some studies.
Controlled Weight Loss 2		Immediately	Adults	Life Long	Consider co morbidities
Acetaminophen up to 4 g/day 1, 2, 4, 8		Immediately	Adults	Can be long term	Consider co morbidities
NSAIDs 2, 4, 12		Immediately, recommend acetaminophen trial first. Some evidence that NSAIDs are equal with acetaminophen in chronic low back pain (21). Some	Adults with no CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors

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# Non-Opioid Pain Management Tool by Jeremy Biggs MD MSPH

	evidence that it is superior at pain control. (22)	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing, some studies did not show any benefit after 3-4 weeks of injury
Muscle Relaxers 4, 13	Immediately	Adults	Short term	Consider co morbidities, no CV risk factors
Cox-2 inhibitors 1, 2	If unable to tolerate NSAIDs and no CV risk factors	Adults with no CV risk factors	Short term	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain. Swedish Back School program was studied.
Back School 14, 15, 18	After 1-2 weeks of conservative therapy	Adults	For length of program	Have significant side effects profile, consider co morbidities
Tricyclic antidepressants 9, 23	After 3-4 weeks and failing conservative therapy, acetaminophen	Adults	As long as deemed beneficial	Consider co morbidities
Tramadol/acetaminophen 2	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
Tramadol 2	After failing acetaminophen trial, co administration with acetaminophen has been shown to have more favorable results	Adults	Can be long term	Consider co morbidities
Injections, epidural/facet joints 24, 25	After failing conservative treatment	Adults	As long as beneficial, if effective often last 1-4 months in duration, can be used to help diagnosis and evaluate for additional treatment options	Choose population according to guidelines. There are conflicting opinions on efficacy
Physical Therapy 10, 11	Recommend starting immediately	Adults	1-2 visits	Consider co morbidities
Message Therapy 26, 27, 28	Recommended in conjunction exercise and education	Adults	As long as beneficial has been shown to effective for up to one year, >5 visits shows better results, most studies showed results in 6-10 treatments	Some disagreement in literature, but done by licensed therapist found to be more effective
Neuroreflexotherapy 29	Only in Chronic LBP	Adults	Undetermined	Preliminarily this has shown some effect. Requires lengthy training of practitioner to be considered effective
Directed Exercise Program 1, 2, 3, 6, 30	Within 7-10 days of injury	All ages	Life long	Consider co morbidities, can add mechanical manipulation to an exercise program
Acetaminophen 4g/day maximum 2, 6, 31	Immediately	Adults	Can be long term	Consider co morbidities

Neck Pain

# Non-Opioid Pain Management Tool by Jeremy Biggs MD MSPH

	Immediately (recommended to try Acetaminophen first) After 2 weeks of conservative treatment	Younger adults, without any CV, Renal or GI risk factors Adults	Short term treatment 1-2 visits for education, counseling of home exercise Best when combined with exercise One time treatment	Consider co morbidities, no CV, renal or GI risk factors Consider co morbidities
NSAIDs 6, 12, 31	After 2 weeks of conservative treatment	Adults	1-2 visits for education, counseling of home exercise	Consider co morbidities, no CV, renal or GI risk factors
Physical Therapy 6	After 2 weeks of conservative treatment	Adults	Best when combined with exercise	Consider co morbidities
Manipulation 6	Once more conservative measures fail	Adults	One time treatment	Consider co morbidities, rare instances of CVA
IV methylprednisolone 31	Within 8 hours of injury for acute whiplash	Adults	Only a few treatments indicated	Any contraindications to IV steroids.
IM Lidocaine 31	Chronic neck pain with arm symptoms	Adults	Short term	Consider co morbidities
Muscle Relaxers 31	Immediately	Adults	Ideally 6 or more treatments, effects have been shown for short-term pain relief	Consider co morbidities
Acupuncture 32	After failing exercise and/or acetaminophen/NSAIDs	Adults	When the HA is a result of a mechanical neck disorder	Consider co morbidities
Directed exercise program 33	Immediately	Adults	Long term, has not been shown to be effective in migraines	Consider co morbidities
Acetaminophen 4g/day maximum 34	Immediately	Adults	Short term, shown to be effective in both migraine and non-migraine HAs	Consider co morbidities, not to be used with CV, renal or GI risk factors
NSAIDs 12, 35, 36	Immediately	Adults	Beneficial for migraine headaches. IM has been shown to be more effective than oral, but both are superior to placebo. Sumatriptan most studied	Consider co morbidities
Triptans 36, 37	Use if unable to control HA with NSAIDs and or acetaminophen	Adults	Shown to be beneficial in Acute migraines	Consider co morbidities
Excedrin 36	Immediately	Adults	Best for migraine headaches, can be started immediately	Monitor for side effects and complications of medication, can cause drowsiness
Amitriptyline 35	Immediately	Adults	Migraine, tension, and mixed. Studies lasted 4-27 weeks	Independent of depression, SSRI least effective
Antidepressants (other TCAs, SNRIs, SSRIs) 38, 39	After failing conservative therapy	Adults	Has been shown to help with pain and nausea with migraines	Consider co morbidities
Antiemetics 36	With migraine associated nausea	Adults	For prevention of migraine headache	Sodium valproate/divalproex sodium and topiramate are the best studied
Anticonvulsants 40	After failing other therapies, for prevention	Adults	Migraine	Consider co morbidities, metoclopramide can cause dystonia. NNT 3.5
NSAIDs combined with metoclopramide 41	After failing acetaminophen	Adults	Have shown to help migraines, more effective in combination with antiemetics	Consider co morbidities
DHE IM/SC/IV 36	After failing more conservative therapies	Adults	Found effective for mild-	Consider co morbidities
Isometheptene 36	After failing more conservative	Adults		

# Non-Opoid Pain Management Tool by Jeremy Biggs MD MSPH

		therapies	Adults	moderate migraine	Unknown
Osteoarthritis	Normal barometric oxygen therapy 42 TENS 35	Immediately Immediately	Adults Adults	For use in Cluster Headaches Best for cervical tension headaches, mildly affective in some migraine headaches	Do not use in patients with pacemakers, cardiac conduction abnormalities, or over the carotid body or sinus
	Manipulation 35	Immediately	Adults	Best for tension, post-traumatic headache. Can be helpful in some migraine headaches	Choose population according to literature
	Acupuncture 43	As adjuvant treatment	Adults	Shown to be effective for both tension and migraine	Choose population according to literature, not effective for all
	Directed Exercise Program 1, 2, 3, 6, 44	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss 2	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 4g/day maximum 2, 8 NSAIDs 2, 12	Immediately first line Immediately	Adults Younger adults, without any CV, Renal or GI risk factors	Can be long term Short term	Consider co morbidities Consider co morbidities, no CV, renal or GI risk factors
	Non-acetylated salicylates 2	Immediately	Adults	Short term	Consider co morbidities, watch for ototoxicity
	Topical capsaicin 2	Immediately	Adults	Short term	Consider co morbidities
	Intra-articular steroid Injection 2, 45	Immediately	Adults	Can be long term, but if too long can consider joint replacement.	This should be considered first-line therapeutic intervention if OA is confined to a single joint.
	Cox-2 inhibitors 1, 2	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults, not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Diacerein 46, 47	After failing other therapies	Adults	Studies lasted 2 months to 3 years	Consider co morbidities, shown to have minimal pain relief
	Ice/Heat 2	Immediately for first 1-4 days	All ages	For first 1-4 days	Instruct on timing to not cause tissue damage
	Acetaminophen 4g/day maximum 2 NSAIDs 2, 12	Immediately Immediately, recommended to try acetaminophen first	Adults Adults	Can be long term Short term	Consider co morbidities Consider co morbidities
	Acetaminophen 4g/day maximum 48	Immediately	Adults	Can be long term	Consider co morbidities
	Anticonvulsants 49, 50	After failing acetaminophen	Adults	Can be long term	Have a side effect profile that must be monitored. Carbamazepine and Gabapentin found to most effective, some showing carbamazepine to be more

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								effective with lower NNT and higher NNH
	Systemic administration of local anesthetics 51	After failing acetaminophen	Adults		Undetermined			Can be as effective as anticonvulsants. Monitor for side effects
	Antidepressants 34, 52	After failing acetaminophen.	Adults		Can be long term, TCAs (amitriptyline) and Venlafaxine shown to be most effective. Not shown to be effective in HIV neuropathies			Monitor for side effects, follow black box warnings. Newer SSRIs have less evidence supporting their use in neuropathic pain
Post-Herpetic Pain Fibromyalgia	Anticonvulsants 49	Immediately	Adults		While symptoms last			Can cause drowsiness
	Supervised Aerobic/Strength training exercise 53, 54, 55	Immediately, for at least 20 minutes a day 3 times a week	All ages		Life long, most studies were conducted on average for 12 weeks, 3-24 weeks.			Consider co morbidities
	Cognitive Behavioral Therapy 54, 56	Immediately	Adults		Data showed results from 6-30 months			Works best as a multidisciplinary approach
	Amitriptyline 54, 57, 58	Immediately	Adults		While beneficial			Does have side effect profile, tolerance to effect can occur
	Cyclobenzaprine 54, 57	Typically is after exercise, acetaminophen and amitriptyline	Adults		While beneficial			Significant side effects
	Acupuncture 54, 59, 60	After exercise and amitriptyline	Adults		While beneficial			Mild/weak evidence
	Deep tissue massage 54	Immediately	Adults		While beneficial			Mild/weak evidence
	Fluoxetine 54	Typically start with exercise, acetaminophen, and amitriptyline first	Adults		While beneficial			Secondary to amitriptyline, can be used in conjunction with tricyclics
	Dual-reuptake inhibitors (SNRIs): 54	Immediately	Adults		While beneficial			Weaker evidence than previous medications
	Gabapentin 61	Immediately	Adults		While beneficial, studied over a 12 week period			Consider co morbidities
Dental Pain	Pregabalin 54, 62, 63	Immediately	Adults		While beneficial			Still under investigation, one study showing positive results
	Acetaminophen 54, 65	Immediately	All ages		As needed			Consider co morbidities
Pelvic Pain (dysmenorrheal)	NSAIDs 65	Immediately	Adults		As needed			Consider co morbidities
	Acupuncture 57, 66	Immediately postop	Adults		1-4 sessions			Consider co morbidities
	Directed exercise program 67	Immediately	All ages		Life long			Consider co morbidities
	Acetaminophen 68	During first 3 days of menstruation	Adults		While beneficial			Consider co morbidities
	NSAIDs 68, 69	During first 3 days of menstruation	Adults		While beneficial			Consider co morbidities
	Oral contraceptives 70	Immediately	Adults/Adolescents		While beneficial			Consider co morbidities, can be traditional or extended continuous cycle
	Acupuncture 71	Immediately	Adults		10 visits over 3 months			Consider co morbidities
Chinese herbal medication 72	After other interventions	Adults		While beneficial			Not all interactions known	

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	Directed exercise program 73 Medroxyprogesterone acetate 73	Immediately Immediately	All ages Adults	Life long Not found to be effected after 9 months	with other medications Consider co morbidities
Pelvic Pain (chronic pelvic pain)	Goserelin 73	After failing more conservative therapies	Adults	As long as beneficial, cannot be taken longer than six months	Consider co morbidities, extensive side effects
Pelvic Pain (Endometriosis)	Danazol 74	After failing conservative therapy	Adults	For up to 6 months	Consider co morbidities, extensive side effects
	OCPs 75	Immediately	Adults	While beneficial	Consider co morbidities
	Goserelin 75	After failing more conservative therapies	Adults	While beneficial, cannot be taken for longer than six months	Consider co morbidities, extensive side effects

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**Appendix 12 – Suggested Language on Naloxone for Pain Management Agreement**

- I understand that “overdose” is a risk of opioid therapy which can lead to death. I understand and can recognize the signs and symptoms of overdose including respiratory depression.
  
- I understand that I will be prescribed naloxone because overdose is a risk of opioid therapy. I understand that naloxone is a drug that can reverse opioid overdose. I understand when and how to use naloxone.
  - I understand it is strongly encouraged to share information about naloxone with my family and friends.
  - I understand it is strongly encouraged to teach family and friends how to respond to an overdose.

# PATIENT PAIN MEDICATION AGREEMENT AND CONSENT

*This agreement is important for you:*

- *You will have a safe and controlled pain treatment plan.*
- *Your medicines have a high potential for abuse. They can be dangerous if used in the wrong way. You need to understand the risks that come from use of pain medicines.*

**Please read and make sure you understand each statement here. Here are rules about refills and health risks. Here are also reasons for stopping your pain control treatment.**

**I WILL:**

- I will only get my pain medicine from this clinic during scheduled appointments.
- I will take my pain medicine the way that my healthcare provider has ordered.
- I will be honest with all my healthcare providers if I am using street drugs.
- I will be honest about all the medicine I use. This includes medicine from stores and herbal medicines.
- I will be honest about my full health history.
- I will tell my healthcare provider if I go to an emergency room for any reasons.
- If I get pain medicine from an emergency room, I will tell my healthcare provider.
- I will call this office if I am prescribed any new medicine.
- I will call this office if I have a reaction to any medicine.
- I will tell all other healthcare providers that I have a pain medication agreement.
- I will tell the emergency room people that I have a pain medication agreement.
- I will take drug tests and other tests when I am told to do so.
- I will go to office visits when I am told to do so.
- I will go to physical therapy when I am told to do so.
- I will go to counseling when I am told to do so.
- I will follow directions for all treatment.
- I will show up on time for all appointments.
- I will make an appointment for refills before I run out of medicine.
- I will tell my health provider if I will be out of town so that I can get my refills.
- I will get past health records from other offices when needed.
- I will deliver these records by hand if needed. I will do this within one month of being asked.  
I will pay for these records if needed.
- I will give permission to this clinic to talk about my treatment with pharmacies, doctors, nurses, and others who are helping me.
- I will give permission to any healthcare provider to get information from this clinic about my health and my pain treatment.
- I will take responsibility if I overdose myself accidentally or on purpose.
- I will tell my healthcare provider if I plan to become pregnant.
- I will tell my healthcare provider if I am pregnant while I am taking pain medicine.
- I will only take this medicine the way I was told to take it.

**CONTINUED ON NEXT PAGE**

**I WILL NOT:**

- I will not share or sell, or trade any of my medicine.
- I will not drink alcohol or take street drugs while I am taking pain medicine.
- I know that I cannot call the office to have my medicine refilled over the phone.
- I will not go to the emergency room or other doctors for more pain medicine or other drugs.
- I know that when I drive a car, I must be fully alert. I know that when I use machines, I must also be fully alert. Pain medicines can make me less alert. When I am taking pain medicines, I need to be sure that I am alert. I need to be sure that it is safe for me to drive a car or use a machine.
- I will not stand in high places or do anything to hurt others after I have taken pain medicine.
- I will not leave my medicine where it can be stolen or where others can take it.
- I will not leave my medicine where children can find it.
- I will not suddenly stop taking my medicine. I know that if I do this, I can have withdrawals.

**WHEN USING A PHARMACY, I WILL:**

- I will use the same pharmacy for all my medicines. This is the pharmacy that I have picked: \_\_\_\_\_
- I will not ask for early refills or more pain medicine, even if I lose my medicine.

**I KNOW THAT**

- Pain management may include other treatment. Some treatment may not include medicine.
  - Pain medicine will probably not get rid of all of my pain. Pain medicine can reduce my pain so that I can do more and have a better life.
  - Part of my treatment is to reduce my need for pain medicine.
  - If the pain medicines work, I will continue to use them. If the pain medicine does not help me, it will be stopped.
  - My medicines will not be replaced if any of these things happen: Medicine is lost. Medicine gets wet. Medicine is destroyed
  - If my medicine is stolen, I might be able to get more medicine if I get a report from the police about the medicine being stolen.
  - Any of my healthcare providers can find out from the California Prescription Drug Monitoring Program about any other medicines I get from any other pharmacy in California. This is called a CURES report.
  - My healthcare provider may contact the drug enforcement agency, if I try to get other doctors to give me pain medicine.
  - Healthcare providers may contact the drug enforcement agency if I am not honest about how I take pain medicine.
  - My doctor and my clinic will help with any investigation if I am suspected of prescription drug abuse.
  - I may be sent somewhere else for drug abuse or addiction help if I need it.
  - Pain medicine can be addictive. This means that my body may need more and more pain medicine or that it can be hard for me to stop taking this medicine.
  - If I suddenly stop using the medicine, I can get withdrawals.
  - If I use too much pain medicine, I can end up with health problems. I could die.
  - If I mix medicines, I could also end up with health problems. I could die.
  - Here are some things that could go wrong if I use too much medicine or mix medicines:
- |                   |           |                           |                   |            |
|-------------------|-----------|---------------------------|-------------------|------------|
| Overdose          | Addiction | Constipation              | Vomiting          | Sleepiness |
| Slower reflexes   | Nausea    | Difficulty with urination | Confusion         | Itching    |
| Problems with sex | Dry mouth | Depression                | Trouble breathing | Death      |

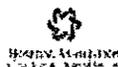
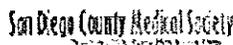
**CAUSE FOR DISMISSAL FROM THIS CLINIC**

- I know that the pain medicines may be stopped if I break any part of this contract.
- My signature below means that I have read this contract. I am signing this to say that I understand all of this contract.

Patient Name \_\_\_\_\_ Doctor Name \_\_\_\_\_

Patient Signature \_\_\_\_\_ Doctor Signature \_\_\_\_\_

Date: \_\_\_\_\_



## Appendix 14 – Suggested Treatment Plan Using Prescription Opioids

### Treatment Plan Using Prescription Opioids

Patient name: \_\_\_\_\_

Prescriber name: \_\_\_\_\_

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**THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.**

---

I (patient) understand the following (initial each):

\_\_\_\_\_ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: \_\_\_\_\_

\_\_\_\_\_ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: \_\_\_\_\_

\_\_\_\_\_ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

\_\_\_\_\_ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

\_\_\_\_\_ There is a small risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

I agree to the following (initial each):

\_\_\_\_\_ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

\_\_\_\_\_ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

\_\_\_\_\_ I agree not to share, sell, or in any way provide my medication to any other person.

\_\_\_\_\_ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

\_\_\_\_\_ I agree not to seek or obtain ANY mood-modifying medication, including pain relievers or tranquilizers from ANY other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

\_\_\_\_\_ I agree to refrain from the use of ALL other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

\_\_\_\_\_ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

\_\_\_\_\_ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

## Appendix 15 – Suggested Strategies for Tapering and Weaning

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain

### Strategies for Tapering & Weaning

#### Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

#### Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation ("You are indifferent to my suffering")
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

TOOLS

Washington State Agency Medical Directors' Group, 2007

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## MSD Guidelines for the Use of Controlled Substances for the Treatment of Pain

To address the current epidemic of prescription drug abuse, your Medical Society has been working closely with the Division of Public Health (DPH), the Division of Professional Regulation, and other stakeholders to move towards a solution in Delaware. (See: Kahlon RS. The Prescription Drug Abuse Crisis: MSD in Action. *Del Med J.* 2012;84:49-51.)

As part of this effort, MSD developed “Guidelines for the Use of Controlled Substance for the Treatment of Pain” (which are presented here) for the purpose of reconciling the changing regulatory environment with clinical best practices and maintaining access to care.

### Purpose and Goals

The Guidelines were developed in conjunction with your Medical Society's active leadership in the state-wide Prescription Drug Action Committee (PDAC) – a multi-stakeholder group started by MSD and DPH to bring everyone to the same table to work together. In addition, MSD convened the Physicians Advisory Committee on Controlled Substances (PACCS) to provide real-time boots-on-the-ground clinical input on the PDAC work.

The PACCS took up the task of creating current clinical practice guidelines for the treatment of pain with controlled substances tailored to relevant individual practice types – acute/subacute, chronic, emergency department, and hospice patients. These Guidelines thus become the first of their kind as no other set of policies exist which are applicable in this manner to different practice types. In addition, the Guidelines allow for specialty-specific enhancements and this feature was implemented by our Emergency Medicine colleagues (see section 2.5). Other submissions for enhancements are encouraged.

### Development

In developing the Guidelines, the PACCS reviewed the Federation of State Medical Boards Model Policy, the Delaware Board of Medical Licensure and Disci-

pline (BMLD) Regulation 31 (adopted as part of 15 DE Reg. 1184 on February 1, 2012), multiple other clinical guidelines, and multiple studies regarding the optimal usage of controlled substances (see [www.guidelines.gov](http://www.guidelines.gov)). In May 2012, an MSD town hall meeting on the topic was held involving sites and physicians in all three counties. In early 2013, MSD obtained feedback through a Society-wide web survey. The result is a set of Guidelines that (a) satisfy Regulation 31 and (b) create a clinical environment that encourages clinical best practices and maintains access to care.

### Implementation and Education

These Guidelines may directly affect your daily practice if you are prescribing controlled substances and/or treating pain. You are encouraged to review them and familiarize yourself with the risk assessment, clinical evaluation, and treatment protocol recommendations. Over the next year, additional physician education and implementation strategies will be developed to help integrate these Guidelines into clinical practice. For more information and education on prescribing controlled substances in Delaware, please review the MSD Prescription Drug Abuse webpage. ([www.MedicalSocietyofDelaware.org/GovernmentAffairs/StateLevel/PrescriptionDrugAbuse.aspx](http://www.MedicalSocietyofDelaware.org/GovernmentAffairs/StateLevel/PrescriptionDrugAbuse.aspx))

Thank you for your contributions to ensure both the safety of and access to treatment for Delawareans.

### *Physicians Advisory Committee on Controlled Substances (PACCS)*

Randeep Kahlon, M.D., Chair  
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 John Goodill, M.D. Jeffry Zern, M.D.  
 Jeffrey Hawtof, M.D.

*Approved August 13, 2012*

## Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s)
<p><b>1.0 Purpose: Use of Controlled Substances for the Treatment of Pain</b></p> <p>The Physicians Advisory Committee for Controlled Substances of the Medical Society of Delaware supports the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain" ("Model Policy"). These guidelines have been developed to define specific requirements applicable to pain control, particularly related to the use of controlled substances, to alleviate licensed practitioners' uncertainty, to encourage better pain management, and to minimize practices that deviate from the appropriate standard of care and lead to abuse and diversion. The principles of quality medical practice dictate that citizens of Delaware have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The inappropriate treatment of pain includes a wide spectrum of issues that do not provide treatment appropriate to the patients' specific needs.</p> <p>The diagnosis and treatment of pain is integral to the practice of medicine. Licensed practitioners view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. Licensed practitioners should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. These guidelines are directed to the treatment of pain.</p> <p>Inappropriate pain treatment may result from the practitioner's lack of knowledge about pain management. Fears of investigation or sanction by federal, state, and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating practitioner's responsibility. The Committee recognizes that some types of pain cannot be completely relieved.</p> <p>The Committee recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the licensed practitioner. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Licensed practitioners should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and alone are not the same as addiction.</p> <p>The Committee recognizes that the use of opioid analgesics for other than legitimate medical purposes can pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, these guidelines mandate that licensed practitioners incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.</p>	<p><b>Chronic pain</b>  <b>Acute/Subacute pain</b>  <b>Emergency Medicine</b>  <b>Hospice</b></p>

## Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s)
<p><b>1.0 Purpose: Use of Controlled Substances for the Treatment of Pain Continued</b></p> <p>These guidelines support the ordering, prescribing, dispensing or administering of controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a licensed practitioner-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.</p> <p>The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.</p>	<p><b>Chronic pain Acute/Subacute pain Emergency Medicine Hospice</b></p>
<p><b>2.0 Guidelines</b> - The following criteria must be used when evaluating the treatment of pain, including the use of controlled substances:</p> <p>2.1 Evaluation of the Patient- A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The evaluation must document:</p> <p>2.1.1 etiology, the nature and intensity of the pain, current and past treatments for pain;</p> <p>2.1.2 underlying or coexisting diseases or conditions;</p> <p>2.1.3 the effect of the pain on physical and psychological function and history of substance abuse; and</p> <p>2.1.4 the presence of one or more recognized medical indications for the use of a controlled substance.</p>	<p><b>Chronic pain Acute/Subacute pain Emergency Medicine Hospice</b></p>
<p><b>2.2 Treatment Plan</b> - A treatment plan should be discussed and should include goals and objectives that will be used to determine treatment outcomes, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. The treatment plan should address whether treatment modalities or a rehabilitation program are necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. After treatment begins, the practitioner should adjust drug therapy to the individual medical needs of each patient.</p>	<p><b>Chronic pain Acute/Subacute pain Hospice</b></p>
<p><b>2.2 Treatment Plan</b> - Prescribing pain medicine for chronic pain from the Emergency Department should be limited to only the immediate treatment of acute exacerbations of pain associated with objective findings of uncontrolled pain, all of which shall be discussed with the patient up front. [Chronic pain treatment requires monitoring the effects of the medication on pain levels and patient's level of functioning. Such monitoring would be impossible to provide for the emergency medical provider who, therefore, is unable to provide a long term treatment plan as it relates to the patient's response to the prescription of chronic opioids.]</p>	<p><b>Emergency Medicine</b></p>

## Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s)
<p><b>2.3 Informed Consent</b> - The practitioner should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity.</p>	<p><b>Chronic pain</b> <b>Acute/Subacute pain</b> <b>Emergency Medicine</b> <b>Hospice</b></p>
<p><b>2.4 Agreement for Treatment</b> - The practitioner should use a written agreement between the practitioner and patient outlining mutual responsibilities, including;</p> <ul style="list-style-type: none"> <li>2.4.1 urine/serum medication levels screening when requested;</li> <li>2.4.2 number and frequency of all prescription refills;</li> <li>2.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement); and.</li> <li>2.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.</li> </ul>	<p><b>Chronic pain</b></p>
<p><b>2.4 Agreement for Treatment</b> - If, based on clinical assessment, the patient is at high risk for medication abuse or has a history of substance abuse, or a past history of chronic pain, the practitioner should use an agreement (or should document a discussion) between the practitioner and patient outlining mutual responsibilities, including;</p> <ul style="list-style-type: none"> <li>2.4.1 urine/serum medication levels screening when requested;</li> <li>2.4.2 number and frequency of all prescription refills;</li> <li>2.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement); and</li> <li>2.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.</li> </ul>	<p><b>Acute/Subacute pain</b></p>
<p><b>2.4 Agreement for Treatment</b>- Not applicable</p>	<p><b>Emergency Medicine</b> <b>Hospice</b></p>
<p><b>2.5 Periodic Review</b>- The licensed practitioner shall periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Periodic review shall include, at a minimum, evaluation of the following:</p> <ul style="list-style-type: none"> <li>2.5.1 continuation or modification of controlled substances for pain management therapy depending on the practitioner's evaluation of the patient's progress toward treatment goals and objectives.</li> <li>2.5.2 satisfactory response to treatment as indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function must be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment.</li> <li>2.5.3 if the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.</li> </ul>	<p><b>Chronic pain</b> <b>Acute/Subacute pain</b> <b>Hospice</b></p>

## Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s)
<p><b>2.5 Review of Emergency Department Care (in lieu of Periodic Review)</b></p> <p>2.5.1 Ideally, one medical provider should provide all opioids to treat a patient’s chronic pain.</p> <p>2.5.2 The administration of intravenous and intramuscular opioids in the Emergency Department (ED) for the relief of acute exacerbations of chronic pain should be carefully considered.</p> <p>2.5.3 The administration of Demerol R-(Meperidine) in the ED is discouraged.</p> <p>2.5.4 Emergency medical providers should not provide replacement prescriptions for controlled substances that were lost, destroyed, or stolen.</p> <p>2.5.5 Emergency medical providers should not provide replacement doses of methadone for patients in a methadone treatment program.</p> <p>2.5.6 Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches, and methadone) should not be prescribed from the ED.</p> <p>2.5.7 Patients who are found to receive prescriptions for controlled substances from multiple providers should not receive additional prescriptions for controlled substances from the ED.</p> <p>2.5.8 Emergency medical providers should attempt to coordinate care with primary care and pain management physicians for patients presenting to the ED with acute exacerbations of chronic pain.</p> <p>2.5.9 EDs should coordinate the care of patients who frequently visit the ED using an ED care coordination program.</p> <p>2.5.10 EDs should maintain a list of primary care providers for patients of all payer types.</p> <p>2.5.11 Prescriptions for opioid pain medication from the ED for acute injuries, such as fractured bones, or acute painful conditions, such as kidney stones, in most cases should not exceed 30 pills. If the provider prescribes greater than a 72-hour supply of opiates, the Delaware Prescription Monitoring Program should be accessed as per Delaware law.</p> <p>2.5.12 The emergency physician is required by law to evaluate an ED patient who reports pain. The law allows the emergency physician to use their clinical judgment when treating pain and does not require the use of opioids.</p>	<p><b>Emergency Medicine</b></p>
<p><b>2.6 Consultation</b> - The practitioner should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those patients with pain who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder requires extra care, monitoring, documentation, and may require consultation with or referral to an expert in the management of such patients. At a minimum, practitioners who regularly treat patients for chronic pain must educate themselves about the current standards of care applicable to those patients.</p>	<p><b>Chronic pain Acute/Subacute pain Hospice</b></p>
<p><b>2.6 Consultation-</b> Not applicable.</p>	<p><b>Emergency Medicine</b></p>

## Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s)
<p><b>2.7 Medical Records</b> - The practitioner (or hospice, if applicable) shall keep accurate and complete records. The entire record must include the:</p> <ul style="list-style-type: none"> <li>2.7.1 medical history and physical examination;</li> <li>2.7.2 relevant diagnostic, therapeutic, and laboratory results;</li> <li>2.7.3 relevant evaluations and consultations;</li> <li>2.7.4 documentation of etiology;</li> <li>2.7.5 treatment objectives;</li> <li>2.7.6 discussion of risks and benefits;</li> <li>2.7.7 informed consent, as per Section 1.3;</li> <li>2.7.8 treatments;</li> <li>2.7.9 medications (including date, type, dosage and quantity prescribed);</li> <li>2.7.10 instructions and agreements; and</li> <li>2.7.11 periodic review and/or appropriate referral.</li> </ul>	<p><b>Chronic pain</b>  <b>Acute/Subacute pain</b>  <b>Hospice</b></p>
<p><b>2.7 Medical Records</b> - The practitioner shall keep accurate and complete records. The entire record must include the:</p> <ul style="list-style-type: none"> <li>2.7.1 medical history and physical examination;</li> <li>2.7.2 relevant diagnostic, therapeutic and laboratory results;</li> <li>2.7.3 relevant evaluations and consultations;</li> <li>2.7.4 documentation of etiology;</li> <li>2.7.5 treatment objectives;</li> <li>2.7.6 discussion of risks and benefits;</li> <li>2.7.7 informed consent;</li> <li>2.7.8 treatments;</li> <li>2.7.9 medications (including date, type, dosage, and quantity prescribed); and</li> <li>2.7.10 instructions, and appropriate referral.</li> </ul>	<p><b>Emergency Medicine</b></p>
<p><b>2.8 Records should remain current and be maintained in an accessible manner and readily available for review.</b> Each practitioner should include documentation appropriate for each visit's level of care and will include the:</p> <ul style="list-style-type: none"> <li>2.8.1 interim history and examination, when applicable;</li> <li>2.8.2 vital signs, when appropriate;</li> <li>2.8.3 assessment of progress; and</li> <li>2.8.4 medication plan.</li> </ul>	<p><b>Chronic pain</b>  <b>Acute/Subacute pain</b>  <b>Emergency Medicine</b>  <b>Hospice</b></p>
<p><b>2.9 Compliance with Controlled Substances Laws and Regulations</b> - To prescribe, dispense, or administer controlled substances, the practitioner must be licensed in the state and comply with all applicable federal and state regulations. Licensed practitioners are referred to the Practitioner's Manual of the U.S. Drug Enforcement Administration and specific rules governing controlled substances, as well as applicable state regulations.</p>	<p><b>Chronic pain</b>  <b>Acute/Subacute pain</b>  <b>Emergency Medicine</b>  <b>Hospice</b></p>

## Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s)
<p><b>3.0 Definitions</b> - The following terms are defined as follows:</p> <p>3.1 Acute/Subacute Pain- Acute pain is the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. It is generally time-limited.</p> <p>3.2 Addiction - A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.</p> <p>3.3 Chronic Pain - A state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.</p> <p>3.4 Licensed Practitioner - Those licensed individuals with prescriptive authority regulated under the Medical Practice Act including, but not limited to, physicians, physician assistants, and nurse practitioners.</p> <p>3.5 Pain - An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.</p> <p>3.6 Physical Dependence - A state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.</p> <p>3.7 Pseudo addiction - The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.</p> <p>3.8 Substance Abuse - The use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.</p> <p>3.9 Tolerance - A physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.</p> <p>3.10 Emergency Medicine - The care provided within an Emergency Department.</p> <p>3.11 Hospice care - Hospice pain management is pain relief provided to patients in a certified Hospice program where patients are terminally ill with survival of six to 12 months. The goal is to relieve suffering and pain, not necessarily to extend life. Hospice organizations are responsible for a policy to safeguard controlled substances in the home and to educate staff on this matter.</p>	<p><b>Chronic pain</b>  <b>Acute/Subacute pain</b>  <b>Emergency Medicine</b>  <b>Hospice</b></p>

*Disclaimer: These guidelines are only an educational tool. Clinicians should use their own clinical judgment and not base clinical decisions solely on this document. This document should not be used to establish any standard of care. No legal proceeding, including medical malpractice proceedings or disciplinary hearings, should reference a deviation from any part of this document as constituting a breach of professional conduct.*

## GEORGIA COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

### Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps

#### *Disclaimer*

*These guidelines are primarily intended to provide orientation for physicians intending to prescribe schedule II and III analgesics for the purpose of treating chronic pain conditions and do not necessarily apply to clinical conditions where rapid adjustments in medical management are required such as acute pain management following surgery, emergency care pain management and end-of-life care.*

The Georgia Composite State Board of Medical Examiners (the Medical Board) recognizes that principles of quality medical practice dictate that the people of the state of Georgia have access to appropriate and effective pain relief by licensed physicians. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of these guidelines, the inappropriate treatment of pain includes no treatment, under treatment, over treatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as an essential part of quality medical practice for all patients with pain, including both acute and chronic disease. All physicians should be or seek to become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as becoming familiar with statutory requirements for prescribing controlled substances. These guidelines have been developed to clarify the Board's position on pain management, particularly as it relates to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management practices. The guidelines are also intended to curtail drug diversion, a serious public safety concern for the Board and law enforcement agencies.

Adherence to the guidelines outlined here will not only improve quality medical practice but will also improve the board's efficiency in its investigations by distinguishing legitimate practice from foul play.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice.

To prevent any misunderstanding, it is necessary to state what the Board does not have.

The Board does not have a list of “bad” or “disallowed” drugs. All formulary drugs are generally effective if prescribed and administered when properly indicated. Conversely, drugs are potentially ineffective, dangerous, or even lethal when used inappropriately.

The Board does not have a “magic formula” for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case and continued under proper monitoring. What is good for one patient may be insufficient or fatal for another.

The Board does have the expectation that physicians will create a record that shows evaluation of every patient receiving a controlled substance prescription as follows:

- Proper indication for the use of drug or other therapy
- Monitoring of the patient where necessary
- The patient’s response to therapy on follow-up visits
- All rationale for continuing or modifying the therapy
- Discussion of risks/benefits
- Periodic medical record review
- Prescription records

### **STEP ONE**

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance. Perform a workup sufficient to support a diagnosis including all necessary tests, history and physical examination. If medical testing is negative, carefully document the rationale of therapy and its effectiveness. When a diagnosis is undetermined, despite the complaint of severe pain, consider consultation for further analysis. The medical record will need to document sufficient and appropriate H&P and diagnostic testing to support the diagnosis necessitating the use of controlled substances.

### **STEP TWO**

Create a treatment plan, which includes the use of appropriate non-controlled drugs, and consider referrals to appropriate specialists, such as neurologists, orthopedists, pain management specialists,

addictionologists, psychiatrists, etc. The result of the referral should be included in the patient's chart. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.

### **STEP THREE**

Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history and physical that non-controlled drugs are not appropriate or effective for the patient's condition. The above does NOT apply to acutely painful conditions such as an acute injury or surgery, nor does it apply to the management of pain in cancer or hospice patients. It may also not apply for patients who have a contraindication to, or are at high risk of experiencing side effects from non-steroidal anti-inflammatory drugs such as the elderly.

Although non-controlled drugs (e.g., aspirin, acetaminophen, NSAIDS) often are adequate to treat painful conditions of mild severity, the Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. This does not mean that opioids and other controlled substances cannot be used as a first-line therapy, but it is important to document the rationale when used as such.

### **STEP FOUR**

Review the patient's prescription records and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history and medication allergies, and discuss chemical use and family chemical history with the patient and obtain old records which may include pharmacy records.

### **STEP FIVE**

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient does not have decision making capacity. The physician must remain in compliance with HIPAA regulations. Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done. When embarking on what appears to be the long-term use of a dependence-causing or potentially addictive substance, it may be wise to hold a family conference and explain differences between physical dependence, tolerance and addiction.

### **STEP SIX**

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for prolonged need for the drug use it is very important to monitor the patient for the underlying condition which necessitates the drug and for the side effects of the drug itself. This is true no matter what type of controlled substance is used or to what schedule it belongs. It is very important to monitor the patient for the underlying condition which necessitates the use of controlled substances. It is also important to monitor the patient for side effects that may occur with the use of the selected controlled substance(s).

## **STEP SEVEN**

The physician must keep detailed records of the type, dosage and amount of the drug prescribed. Prescribing physicians should also monitor and personally control all refills. One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time. Records of the cumulative dosage and average daily dosage are especially valuable. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities and checking on whether the patient is obtaining drugs from other physicians. Checking with pharmacies may indicate a patient is obtaining additional drugs or is doctor shopping. It is a felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time. If you are aware of these situations occurring, contact your local police or the Georgia Drug and Narcotics Agency.

## **STEP EIGHT**

With the patient's permission, the patient's family may be a valuable source of information on the patient's response to the therapy regimen and the patient's functional status, and may provide more accurate and objective feedback than the patient alone.

Family may be a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is discontinued. These changes, at the time, may be symptoms of dependency or addiction. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

## **STEP NINE**

Maintaining adequate records is extremely important. The physician who carefully manages pain treatment and maintains detailed records which reflect all the steps involved in the process will be able to assess and review the treatment course and progress.

## STEP TEN

Document

Document

Document

Keep accurate and complete records to include:

The medical history and physical examination

Diagnostic, therapeutic and laboratory results

Evaluations and consultations

Treatment objectives

Medications (including date, type, dosage and quantity prescribed)

Instructions and agreements, pain contracts (where applicable)

### **Definitions:**

**Addiction**—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

**Physical Dependence**—Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

**Tolerance**—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

## Iowa Medical Board Regulations

MEDICINE BOARD[653]

### CHAPTER 13: STANDARDS OF PRACTICE AND PRINCIPLES OF MEDICAL ETHICS

653-13.2(148,272C) Standards of practice--appropriate pain management.

This rule establishes standards of practice for the management of acute and chronic pain. The board encourages the use of adjunct therapies such as acupuncture, physical therapy and massage in the treatment of acute and chronic pain. This rule focuses on prescribing and administering controlled substances to provide relief and eliminate suffering for patients with acute or chronic pain.

1. This rule is intended to encourage appropriate pain management, including the use of controlled substances for the treatment of pain, while stressing the need to establish safeguards to minimize the potential for substance abuse and drug diversion.
2. The goal of pain management is to treat each patient's pain in relation to the patient's overall health, including physical function and psychological, social and work-related factors. At the end of life, the goals may shift to palliative care.
3. The board recognizes that pain management, including the use of controlled substances, is an important part of general medical practice. Unmanaged or inappropriately treated pain impacts patients' quality of life, reduces patients' ability to be productive members of society, and increases patients' use of health care services.
4. Physicians should not fear board action for treating pain with controlled substances as long as the physicians' prescribing is consistent with appropriate pain management practices. Dosage alone is not the sole measure of determining whether a physician has complied with appropriate pain management practices. The board recognizes the complexity of treating patients with chronic pain or a substance abuse history. Generally, the board is concerned about a pattern of improper pain management or a single occurrence of willful or gross overtreatment or undertreatment of pain.
5. The board recognizes that the undertreatment of pain is a serious public health problem that results in decreases in patients' functional status and quality of life, and that adequate access by patients to proper pain treatment is an important objective of any pain management policy.
6. Inappropriate pain management may include nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments. Inappropriate pain management is a departure from the acceptable standard of practice in Iowa and may be grounds for disciplinary action.

13.2(1) Definitions. For the purposes of this rule, the following terms are defined as follows:

"Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Generally, acute pain is self-limited, lasting no more than a few weeks following the initial stimulus.

"Addiction" means a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

"Chronic pain" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient. If pain persists beyond the anticipated healing period of a few weeks, patients should be thoroughly evaluated for the presence of chronic pain.

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is an individual, multifactorial experience influenced by culture, previous pain events, beliefs, mood and ability to cope.

"Physical dependence" means a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

"Pseudoaddiction" means an iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

"Substance abuse" means the use of a drug, including alcohol, by the patient in an inappropriate manner that may cause harm to the patient or others, or the use of a drug for an indication other than that intended by the prescribing clinician. An abuser may or may not be physically dependent on or addicted to the drug.

"Tolerance" means a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

"Undertreatment of pain" means the failure to properly assess, treat and manage pain or the failure to appropriately document a sound rationale for not treating pain.

13.2(2) Laws and regulations governing controlled substances. Nothing in this rule relieves a physician from fully complying with applicable federal and state laws and regulations governing controlled substances.

13.2(3) Undertreatment of pain. The undertreatment of pain is a departure from the acceptable standard of practice in Iowa. Undertreatment may include a failure to recognize symptoms and signs of pain, a failure to treat pain within a reasonable amount of time, a failure to allow interventions, e.g., analgesia, to become effective before invasive steps are taken, a failure to address pain needs in patients with reduced cognitive status, a failure to use controlled substances for terminal pain due to the physician's concern with addicting the patient, or a failure to use an adequate level of pain management.

13.2(4) Assessment and treatment of acute pain. Appropriate assessment of the etiology of the pain is essential to the appropriate treatment of acute pain. Acute pain is not a diagnosis; it is a symptom. Prescribing controlled substances for the treatment of acute pain should be based on clearly diagnosed and documented pain. Appropriate management of acute pain should include an assessment of the mechanism, type and intensity of pain. The patient's medical record should clearly document a medical history, a pain history, a clinical examination, a medical diagnosis and a treatment plan.

13.2(5) Effective management of chronic pain. Prescribing controlled substances for the treatment of chronic pain should only be accomplished within an established physician-patient relationship and should be based on clearly diagnosed and documented unrelieved pain. To ensure that chronic pain is properly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of chronic pain shall exercise sound clinical judgment and establish an effective pain management plan in accordance with the following:

a. Patient evaluation. A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.

b. Treatment plan. The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any other treatment modalities and rehabilitation programs utilized. The patient's short- and long-term needs for pain relief shall be considered when drug therapy is prescribed. The patient's ability to request pain relief as well as the patient setting shall be considered. For example, nursing home patients are unlikely to have their pain control needs assessed on a regular basis, making prn (on an as-needed basis) drugs less effective than drug therapy prescribed for routine administration that can be supplemented if pain is found to be

worse. The patient should receive prescriptions for controlled substances from a single physician and a single pharmacy whenever possible.

c. Informed consent. The physician shall document discussion of the risks and benefits of controlled substances with the patient or person representing the patient.

d. Periodic review. The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. The physician should adjust drug therapy to the individual needs of each patient. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of other treatment modalities if periodic reviews indicate that the objectives of the treatment plan are not being met or that there is evidence of diversion or a pattern of substance abuse. Long-term opioid treatment is associated with the development of tolerance to its analgesic effects. There is also evidence that opioid treatment may paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia. Thus, increasing opioid doses may not improve pain control and function.

e. Consultation/referral. A specialty consultation may be considered at any time if there is evidence of significant adverse effects or lack of response to the medication. Pain, physical medicine, rehabilitation, general surgery, orthopedics, anesthesiology, psychiatry, neurology, rheumatology, oncology, addiction medicine, or other consultation may be appropriate. The physician should also consider consultation with, or referral to, a physician with expertise in addiction medicine or substance abuse counseling, if there is evidence of diversion or a pattern of substance abuse. The board encourages a multidisciplinary approach to chronic pain management, including the use of adjunct therapies such as acupuncture, physical therapy and massage.

f. Documentation. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including patient evaluation, diagnostic studies, treatment modalities, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.

g. Pain management agreements. A physician who treats patients for chronic pain with controlled substances shall consider using a pain management agreement with each patient being treated that specifies the rules for medication use and the consequences for misuse. In determining whether to use a pain management agreement, a physician shall evaluate each patient, taking into account the risks to the patient and the potential benefits of long-term treatment with controlled substances. A physician who prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain shall utilize a pain management agreement if the physician has reason to believe a patient is at risk of drug abuse or diversion. If a physician prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain and chooses not to use a pain management agreement, then the physician shall document in the patient's medical records the reason(s) why a pain management agreement was not used. Use of pain management agreements is not necessary for hospice or nursing home patients. A sample pain management agreement and prescription drug risk assessment tools may be found on the board's Web site at [www.medicalboard.iowa.gov](http://www.medicalboard.iowa.gov).

h. Substance abuse history or comorbid psychiatric disorder. A patient's prior history of substance abuse does not necessarily contraindicate appropriate pain management. However, treatment of patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care and communication with the patient, monitoring, documentation, and consultation with or referral to an expert in the management of such patients. The board strongly encourages a multidisciplinary approach for pain management of such patients that incorporates the expertise of other health care professionals.

i. Drug testing. A physician who prescribes controlled substances to a patient for more than 90 days for the treatment of chronic pain shall consider utilizing drug testing to ensure that the patient is receiving appropriate therapeutic levels of prescribed medications or if the physician has reason to believe that the patient is at risk of drug abuse or diversion.

j. Termination of care. The physician shall consider termination of patient care if there is evidence of noncompliance with the rules for medication use, drug diversion, or a repeated pattern of substance abuse.

13.2(6) Pain management for terminal illness. The provisions of this subrule apply to patients who are at the stage in the progression of cancer or other terminal illness when the goal of pain management is comfort care. When the goal of treatment shifts to comfort care rather than cure of the underlying condition, the board recognizes that the dosage level of opiates or controlled substances to control pain may exceed dosages recommended for chronic pain

and may come at the expense of patient function. The determination of such pain management should involve the patient, if possible, and others the patient has designated for assisting in end-of-life care.

13.2(7) Prescription monitoring program. The Iowa board of pharmacy has established a prescription monitoring program pursuant to *Iowa Code sections 124.551 to 124.558* to assist prescribers and pharmacists in monitoring the prescription of controlled substances to patients. The board recommends that physicians utilize the prescription monitoring program when prescribing controlled substances to patients if the physician has reason to believe that a patient is at risk of drug abuse or diversion. A link to the prescription monitoring program may be found at the board's Web site at [www.medicalboard.iowa.gov](http://www.medicalboard.iowa.gov).

13.2(8) Pain management resources. The board strongly recommends that physicians consult the following resources regarding the proper treatment of chronic pain. This list is provided for the convenience of licensees, and the publications included are not intended to be incorporated in the rule by reference.

a. American Academy of Hospice and Palliative Medicine or AAHPM is the American Medical Association-recognized specialty society of physicians who practice in hospice and palliative medicine in the United States. The mission of the AAHPM is to enhance the treatment of pain at the end of life.

b. American Academy of Pain Medicine or AAPM is the American Medical Association-recognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

c. American Pain Society or APS is the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

d. DEA Policy Statement: Dispensing Controlled Substances for the Treatment of Pain. On August 28, 2006, the Drug Enforcement Agency (DEA) issued a policy statement establishing guidelines for practitioners who dispense controlled substances for the treatment of pain. This policy statement may be helpful to practitioners who treat pain with controlled substances.

e. Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. In March 2007, the Washington State Agency Medical Directors' Group published an educational pilot to improve care and safety of patients with chronic, noncancer pain who are treated with opioids. The guidelines include opioid dosing recommendations.

f. Responsible Opioid Prescribing: A Physician's Guide. In 2007, in collaboration with author Scott Fishman, M.D., the Federation of State Medical Boards' (FSMB) Research and Education Foundation published a book on responsible opioid prescribing based on the FSMB Model Policy for the Use of Controlled Substances for the Treatment of Pain.

g. World Health Organization: Pain Relief Ladder. Cancer pain relief and palliative care. Technical report series 804. Geneva: World Health Organization.

# MAINE

02	DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
313	BOARD OF DENTAL EXAMINERS
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396	BOARD OF LICENSURE OF PODIATRIC MEDICINE

## Chapter 21: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

Summary: Chapter 21 is a joint rule of the Board of Osteopathic Licensure, the Board of Licensure in Medicine, the Board of Dental Examiners, the Board of Nursing and the Board of Podiatric Medicine to ensure adequate relief of pain to the citizens of Maine.

### Rule Index

Section I:	Definitions
Section II:	Joint Statement on the Treatment of Pain
Section III:	Principles of Proper Pain Management
Section IV:	Controlled Substances Contract

Section I: Definitions. As used by the Boards when evaluating practice and prescribing issues, the following terms are defined as follows:

1. **Acute pain** – Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.
2. **Addiction** – Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.
3. **Chronic Pain** – Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.
4. **Clinician** – An allopathic (MD) or osteopathic (DO) physician, physician assistant (PA), nurse practitioner (NP) or certified nurse midwife (CNM), dentist (DMD or DDS), or podiatrist (DPM).
5. **Pain** – An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
6. **Physical Dependence** – Physical dependence is a state of adaptation manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction,

decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

7. **Pseudoaddiction** – the iatrogenic syndrome (medically caused) resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

8. **Substance Abuse** – Substance abuse is the use of any substance(s) for non-therapeutic purposes of medication for purposes other than those for which it is prescribed.

9. **Tolerance** – Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

## Section II: Joint Statement on the Treatment of Pain.

The Boards recognize that principles of quality medical, dental and advanced nursing practice dictate that the people of the State of Maine have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this rule, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine, dentistry and advanced nursing. The Boards encourage clinicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All clinicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this rule has been developed to clarify the Boards' position on pain control, particularly as related to the use of controlled substances, to alleviate clinician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from clinicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating clinician's responsibility. As such, the Boards will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Boards recognize controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Boards will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the clinician. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain and treatment outcomes. Clinicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Boards are obligated under the laws of the State of Maine to protect the public health and safety. The Boards recognize that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Boards expect that clinicians will incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Clinicians should not fear disciplinary action from the Boards for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Boards will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a clinician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and/or federal law is required.

The Boards will judge the validity of the clinician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Boards will not take disciplinary action against a clinician for deviating from this rule when contemporaneous medical records document reasonable cause for deviation. The clinician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

### Section III: Principles of Proper Pain Management

The Boards have adopted the following criteria when evaluating the clinician's treatment of pain including the use of controlled substances. Each of these principles is essential in the treatment of patients with pain.

1. **Evaluation of the Patient** — A medical history and appropriate physical examination must be obtained, evaluated and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse. It is recommended that the State's Controlled Substance Prescription Monitoring Program Database (PMP) be utilized. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. **Treatment Plan** — The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the clinician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. **Informed Consent and Agreement for Treatment** — The clinician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one clinician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse or substance dependence, the clinician should use a written agreement between clinician and patient outlining patient responsibilities, including:

- a. urine/serum medication levels screening when requested;
- b. pill count when requested;
- c. number and frequency of all prescription refills; and
- d. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. **Periodic Review of Treatment Efficacy** — The clinician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the clinician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the clinician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. Likewise, the clinician should periodically review the course of treatment where psychoactive drugs are used for the treatment of components of chronic pain, e.g., emotional, psychological, or psychosocial stressors, and assess the appropriateness of continued use of the current treatment plan if the patient's progress is unsatisfactory.

5. **Consultation or Referral** — The clinician should consult or refer, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. Chronic pain often has, as a component, emotional, psychological, or psychosocial stress. In these situations, a number of patients may benefit from psychoactive medications, as well as controlled substances for pain control. The combination of opiates with psychoactive medications, e.g., benzodiazepines, may place the patient at greater risk. The risk may be associated with drug interaction, potentiation, or abuse. In these situations, consultation with or referral to an expert in the management of such patients may be required.

6. **Medical Records** — The clinician should keep accurate and complete records to include:

- a. the medical history and appropriate physical examination;
- b. diagnostic, therapeutic and laboratory results;
- c. evaluations and consultations;
- d. treatment objectives;
- e. discussion of risks and benefits;
- f. informed consent;

- g. treatments;
- h. medications (including date, type, dosage and quantity prescribed);
- i. instructions and agreements; and
- j. periodic reviews.

Records should remain current and be maintained in an accessible manner, readily available for review.

7. **Reportable Acts** — Generally, information gained as part of the clinician/patient relationship remains confidential. However, the clinician has an obligation to deal with persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Information suggesting inappropriate or drug-seeking behavior, should be addressed appropriately and documented. Use of the PMP is recommended.

8. **Compliance With Controlled Substances Laws and Regulations** — To prescribe, dispense or administer controlled substances, the clinician must be licensed or otherwise authorized and comply with applicable federal and state regulations. Clinicians are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* and any relevant documents issued by the appropriate board or agency for specific rules governing controlled substances as well as applicable state regulations.

#### Section IV: Controlled Substances Contract.

Suggested elements of a controlled substance contract are as follows:

1. Specifies that the clinician is the single source of controlled substances;
2. May specify the pharmacy;
3. Provides written, informed consent to release contract to local emergency departments and pharmacies;
4. If written consent is given for release to local emergency departments and/or pharmacies, consent is also being given to the other clinicians and providers such as pharmacists to report violations of the contract back to the prescribing clinician;
5. Specifies that if the clinician becomes concerned that there has been illegal activity, the clinician may notify the proper authorities;
6. Provides that if the clinician has obtained a written release, ER personnel and other providers shall report violations of the contract back to the doctor who prescribed the controlled substance(s);
7. Specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;
8. Specifies that a risk of chronic narcotics treatment is physical dependence (as defined);

9. Specifies that a risk of chronic narcotics treatment is addiction (as defined);
10. Specifies that it is the responsibility of the patient to be discreet about possessing narcotics and keeping medications in an inaccessible place so that they may not be stolen;
11. If the patient violates the terms of the contract, the violation should be documented. The clinician response to the violation should be documented, as well as the rationale of and changes in the treatment plan;
12. Clinician may consider “fill only at \_\_\_\_\_ pharmacy” on the prescription form;
13. Specifies use of urine/serum medications levels screening when appropriate; and
14. Specifies use of a pill count when appropriate.

STATUTORY AUTHORITY:

- R. 2009, c. 56
- 32 MRSA §1072 and 1073(2) (Board of Dental Examiners)
- 32 MRSA §§2102(2-A) and 2153-A(1) (State Board of Nursing)
- 32 MRSA §2562 (Board of Osteopathic Licensure)
- 32 MRSA §3269(3), (7) (Board of Licensure in Medicine)
- 32 MRSA §3605-B (Board of Licensure of Podiatric Medicine)

EFFECTIVE DATE: JUNE 13, 2010

# MASSACHUSETTS

## COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE

### PRESCRIBING PRACTICES POLICY AND GUIDELINES



**Policy 15-05**  
**Adopted October 8, 2015**

## COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE

*“Prescribing Practices Policy and Guidelines” (Prescribing Policy) was first adopted on August 1, 1989 as Board Policy 89-01. The Policy was amended on November 17, 2010. The November 17, 2010 amendment superseded all previous versions of this Prescribing Policy.*

*“Prescribing Practices Policy and Guidelines” is amended on October 8, 2015. This amendment supersedes all previous versions. “Prescribing Practices Policy and Guidelines” is hereby renumbered as Board Policy 15-05.*

*The Board is not responsible for any third party content which can be accessed through the Prescribing Practices Policy and Guidelines. The Prescribing Policy provides links to other sites without endorsement.*

*While the Board strives to keep this Prescribing Policy current, that is not always possible. In the event of any discrepancies between third party content and the Board’s statutes, regulations or policies, the Board statutes, regulations or policies control.*

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# PRESCRIBING POLICY PRACTICES AND GUIDELINES

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## INTRODUCTION

The Massachusetts Board of Registration in Medicine has prepared these “Prescribing Practices Policy and Guidelines” to provide physicians with greater understanding of their responsibilities and the standards the Board applies in reviewing their prescribing practices. The Board believes that, by providing a comprehensive overview of the physician’s responsibilities related to prescribing, this publication will help further its overall mission to foster the delivery of competent, high quality health care in Massachusetts. The Board also believes that this information will help physicians maintain a high level of quality in their prescribing practices.

Scientific and legal developments in the area of prescribing occur frequently. It is the obligation of the physician to stay abreast of this rapidly-changing subject matter. The Board encourages all physicians who prescribe to educate themselves on the drugs they prescribe, and to continuously reevaluate prescribing practices in the light of clinical outcomes.

This publication is available on the Board’s website at [www.mass.gov/massmedboard](http://www.mass.gov/massmedboard). Physicians should check the website regularly. In addition to this publication, the Board has issued other policies and guidelines that are available on the Board’s website. Policies related to prescribing are attached to this publication as Appendices.

### **2015 UPDATE**

In 2015, Governor Charles Baker announced that Massachusetts was in the midst of an opioid epidemic. According to the Massachusetts Department of Public Health, there were over 1,000 estimated unintentional opioid-related deaths in 2014. There were 312 opioid-related deaths in the first three months of 2015. In February 2015, Governor Baker convened an Opioid Working Group, an 18-member statewide, expert panel.

On June 22, 2015, Governor Charles Baker announced the findings of his Opioid Working Group. The task force issued 65 recommendations to address the opioid epidemic in Massachusetts.) These recommendations include plans to establish 100 new addiction-treatment beds within one year. The task force called for access to evidence-based medication-assisted therapy and for greater availability of medication that can treat opioid overdose. *See* <http://www.mass.gov/eohhs/gov/departments/dph/stop-addiction/recommendations-from-the-governors-opioid-addiction-working-group.html>

One key element of the Governor’s plan is public education – for parents, about the hazards of prescription painkillers in the home, for students, on the dangers of opioids, and for health care professionals. Education is seen as the way to change the stigma against substance use disorder and to redefine addiction as a public health issue. Primary care practitioners are called upon to screen for and treat addiction as they would any other medical condition, in order to expedite interventions and treatment referrals.

Also in 2015, the Massachusetts Medical Society issued opioid prescribing guidelines for physicians. These guidelines are included in this Policy in Part 1, Section 5.

## **EXECUTIVE SUMMARY**

This Executive Summary is a short review of the material contained in the Guidelines. Please refer to each individual section for more comprehensive information.

### **Part I - Boundaries of Acceptable Medical Practice**

Part I of this publication provides guidance on the legal standards and boundaries applicable to prescribing in medical practices.

#### **Section 1: Basic Requirements of Acceptable Medical Practice**

To be valid, a prescription must be issued for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice. As with every aspect of medical care, a physician's prescription practices should be guided by medical knowledge, best-practices, professional guidelines and consensus standards. The Board encourages physicians to understand their roles and responsibilities in preventing medication errors.

#### Section 2: Prescribing to Immediate Family Members

Board regulations prohibit physicians, except in an emergency, from prescribing Schedule II controlled substances to a member of their immediate family.

#### Section 3: Prescribing to Self

Physicians are prohibited from prescribing controlled substances in Schedules II through IV for their own use.

#### Section 4: Internet Prescribing

To be valid, a prescription must be issued in the usual course of the physician's professional practice, and within a physician-patient relationship that is for the purpose of maintaining the patient's well-being. In addition, the physician must conform to certain minimum standards of patient care, such as taking an adequate medical history, doing a physical and/or mental status examination and documenting the findings. This rule applies to any prescription, issued by any means, including the Internet or other electronic process. Prescribing that does not meet these requirements is unlawful.

#### Section 5: Prescribing for the Treatment of Chronic Pain

Chronic pain is a major public health problem. At the same time, however, opioid misuse and overdoses have also become very serious public health problems. Physicians must be aware of the legitimate medical uses of controlled substances for the treatment of pain, while safeguarding against opioid misuse and diversion. The MMS Opioid Therapy and Physician

Communication Guidelines are included as a useful tool for physicians, especially primary care physicians.

#### Section 6: Treating Drug-Dependent Persons

Treating patients for drug dependency usually requires specialized knowledge beyond the substance abuse training that is received in medical school. Physicians should not undertake to treat patients for addiction unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to an addiction medicine specialist or to another qualified physician.

Physicians who use drugs to treat drug dependency are subject to special requirements under Massachusetts and federal laws. Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should review Part I, Section 1, “Special Authorizations Required to Treat Addiction,” and Part II, Section 7, “Medication-Assisted Treatment of Opioid Addiction.”

Physicians who are not specially registered with the DEA are permitted to administer buprenorphine or methadone to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. However, in such cases, not more than one day’s medication may be administered at a time and such treatment may not continue for more than three days.

#### Section 7: Medication-Assisted Treatment of Opioid Addiction

Before any physician can treat opioid addicted patients in an office-based setting, the physician must apply for a waiver. *See* Part I, Section 1, “Special Authorizations Required to Treat Addiction.” Once a physician has received that waiver, the Board expects that the

physician will work within the boundaries of accepted professional practice for medication-assisted treatment of opioid addiction.

#### Section 8: Enhancing Patient Adherence

This section discusses means for enhancing patient adherence to their prescription medicine regimens. To help prevent the potential misuse of medications, physicians should talk with their patients about safely storing and disposing of prescription medications.

#### Section 9: The Importance of Continuing Professional Development

Some physicians may inadvertently engage in improper and uninformed prescribing practices because they have not kept abreast of new developments in pharmacology and drug therapy. The Board urges all physicians to keep up-to-date on current information that affects the proper prescribing of controlled substances by taking Continuing Professional Development (CPD) courses. Pursuant to M.G.L. c. 94C, § 19(6)(e), the Board requires active licensees who prescribe controlled substances to complete three (3) credits in opioid education and pain management training on a biennial basis as a prerequisite to licensure, renewal or revival of a license.

### **Part II – Technical Requirements**

Part II of this publication summarizes the practical and technical requirements related to prescribing in Massachusetts.

#### Section 1: Registration

Prior to prescribing any controlled substance in Massachusetts, physicians should:

- Have an active Massachusetts license to practice medicine; and
- Register with the United States Drug Enforcement Agency (DEA) to prescribe substances in Schedules II-V; and

- Obtain a Massachusetts Controlled Substance Registration (MCSR) number to prescribe substances in Schedules II-VI.<sup>1</sup>

The Board expects physicians to be aware of and comply with the registration requirements of both the DEA and the DPH. These requirements are summarized in Part I, Section 1 of these Guidelines.

Special authorization from the DEA is necessary to be considered a narcotic treatment program. Physicians who wish to run a narcotic treatment program must:

- Be separately registered with the DEA as a narcotic treatment program;
- Comply with all DEA regulations regarding drug addiction treatment;
- Be licensed by the Massachusetts DPH as a substance abuse treatment program; and
- Obtain a DEA waiver to treat opioid addiction outside a treatment program, if the physician wants to prescribe in the office setting.

## Section 2: Drug Schedules

In Massachusetts, all prescription medications are “controlled substances.” This section describes each of the six schedules, and lists examples of the drugs in each Schedule.

## Section 3: Prescriptions

This section sets out the requirements for issuing prescriptions, including verbal, faxed, and electronic prescriptions. It discusses the elements of a written prescription.

## Section 4: Dispensing

This section sets out the requirements for dispensing controlled substances.

## Section 5: The Prescription Monitoring Program.

The Prescription Monitoring Program (PMP) is a repository for a patient’s prescription history for Schedule II-V prescriptions. The PMP is administered by the Department of Public

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<sup>1</sup> All physicians registered with the MCSR are automatically enrolled in the Massachusetts Prescription Monitoring Program, *see* Section 5, *infra*.

Health. All Massachusetts pharmacies and out-of-state pharmacies delivering to people in Massachusetts provide prescription data to the PMP.

#### Section 6: The Medical Marijuana Law

Effective January 1, 2013, Massachusetts voters passed a Medical Marijuana law through the initiative petition process. The law allows physicians to advise a qualifying patient about the risks and benefits of the medical use of marijuana. The physician may provide a qualifying patient with written certification that the medical use of marijuana may benefit that particular patient. The physician's written certification must be based on a full assessment of the qualifying patient's medical history and condition.

Marijuana is a Schedule I substance under federal law. The Massachusetts law does not give immunity under federal law or prevent the federal government from enforcing federal law.

#### Section 7: Supervision of Healthcare Practitioners with Prescriptive Authority

Practitioners with Prescriptive Authority, including Advanced Practice Registered Nurses (APRN), Physician Assistants (PA) and Pharmacists may issue orders for a controlled substance in the course of professional practice. All PAs who have prescriptive authority must be in written guidelines with and supervised by a Massachusetts licensed physician. Some APRNs with prescriptive authority, i.e., certified nurse practitioners (CNP), psychiatric clinical nurse specialists (PCNS) and certified registered nurse anesthetists (CRNA), must be in written guidelines with a supervising physician. Certified nurse midwives (CNM) must practice within a healthcare system and be in a clinical relationship with an obstetrician-gynecologist.

Pharmacists may have prescriptive authority under the Collaborative Drug Therapy Management Act, which permits certain pharmacists and physicians to enter into a collaborative

practice agreement, under which the pharmacist may then initiate, monitor, modify or discontinue a patient's drug therapy.

Additionally, pharmacists with appropriate training may administer vaccines.

#### Section 8: Gifts Or Inducements From The Pharmaceutical Industry

The Commonwealth takes seriously the potential for impropriety or the appearance of impropriety which may occur when pharmaceutical companies or medical device manufacturers give gifts to physicians. This section discusses the AMA's ethical opinion on gifts from those industries and reviews the Massachusetts law that prohibits certain gifts to physicians from pharmaceutical and medical device manufacturing companies.

## **PART I - BOUNDARIES OF ACCEPTABLE MEDICAL PRACTICE**

### **1. BASIC REQUIREMENTS OF ACCEPTABLE PRESCRIPTIVE PRACTICE**

#### **Valid Prescriptions**

To be valid, a prescription must be issued for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice.<sup>2</sup>

#### **Legitimate Medical Purpose**

The general standard for whether a prescription is issued for a legitimate medical purpose is often regarded as a question of whether the physician was acting in good faith in issuing the prescription.<sup>3</sup> There are several factors the Board looks at as indicia of the lack of good faith, including the following:

- Failure to follow at least minimum professional procedure;
- Permitting the patient to name the drug he desires;<sup>4</sup>
- Expressing concern during a patient encounter as to how and where a prescription would be filled in a manner that does not indicate a good faith concern for the patient;
- Repeated refills over relatively short periods;<sup>5</sup>
- General remarks of the physician indicating his or her experience with nontherapeutic uses of the drug and of drug enforcement actions and procedures;
- Failure to schedule appropriate additional appointments for return visits and other factors indicating a lack of interest in follow-up care; and
- Conversations and other circumstances that demonstrate that the physician knew that the drugs were not intended to be used for a therapeutic or medical purpose.<sup>6</sup>

#### **In the Usual Course of a Practitioner's Practice**

To satisfy the requirement that a prescription be issued by a practitioner in the usual course of his or her professional practice, there must be a physician-patient relationship that is

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<sup>2</sup> Mass. Gen.Laws c. 94C, §19(a).

<sup>3</sup> *Commonwealth v. Noble*, 230 Mass. 83 (1918); *Commonwealth v. Miller*, 361 Mass. 644 (1972) and *Commonwealth v. Pike*, 430 Mass. 317 (1999).

<sup>4</sup> The fact that a patient has named the drug he or she is eventually prescribed does not, by itself, make the prescription of that drug inappropriate.

<sup>5</sup> The Board realizes that there are situations where repeated refills over short periods may be appropriate. Whether this indicates bad faith depends on the context in which the refills are given.

<sup>6</sup> See *In the Matter of Arthur E. Baer, M.D.*, Board of Registration in Medicine, Adjudicatory Case No. 205 (Final Decision and Order, July 14, 1978).

for the purpose of maintaining the patient's well-being and the physician must conform to certain minimum norms and standards for the care of patients.<sup>7</sup> A minimum standard of proper medical practice requires that the physician establish a proper diagnosis and regimen of treatment. At a minimum, on first encounter with a patient, a physician must take and record an appropriate medical history and carry out an appropriate physical or mental status exam and record the results. The paramount importance of a complete medical history and a thorough and accurate physical examination is well established. The observance of these procedures as a function of the "usual course of professional practice" is of particular importance when controlled substances are part of treatment. It is the responsibility of the physician to prescribe drugs with proper regard for their action and potential dangers. Such procedures not only ensure that the patient obtains correct treatment but they may also prevent adverse reactions to drugs, which are a common cause of morbidity or mortality.

The Board recognizes that covering and cross-covering for fellow physicians is part of the practice of medicine and in such situations it may be appropriate to prescribe drugs to a patient whom the covering physician has not seen or examined. In these circumstances, the covering physician is relying on the treating physician's examination and diagnosis, This is permissible so long as the reliance is reasonable.

Failure to obtain an appropriate medical history and conduct an appropriate examination may have serious consequences for both the patient and the physician. Careless diagnosis and careless treatment lead to allegations of misconduct. Physicians who have been disciplined by the Board for prescription practice violations have written prescriptions for potentially dangerous

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<sup>7</sup> Id.

controlled substances without conducting any physical examinations or after conducting only cursory examinations.<sup>8</sup>

Beyond documenting appropriate medical histories and physical examinations, physicians must maintain medical records that are detailed enough in nature that the physician's clinical reasoning is discernible from his or her documentation. Treatment plans should be explicitly recorded. All patient visits and telephone calls relating to treatment should be documented. Prescriptions should be documented and changes in medications or dosage should be explained. These are just some of the rudiments of complete medical records.

#### Expedited Partner Therapy for the Treatment of Chlamydia

In order to combat the risk to the public health of untreated Chlamydia, the Massachusetts Legislature passed a law permitting the prescribing and dispensing of prescription medication without a physical examination, in certain limited circumstances. Physicians, physician assistants, nurse practitioners, and certified nurse midwives who are authorized to prescribe and dispense prescription drugs, and who diagnose infections due to Chlamydia trachomatis in individual patients, may prescribe and dispense prescription drugs to a patient's sexual partners for the presumptive treatment of Chlamydia infection without an examination of the patient's sexual partners.<sup>9</sup> Such prescribing practices are referred to as "Expedited Partner Therapy." In Massachusetts, Expedited Partner Therapy is permitted only for the treatment of Chlamydia.<sup>10</sup>

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<sup>8</sup> Some specialists, such as psychiatrists in private office settings, are permitted to prescribe drugs for mental ailments without conducting a physical examination where the general standards of good medical care indicate that a physical examination is not appropriate. Medical doctors, including psychiatrists, are permitted to treat illnesses outside their specialized area of practice when they have adequate training and the proper facilities to do so. However, a psychiatrist in a private office setting who does not have the facilities to conduct a proper physical examination should not be treating physical illnesses (such as back pain) where a physical examination is required.

<sup>9</sup> St. 2010, c. 131, § 62, codified at M.G.L. c. 111, §121B (effective July 1, 2010).

<sup>10</sup> See Policy No. 2015-03: *Guidance for Filling Expedited Partner Therapy Prescriptions*, Appendix H.

M.G.L. c. 111, § 121B applies to physicians' prescribing practices, and the prescribing practices of any healthcare practitioner with prescriptive authority whom a physician is supervising.

Regulations governing Expedited Partner Therapy (EPT) for the treatment of Chlamydia are located at 105 CMR 700.003(J) and 105 CMR 721.000. The Board recognizes that the Legislature has authorized Expedited Partner Therapy in order to address a serious public health concern, but notes that it should not be interpreted as an abandonment of the Board's long-held position that the act of prescribing medication must be performed only in the context of a bona fide provider-patient relationship, and after the physician has taken and recorded an appropriate medical history and an appropriate physical examination.

### **General Medical Standards and Preventing Medication Errors**

As with every aspect of medical care, a physician's prescription practices should be guided by medical knowledge, best-practices, guidelines and consensus standards. Physicians should involve patients in decisions about treatment and adhere to requirements for informed consent. Physicians are expected to prescribe only within their scope of practice or expertise. Physicians must regularly review their prescribing practices and must have a system in place that enables them to stay up-to-date with drug information.

According to the Centers for Disease Control and Prevention, 48.5% of U.S. citizens have used at least one prescription drug in the past 30 days.<sup>11</sup> Establishing and maintaining a strong provider-patient partnership is essential to reducing medication errors. In addition, decreasing errors requires a comprehensive approach that includes participation by physicians,

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<sup>11</sup> Centers for Disease Control and Prevention, *Fast Stats*, accessible at: <http://www.cdc.gov/nchs/faststats/drug-use-therapeutic.htm>.

nurses, pharmacists, and others in the health care community.<sup>12</sup> The Board encourages physicians to understand their roles and responsibilities in preventing medication errors.

## **2. PRESCRIBING TO IMMEDIATE FAMILY MEMBERS**

Board regulations prohibit physicians, “[e]xcept in an emergency, . . . from prescribing Schedule II controlled substances to a member of his immediate family, including a spouse (or equivalent), parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or other relative permanently residing in the same residence as the licensee.”<sup>13</sup>

The American Medical Association (AMA) has issued an ethical opinion on self-treatment and the treatment of families, and in that opinion states that physicians generally should not treat members of their immediate families.<sup>14</sup> The AMA notes that, among the risks that arise when a physician establishes a physician-patient relationship with an immediate family member are: professional objectivity may be compromised; the physician may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination; patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member, and physicians may be tempted to treat problems that are beyond their expertise or training.

Accordingly, the Board suggests that physicians consider refraining from prescribing all controlled substances for family members and significant others in non-emergency situations. Physicians who do choose to prescribe controlled substances for family members must take extra

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<sup>12</sup> Institute of Medicine, *Preventing Medication Errors*, ed. Aspden, Wolcott, *et al.*, (2006).

<sup>13</sup> 243 Code Mass. Regs 2.07(19).

<sup>14</sup> American Medical Assn., *Code of Medical Ethics*, “Opinion 8.19 – Self-Treatment or Treatment of Immediate Family Members.” The AMA does recognize that “It would not always be inappropriate to undertake . . . treatment of immediate family members. In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat . . . family members until another physician becomes available. In addition . . .there are situations in which routine care is acceptable for short-term, minor problems.”

precautions to insure that this privilege is not abused. The same documentation and examination requirements applicable to patients who are not related to the physician apply when the physician is prescribing controlled substances to the physician's immediate family members. Physicians should document examination results, diagnosis and treatment plans carefully and accurately.

### **3. PRESCRIBING TO SELF**

Physicians are prohibited from prescribing controlled substances in Schedules II through IV for their own use.<sup>15</sup>

Physician self-prescribing presents even deeper concerns than prescribing to family members. The prescription of drugs to oneself creates an enormous potential for abuse. The Board has concluded that the potential for misuse of drugs in Schedules II through IV far outweighs the relatively minor inconvenience that is caused by requiring physicians to obtain prescriptions for their own use from other physicians.

### **4. INTERNET PRESCRIBING**

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.<sup>16</sup> This standard applies to any prescriptions issued or dispensed via the Internet. The Board has interpreted M.G.L. c. 94C, §19A in issuing Policy No. 03-06: "Internet Prescribing."<sup>17</sup> The policy states that to be valid, a prescription must be issued in the usual course of the physician's professional practice and within a physician-patient relationship that is for the purpose of maintaining the patient's well-being. In addition, the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. "Issuance of a

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<sup>15</sup> 243 CMR 2.07(19).

<sup>16</sup> M.G.L. c. 94C, §19A.

<sup>17</sup> See Appendix B.

prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.”<sup>18</sup>

The federal standards for distributing or dispensing controlled substances by means of the Internet are defined at 21 C.F.R. 1300.04. While pharmacies are permitted to dispense controlled substances via orders made on the Internet, the original prescriptions must be issued for a legitimate medical purpose by a physician in the usual course of his or her professional practice.<sup>19</sup>

In April 2002, the Federation of State Medical Boards (FSMB) issued “Model Guidelines for the Appropriate Use of the Internet in Medical Practice,” which states, in part: “Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.”

In 2003, the AMA adopted a policy on Internet Prescribing.<sup>20</sup> This policy calls for physicians who prescribe medications via the Internet to establish a valid patient-physician relationship. The AMA cautioned, “A physician prescribing medication across state lines must possess appropriate licensure in all jurisdictions where patients reside.”<sup>21</sup> The AMA further stated, “Physicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which licensure is held.”<sup>22</sup> Both the AMA and FSMB policies caution that physicians using Internet Prescribing should transmit prescriptions over secured networks.

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<sup>18</sup> Mass. Board of Reg. in Medicine, Policy No. 03-06: “*Internet Prescribing*,” Appendix B.

<sup>19</sup> 21 Code Fed. Reg. § 1300.04(l)(1).

<sup>20</sup> AMA Policy H-120.949, *Guidance for Physicians on Internet Prescribing*.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

In April 2014, the FSMB issued a “Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine,” wherein it addressed again the issue of Internet prescribing.<sup>23</sup> Specifically, the FSMB noted that measures should be employed to “uphold patient safety in the absence of traditional physical examination” and that the use of telemedicine to prescribe be “in accordance with current standards of practice and consequently carry the same professional accountability as prescriptions delivered during an encounter in person.” The Board has recognized telemedicine as the “practice of medicine.”<sup>24</sup>

## **5. PRESCRIBING OPIOIDS FOR THE TREATMENT OF CHRONIC PAIN**

Chronic pain is a major public health problem in the United States. One estimate is that 30% of the U.S. population suffers from chronic pain.<sup>25</sup> Opioid therapy is a common treatment for chronic pain and its use has been increasing over the past 15 years. Opioid therapy for use in the treatment of chronic pain differs from opioid therapy used to treat cancer pain or at the end of life, which are not discussed herein.

It should be emphasized that patients who legitimately take controlled substances for extreme pain can become tolerant to their medications. Physicians should be aware of the following criteria for problematic opioid use:

- “The patient displays an overwhelming focus on opiate issues during pain clinic visits that occupies a significant proportion of the pain clinic visit and impedes progress with other issues regarding the patient’s pain. This behavior must persist beyond the third clinic treatment session.
- The patient has a pattern of early refills (3 or more) or escalating drug use in the absence of an acute change in his or her medical condition.

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<sup>23</sup> “FSMB Model Policy for the Appropriate Use of Telemedicine Technologies,” accessible at: [http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB\\_Telemedicine\\_Policy.pdf](http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf).

<sup>24</sup> 243 CMR 2.01(4), (effective 2/1/2012).

<sup>25</sup> Johannes CB, Le TK, Zhou X, Johnston, JA, Dworkin RH. “The prevalence of chronic pain in United States adults: results of an Internet-based survey.” *The Journal of Pain*; 2010; 11:1230-9.

- The patient generates multiple telephone calls or visits to the administrative office to request more opiates, requests early refills, or has problems associated with the opiate prescription. A patient may qualify with fewer visits if he or she creates a disturbance with the office staff.
- There is a pattern of prescription problems for a variety of reasons that may include lost medications, spilled medications or stolen medications.
- The patient has supplemental sources of opiates obtained from multiple providers, emergency rooms, or illegal sources.”<sup>26</sup>

In 2013, the Federation of State Medical Boards (FSMB) adopted a “Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain.”

“There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated. Since the 2004 [FSMB Pain Policy] revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffer from pain so intense as to interfere with the activities of daily living.”<sup>27</sup>

Recent scientific studies have provided new information on opioid use for chronic pain, and the FSMB has indicated it intends to revise its 2013 Model Policy so that it more closely align with the latest scientific information.<sup>28</sup> When the FSMB finalizes its revisions, the Board will review the Model Policy and consider whether to adopt it, in whole or in part.<sup>29</sup>

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<sup>26</sup> These criteria are set out in the AMA Council on Science and Public Health Report 2 (I-08) “Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction.”

<sup>27</sup> Federation of State Medical Boards, “*Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*” (July 2013) is accessible at: [http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain\\_policy\\_july2013.pdf](http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf)

<sup>28</sup> Resolution 15-4, FSMB House of Delegates Meeting, Approved April 25, 2015. “*Resolved*: that the Federation of State Medical Boards will establish a workgroup ... to review the current science and revise the *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*.”

<sup>29</sup> “*Guideline for the Use of Controlled Substances for the Treatment of Pain*,” was adopted by the Board in December 2004.

## **The Massachusetts Medical Society Guidelines**

On May 21, 2015, the Massachusetts Medical Society (MMS) issued Guidelines related to the prescribing of opioids. (Appendix G.) The MMS issued two sets of Guidelines: Acute Care Guidelines and Chronic Pain Guidelines.

- The Chronic Pain Guidelines apply to patients who receive opioids for more than 90 days, including transferred patients with opioid histories.
- The MMS Guidelines are intended to have general applicability and are most relevant in primary care. Physicians should also review existing guidelines for their individual specialties.
- The Guidelines do not apply to patients with cancer, patients in hospice or palliative care, and inpatients at a hospital or a nursing home.

## **6. TREATING DRUG-DEPENDENT PERSONS**

The American Society of Addiction Medicine defines “addiction” as follows:

“Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction is characterized by inability to consistently abstain, impairment in behavioral control, and craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.”<sup>30</sup>

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<sup>30</sup> “Standards of Care: For the Addiction Specialist Physician,” American Society of Addiction Medicine, 2014.

Treating patients for drug dependency may require specialized knowledge beyond the substance abuse education that is received in medical school. Physicians should not undertake to treat patients for addiction unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to addiction medicine specialists or another qualified physician. The American Society of Addiction Medicine (ASAM) has published standards of care for treating patients with addiction.<sup>31</sup> These standards apply to physicians with addiction specialty certification and to any physician assuming the responsibility for caring for a patient with addiction.

Physicians who use drugs to treat addiction are subject to special requirements under Massachusetts and federal laws.<sup>32</sup> Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid addiction should review Part I, Section 1, “Special Authorizations Required to Treat Addiction,” and Part II, Section 7, “Medication-Assisted Treatment of Opioid Addiction.” To obtain the necessary applications for waivers and detailed information regarding opioid treatment program requirements, physicians should contact the DEA and the Massachusetts Drug Control Program. *See* Appendix A “Contact Information.”

Physicians who are not specially registered with the DEA are permitted to administer buprenorphine or methadone to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment.<sup>33</sup> However, in

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<sup>31</sup> ASAM, accessible at <http://www.asam.org/docs/default-source/publications/standards-of-care-final-design-document.pdf>

<sup>32</sup> 21 C.F.R. § 1306.07(a); M.G.L. c. 111B, §§6, 6A, 6B; M.G.L. c 111E § 7; and 105 CMR 164.000

<sup>33</sup> 21 C.F.R. § 1306.07(b).

such cases, not more than one day's medication may be administered at a time and such treatment may not continue for more than three days.<sup>34</sup>

Physicians may be approached by patients for the specific purpose of securing drugs to support their addiction. Drug dependent persons seeking controlled substances can be any age and often do not look "suspicious." Physicians should beware of transient patients, extremely persuasive patients, and patients who show little interest in the diagnosis and resist attempts to verify their medical history. These are common behaviors among deceptive patients. Physicians who feel that they have been threatened into writing a prescription should immediately notify the police once the patient has left the office.

## **7. MEDICATION-ASSISTED TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE**

### **A. Buprenorphine-containing Products**

Before any physician can prescribe buprenorphine for the medication-assisted treatment of opioid addiction, the physician must apply for a waiver from the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA will notify the DEA if the waiver is granted and the DEA will issue an Identification Number. The Identification Number must appear on all prescriptions for buprenorphine. *See infra* Part I, Section 1, "Special Authorizations Required to Treat Addiction."

Once a physician has received that waiver, the Board expects that the physician will work within the boundaries of accepted professional practice for office-based treatment of opioid addiction. Physicians should note that they are not permitted to delegate the prescribing of buprenorphine to non-physicians.

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<sup>34</sup> *Id.*

The Federation of State Medical Boards issued a Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office.<sup>35</sup> The Board encourages physicians who are engaged in office-based treatment of opioid addiction to review the FSMB’s Model Policy. Physicians are also encouraged to review the materials published by SAMHSA, which administers the Buprenorphine program. *See e.g., SAMHSA’s Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: a Treatment Improvement Protocol TIP 40, which is available through the SAMHSA website.*<sup>36</sup>

## **B. Naltrexone**

In 2010, the Food and Drug Administration approved the use of Naltrexone for the treatment of people with opioid dependence. Naltrexone can be prescribed by any physician who is licensed to prescribe medications. While no special training is required, as with any drug, the Board expects physicians to familiarize themselves with risks and benefits of the naltrexone, and advise their patients accordingly.<sup>37</sup>

## **8. ENHANCING PATIENT ADHERENCE**

“Drugs don’t work in patients who don’t take them.”  
- Former U.S. Surgeon General C. Everett Koop, M.D.

Adherence to prescription medication regimens is a critical factor in achieving optimal patient outcomes; however, many patients do not realize the full benefits of treatment because of a failure to take their medication as prescribed. Non-adherence to medication regimens can lead

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<sup>35</sup> “*FSMB Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office*,” (2013).  
Accessible at: [http://library.fsmb.org/pdf/2013\\_model\\_policy\\_treatment\\_opioid\\_addiction.pdf](http://library.fsmb.org/pdf/2013_model_policy_treatment_opioid_addiction.pdf).

<sup>36</sup> [http://buprenorphine.samhsa.gov/Bup\\_Guidelines.pdf](http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf).

<sup>37</sup> “An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People with Opioid Dependence,” accessible at: <https://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf>.

to poor clinical outcomes, high rates of hospitalization, high utilization of medical services and an overall increase in healthcare costs.<sup>38</sup>

Physicians can have a decisive impact on medication adherence by following a patient-centered approach to care that promotes open avenues of communication between the physician and the patient. Prior to prescribing new medications, physicians should carefully describe to patients the purpose and use of the drug, the benefits, as well as any significant side effects that the patient may experience, and basic information on how to take the medication correctly. Physicians should encourage patients to ask questions, and should provide written information about medication. The Board encourages physicians to provide this type of written information to patients to help patients become more informed participants in their own health care.

Physicians can also assist patients in overcoming barriers to medication adherence by reducing the complexity of the prescribed medication regimens wherever clinically appropriate.<sup>39</sup> Patients should be provided ongoing support and follow-up care throughout their course of therapy to help ensure adherence and optimal treatment outcomes.

Patient non-adherence can also have effects on prescription drug diversion and misuse. SAMHSA's 2009 National Survey on Drug Use and Health showed that the scale of prescription drug misuse is vast, with more than 7 million Americans reporting use of a prescription medication for non-medical purposes in the past 30 days.<sup>40</sup> The Board encourages physicians to talk with patients about the importance of taking medications as directed along with the dangers associated with prescription drug diversion and misuse. Physicians can help alleviate the risk of

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<sup>38</sup> Viswanathan M, Golin CE, Jones CD, *et al*, "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." 157 *Ann. Intern. Med.* 785-795 (2012).

<sup>39</sup> Matchin, R, M.D., "An Rx For Better Outcomes, Lower Costs," *American Medical News Opinion*, December 7, 2009.

<sup>40</sup> SAMHSA, *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, (2010), accessible at <http://oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf>.

diversion and misuse by prescribing only the quantity of medication needed based on the patient's clinical presentation and by not over-prescribing, especially in the case of prescription pain medications such as opioids.

A large source of the prescription drug problem is what is stored in America's medicine cabinets.<sup>41</sup> Patients who fail to properly secure medication in their homes create a risk of drug diversion and misuse within their own household and community. To help prevent the potential misuse of medications, physicians should talk with their patients about safely storing and disposing of prescription medications.<sup>42</sup> Throughout Massachusetts, residents can dispose of prescription and over-the-counter drugs in permanent medication collection kiosks located at many community police stations.<sup>43</sup> Medication collection kiosks offer residents a free and confidential way to dispose of unused or expired medications to help prevent diversion and abuse.

The National Transportation Safety Board has asked that all state guidelines on prescribing controlled substances for pain include a recommendation that health care providers discuss with their patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle, in any mode of transportation.<sup>44</sup>

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<sup>41</sup> Office of National Drug Control Policy, (2011). "*Epidemic: Responding to America's prescription drug abuse crisis.*" Retrieved from [https://www.whitehouse.gov/sites/default/files/ondep/issues-content/prescription-drugs/rx\\_abuse\\_plan.pdf](https://www.whitehouse.gov/sites/default/files/ondep/issues-content/prescription-drugs/rx_abuse_plan.pdf).

<sup>42</sup> Information on the proper storage and disposal of medications can be found at the Centers for Disease Control and Prevention website; <http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/preventiontips.htm>. Information regarding the safe disposal of medications at private residences can be found at the Massachusetts Energy and Environmental Affairs website: <http://www.mass.gov/eea/agencies/massdep/toxics/sources/disposal-of-waste-medications-at-private-residences.html>.

<sup>43</sup> A list of permanent resident waste medication kiosks in Massachusetts is located on the Massachusetts Energy and Environmental Affairs website: [www.mass.gov/eea/docs/dep/toxics/stypes/kiosklist.pdf](http://www.mass.gov/eea/docs/dep/toxics/stypes/kiosklist.pdf).

<sup>44</sup> "Joint Alert on NTSB Study," Appendix F.

## 9. THE IMPORTANCE OF CONTINUING PROFESSIONAL DEVELOPMENT

Some physicians may inadvertently engage in improper and uninformed prescribing practices because they have not kept abreast of new developments in pharmacology and drug therapy. The Board urges all physicians to keep up-to-date on current information that affects the proper prescribing of controlled substances by taking Continuing Professional Development Courses.

In 2010, the Massachusetts Legislature amended the controlled substances law, M.G.L. c. 94C, § 18,<sup>45</sup> to require that all physicians who prescribe controlled substances complete training in effective pain management, identification of patients at high risk of substance abuse and counseling patients about the side effects, addictive nature and proper storage and disposal of controlled substances. M.G.L. c. 94C, § 18 requires that the boards of registration of each professional license that requires such training must develop the standards for appropriate training programs.

In response to this legislation, the Board promulgated a regulation at 243 CMR 2.06(6) (d), effective February 1, 2012. These regulations require that applicants for licensure and licensees seeking to renew their licenses complete three credits in opioid education and pain management training. These three credits must be earned each renewal cycle and count towards a licensee's required risk management credits. Information in regard to meeting this requirement can be found on the Board's website, [www.mass.gov/eohhs/gov/departments/borim](http://www.mass.gov/eohhs/gov/departments/borim).

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<sup>45</sup> St. 2010, c. 283.

## **PART II – TECHNICAL REQUIREMENTS**

### **1. REGISTRATION REQUIREMENTS**

In Massachusetts, all prescription drugs are “controlled substances.”<sup>46</sup> Therefore, to prescribe or dispense any type of prescription drug, physicians who practice medicine in Massachusetts must obtain a Massachusetts Controlled Substances Registration (MCSR) number from the Massachusetts Department of Public Health (DPH).<sup>47</sup> The DPH Drug Control Program is responsible for issuing MCSR numbers. To obtain an application for an MCSR number and information about the application process, contact the DPH Drug Control Program. *See* Appendix A: “Contact Information.”

All physicians who prescribe any controlled substance in Schedules II through V must also have a registration certificate from the United States Drug Enforcement Administration (DEA).<sup>48</sup> To obtain an application for a certificate of registration from DEA, instructions and a copy of the “DEA Practitioner’s Manual,” physicians should contact the DEA Boston Field Office. *See* Appendix A: “Contact Information.”

Massachusetts physicians who issue prescriptions only for Schedule VI drugs must have a MCSR number but are not required to register with the DEA.

Physicians in Massachusetts may not prescribe Schedule I controlled substances, which have no current accepted medical use, with the exception of medical marijuana.<sup>49</sup> Physicians are permitted to provide written certification to patients who qualify for the medical use of

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<sup>46</sup> M.G.L. c. 94C, § 2(a); 105 CMR § 700.002.

<sup>47</sup> M.G.L. c. 94C, § 7; 105 CMR § 700.004(M).

<sup>48</sup> 21 U.S.C. § 823 and 21 C.F.R. § 1301.

<sup>49</sup> M.G.L. c. 94C, § 3. *See infra* Part II, Section 2, “Drug Schedules.”

marijuana, as long as the physician follows the legal requirements for providing such certification.<sup>50</sup> *See*, Part II, Section 6, “Medical Marijuana” section.

In order to prescribe a Schedule II controlled substance (e.g., methadone) or a Schedule III controlled substance containing buprenorphine for the medication-assisted treatment of opioid addiction, physicians must obtain additional specific authorization from the DEA, the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), and the Massachusetts Bureau of Substance Abuse Services (BSAS).

#### Basic Requirements

The DEA and DPH require separate registrations for each practice location at which a physician dispenses or administers controlled substances.<sup>51</sup>

Physicians must obtain separate MCSR numbers for each of their professional activities. For example, separate Massachusetts registrations would be required for work as a researcher and as a practicing physician or chemical analyst.<sup>52</sup> The DEA does not require separate registrations for each professional activity.<sup>53</sup>

#### Change of Address

Because DEA certificates of registration and MCSR numbers are location-specific, physicians must notify the DEA and DPH Drug Control Program when they move from their registered address.<sup>54</sup>

A physician’s DEA registration may be transferred to a new location, if approved by the DEA.<sup>55</sup> A physician’s request for transfer must be made to the DEA in writing and must be

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<sup>50</sup> St. 2012, c. 369; 105 CMR § 725.000 *et seq.*

<sup>51</sup> 21 U.S.C. § 822(e); 21 C.F.R. § 1301.12; M.G.L c. 94C, § 10; 105 CMR § 700.004(F).

<sup>52</sup> 105 CMR § 700.004(A)(2) and 105 CMR § 700.004(C).

<sup>53</sup> 21 U.S.C. § 823(f).

<sup>54</sup> 105 CMR § 700.004(J); 105 CMR § 700.004(K); 21 U.S.C. § 827(g); 21 C.F.R. § 1301.51.

<sup>55</sup> 21 C.F.R. § 1309.63.

accompanied by photocopies of the physician's medical license, MCSR number, and DEA registration certificate.

A physician's MCSR is not transferrable to a new location; a physician must apply for a new registration prior to moving.<sup>56</sup> Physicians must also notify the DPH Commissioner 30 days in advance of their discontinuation of business or professional practice.<sup>57</sup>

#### Registration Renewal and Termination

DEA registration must be renewed every three years.<sup>58</sup> The DEA notifies registrants in advance of the renewal date.

The Commissioner of DPH periodically recalls MCSR numbers. Currently, the Commissioner recalls numbers every three years.<sup>59</sup>

The following conditions will result in termination of the MCSR number:

- A change of name or address as shown on the registration,
- Discontinuation of business or professional practice in Massachusetts,
- Revocation of registration by the DPH Commissioner, or
- Death of the registrant.<sup>60</sup>

Physicians should note, there is no provision for physicians who discontinue their business or professional practice in Massachusetts to remain registered in the state, even if they maintain a home in the state or maintain other contacts with the state. Physicians must apply for a new MCSR number if they return to Massachusetts to practice.<sup>61</sup>

#### Physicians Exempt from Registration Requirements

##### **Limited Licensees**

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<sup>56</sup> 105 CMR 700.004(J)(1) and (K).

<sup>57</sup> 105 CMR 700.004(J)(2).

<sup>58</sup> 21 U.S.C. § 822(a)(2).

<sup>59</sup> M.G.L. c. 94C, § 7(f); 105 CMR § 700.004(D).

<sup>60</sup> 105 CMR § 700.004(J).

<sup>61</sup> *Id.*

Limited licensees (residents and clinical fellows) do not need a MCSR number or their own individual DEA registration number.<sup>62</sup> Limited licensees may “administer, prescribe or otherwise dispense controlled substances . . . under the registration of the hospital or other registered health facility by which they are employed.”<sup>63</sup> Limited licensees may only do so, however, if the dispensing, administering or prescribing is done in the usual course of professional practice and only within the scope of their employment in the facility; and they are specifically authorized by the facility to do so.<sup>64</sup> The hospital or facility designates a specific internal code consisting of a numeric suffix to the hospital’s or health facility’s registration number, preceded by a hyphen for each person so authorized. The hospital or facility must maintain a current list of internal codes and must make such codes available at all times to other registrants, the DPH Commissioner and authorized law enforcement agencies.<sup>65</sup>

### **Physicians in the Employ of the Federal Government**

The DEA registration requirements are waived for physicians who work exclusively for a branch of the U.S. Military, the U.S. Public Health Service, or the U.S. Bureau of Prisons.<sup>66</sup> Such physicians must put their service identification number on all prescriptions, however, and should consult with their agency’s administrators regarding other requirements.<sup>67</sup>

### **Special Authorizations Required to Treat Addiction**

Federal law defines a narcotic treatment program as “a program engaged in maintenance and/or detoxification treatment with narcotic drugs.”<sup>68</sup>

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<sup>62</sup> 21 U.S.C. § 822(c)(1); 21 C.F.R. § 1301.22; 105 CMR § 700.004(B)(5).

<sup>63</sup> 105 CMR 700.004(B)(5).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> 21 C.F.R. 1301.23

<sup>67</sup> 21 C.F.R. 1306.01 *et seq.*

<sup>68</sup> 21 C.F.R. 1300.01(31).

### Prescribing Schedule II Controlled Substances to Treat Opioid Addiction

An individual physician may only prescribe methadone or any other Schedule II controlled substance for purposes of treating opioid addiction if the physician is registered with the DEA as a narcotic treatment program and the physician is in compliance with DEA regulations regarding treatment.<sup>69</sup>

All substance abuse treatment programs operating in Massachusetts must be licensed by the Department of Public Health.<sup>70</sup> Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should contact the DEA, SAMHSA, and DPH to obtain the necessary applications and detailed information regarding opioid treatment program requirements. *See* Appendix A, “Contact Information.”

### Prescribing Schedule III – V Controlled Substances to Treat Opioid Addiction

Physicians who have specific expertise and meet the qualifications set by DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA), may obtain a waiver permitting them to provide medication-assisted treatment of opioid addiction in their offices. Physicians who have been approved for such a waiver may use certain narcotic medications in Schedules III, IV, and V, which have been approved by the U.S. Food and Drug Administration (FDA) for opioid addiction treatment.<sup>71</sup> Currently, a waiver is necessary before a physician can prescribe FDA-approved medications that contain buprenorphine for use in opioid addiction treatment. During their first year under such a waiver, physicians are permitted to treat no more

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<sup>69</sup> 21 C.F.R. 1306.07(a).

<sup>70</sup> M.G.L. c. 111B, §§6, 6A, 6B; M.G.L. c 111E § 7; and 105 CMR § 164.000

<sup>71</sup> The Drug Addiction Treatment Act of 2000 (DATA 2000), 21 U.S.C. § 801. *See also* 21 C.F.R. § 1306.67(d).

than 30 patients. After one year, physicians may submit a notification of the need and intent to treat up to 100 patients.<sup>72</sup>

Physicians do not need a waiver to use extended-release injectable naltrexone to treat opioid addiction.<sup>73</sup> Unless exempted, physicians need to use the Prescription Monitoring Program before prescribing Schedule II or Schedule III narcotic drugs for the first time.<sup>74</sup>

## **2. DRUG SCHEDULES**

The general rule is that a prescription must be issued in the usual course of a practitioner's practice and for a legitimate medical purpose; this rule applies to all controlled substances.<sup>75</sup> There must be a physician-patient relationship that is for the purpose of maintaining the patient's health and the physician must conform to generally accepted standards of patient care, including documentation of the patient's current complaint, medical history, physical examination, appropriate diagnosis and treatment plan.<sup>76</sup>

### **Schedule I**

Schedule I controlled substances<sup>77</sup> have no current accepted medical use, lack safety standards for use under medical supervision, and have a high potential for abuse.<sup>78</sup> Although marijuana is a Schedule I controlled substance, Massachusetts physicians are permitted to provide written certification to patients who qualify for the medical use of marijuana, as long as the physician follows the legal requirements for providing such certification.<sup>79</sup>

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<sup>72</sup> 21 U.S.C. § 823(g)(2).

<sup>73</sup> SAMHSA, *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide* (February 2015).

<sup>74</sup> See *infra*, "Prescription Drug Monitoring Program," pp. 38-42.

<sup>75</sup> M.G.L. c. 94C, §19(a).

<sup>76</sup> See Part I, Section 1, "Basic Requirements of Acceptable Prescriptive Practice."

<sup>77</sup> 21 U.S.C. 812(c), M.G.L. c. 94C, §3(1).

<sup>78</sup> 21 U.S.C. 812(b)(1); M.G.L. c. 94C, §3(1).

<sup>79</sup> See Part II, Section 6, "Medical Marijuana Law;" St. 2012, c. 369; 105 CMR § 725.000 *et seq.*

Physicians may conduct bona fide research with Schedule I controlled substances with the approval of the Secretary of Health and Human Services, the Attorney General of the United States and the DPH Commissioner.<sup>80</sup> The requirements for using Schedule I controlled substances for research are quite restrictive and any physician who is interested in such research should consult with both the DEA and DPH for further information.

Some examples of Schedule I controlled substances include: heroin, lysergic acid diethylamide (LSD), marijuana,<sup>81</sup> and gamma hydroxybutyrate (GHB), and 3, 4-methylenedioxymethamphetamine (“Ecstasy”).<sup>82</sup>

## **Schedule II**

Schedule II controlled substances are considered to have a high potential for abuse, which may lead to severe psychological or physical dependence.<sup>83</sup>

Schedule II prescriptions may only be issued for a 30-day supply of medication.<sup>84</sup> There are two exceptions to this law:

- Prescriptions for methylphenidate and single entity drug products containing dextroamphetamine sulphate and methylphenidate hydrochloride may be issued for up to a 60-day supply when used for the treatment of inattention, impulsivity-hyperactivity disorder or narcolepsy; and
- Prescriptions for implantable infusion pumps containing a Schedule II controlled substance may be issued for a 90-day supply.<sup>85</sup>

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<sup>80</sup> 21 U.S.C. § 823(f); 105 CMR § 700.004(G).

<sup>81</sup> See Part II, Section 6, “Medical Marijuana Law.”

<sup>82</sup> 21 U.S.C. § 812(c).

<sup>83</sup> 21 U.S.C. § 812(b)(2); M.G.L. c. 94C, §3(2).

<sup>84</sup> M.G.L. c. 94C, §23.

<sup>85</sup> M.G.L. c. 94C, §23(d).

Refills of Schedule II drugs are not permitted.<sup>86</sup> Physicians may provide a patient with multiple prescriptions for the same Schedule II controlled substance for a total of up to a 90-day supply.<sup>87</sup> To comply with this federal law, the DPH Drug Control Program, the Board of Registration in Pharmacy, and the Board of Registration in Medicine have adopted a “Joint Policy Regarding Issuance of Multiple Prescriptions for Schedule II Controlled Substances; and Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines.”<sup>88</sup> Under this policy, physicians must date the prescriptions so they must be filled sequentially, with the patient receiving no more than a 30-day supply per prescription. The physician must indicate on subsequent prescriptions a “Do Not Fill Before” date, and must indicate the actual date that the prescription is signed.

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations. “Emergency situations” are defined as “situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines: (a) that the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user, and (b) that no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II, and (c) that it is not reasonably possible for the practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing.”<sup>89</sup> Pharmacists may not fill verbal prescriptions for Schedule II substances in a quantity exceeding that which is “adequate to treat the patient during the emergency period.”<sup>90</sup> A verbal prescription for a

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<sup>86</sup> 21 U.S.C. § 829; M.G.L. c. 94C, § 23(b).

<sup>87</sup> 21 C.F.R. § 1306.

<sup>88</sup> This policy is attached at Appendix C.

<sup>89</sup> 247 CMR 5.03(1). The federal definition of “emergency situations,” from which the Massachusetts regulation was derived, can be found in 21 C.F.R. § 290.10.

<sup>90</sup> 21 C.F.R. § 1306.11(d)(1).

Schedule II drug must be written and filed with the pharmacy within seven days of the event and the prescription should have written on its face, “Authorization for Emergency Dispensing.”<sup>91</sup>

For ambulatory patients, Schedule II substances may be faxed to pharmacies, but a hard copy prescription must accompany the patient before the medication can actually be dispensed.<sup>92</sup>

The Board strongly urges physicians to see patients who are using Schedule II drugs for long-term treatment as often as possible and suggests that patients be clinically re-evaluated at least once every four months. Documentation should be placed in the record if this is impossible, impractical or inappropriate. As a best practice, the physician should speak with the patient or the patient’s primary physician by telephone before issuing a new Schedule II prescription.<sup>93</sup> It is the Board’s position that when a primary care physician and a specialist are both treating a patient, it is the specialist who is obligated to inform the primary physician as to any treatment rendered to a mutual patient.

Because of their extremely high potential for abuse, Schedule II controlled substances may not be prescribed to a member of a physician’s immediate family, except in an emergency.<sup>94</sup> The Board also has prohibited physicians from prescribing controlled substances in Schedules II through IV for their own use.<sup>95</sup>

Some examples of Schedule II narcotics include morphine, codeine, hydromorphone, hydrocodone, methadone,<sup>96</sup> meperidine, oxycodone, oxymorphone, Vicodin®, Lortab®, Lorcet®, and fentanyl. Schedule II stimulants include amphetamine (Dexedrine®, Adderall®),

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<sup>91</sup> 21 C.F.R. § 1306.11(d)(4); M.G.L. c. 94C; §20(c); and 247 CMR § 5.03(3).

<sup>92</sup> 21 C.F.R. § 1306.11(a).

<sup>93</sup> See Scott M. Fishman, M.D., “*Responsible Opioid Prescribing, A Physician’s Guide*,” Federation of State Medical Boards, (2d ed. 2014).

<sup>94</sup> 243 CMR 2.07(19).

<sup>95</sup> *Id.*

<sup>96</sup> Methadone may only be prescribed as an analgesic. Methadone may be prescribed for the treatment of chronic pain. However, when methadone is prescribed for treatment of opiate addiction, it must be through federally regulated opiate treatment programs.

methamphetamine and methylphenidate (Ritalin®).<sup>97</sup> Pursuant to the DEA Final Rule of October 6, 2014, hydrocodone combination products were moved from Schedule III to Schedule II.<sup>98</sup>

### **Prescribing Hydrocodone-only Extended-release Medication**

In 2014, the Board of Medicine promulgated a regulation on hydrocodone-only extended release medication.<sup>99</sup> Prior to prescribing a hydrocodone-only extended release medication that is not in an abuse deterrent form, a licensee must:

- (a) Thoroughly assess the patient, including an evaluation of the patient's risk factors, substance abuse history, presenting condition(s), current medication(s), a determination that other pain management treatments are inadequate, and a check of the patient's data through the online Prescription Monitoring Program;
- (b) Discuss the risks and benefits of the medication with the patient;
- (c) Enter into a Pain Management Treatment Agreement with the patient that appropriately addresses drug screening, pill counts, safe storage and disposal and other requirements based on the patient's diagnoses, treatment plan, and risk assessment unless a Pain Management Treatment Agreement is not clinically indicated due to the severity of the patient's medical condition;
- (d) Supply a Letter of Medical Necessity as required by the Board of Registration in Pharmacy pursuant to 247 CMR 9.04(8)(c); and
- (e) Document 243 CMR 2.07(25)(a) through (d) in the patient's medical record.

The purpose of 243 CMR 2.07(25) is to enhance the public health and welfare by promoting optimum therapeutic outcomes, avoiding patient injury and eliminating medication errors. Nothing in 243 CMR 2.07(25) alters the standard of care a licensee must use when prescribing any Schedule II, III or IV controlled substance.

### **Schedule III**

Schedule III controlled substances have a potential for abuse that is less than substances in Schedules I or II. Abuse of Schedule III substances may still lead to physical dependence or psychological dependence.<sup>100</sup>

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<sup>97</sup> 21 U.S.C. § 812(c).

<sup>98</sup> 79 Fed. Reg. 163 (Aug. 22, 2014).

<sup>99</sup> 243 CMR 2.07(25).

<sup>100</sup> 21 U.S.C. § 812(b)(3); M.G.L. c. 94C § 3(3).

Schedule III prescriptions may be issued for up to a 30-day supply with an exception for implantable infusion pumps with a Schedule III substance, which may be filled with a maximum of a 90-day supply.<sup>101</sup>

Schedule III prescriptions may be refilled up to five times within six months of the date of the prescription.<sup>102</sup> Controlled substances that are prescribed without an indication for refills cannot be refilled without authorization by the prescriber.

A Schedule III drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.<sup>103</sup> Prescriptions for Schedule III substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

The Board believes that good medical practice requires a physician to see a patient at least once every six months when prescribing a Schedule III - VI controlled substance over a long period of time. If this is impractical, inappropriate or impossible, an explanation should be recorded in the patient's chart. These exceptions should be extremely rare.

Board regulations prohibit physicians from prescribing controlled substances in Schedule III for their own use.<sup>104</sup>

Some examples of Schedule III controlled substances include: Subutex® and Suboxone®;<sup>105</sup> and combination products containing not more than 90 milligrams of codeine per dosage unit, such as Tylenol with Codeine®. Examples of Schedule III non-narcotics include:

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<sup>101</sup> M.G.L. c. 94C § 23(d).

<sup>102</sup> 21 U.S.C. § 829 (b).

<sup>103</sup> M.G.L. c. 94C § 17(c) and M.G.L. c. 94C § 20(c).

<sup>104</sup> 243 CMR 2.07(19).

<sup>105</sup> Subutex® and Suboxone® and approved generic equivalents require a DATA-waiver and a unique identification number for office-based opiate addiction treatment.

ketamine, benzphetamine (Didrex®) phendimetrazine, and anabolic steroids such as Depo-Testosterone®.<sup>106</sup>

#### **Schedule IV**

Schedule IV controlled substances have a low potential for abuse relative to the substances in Schedule III, but may still lead to physical or psychological dependence.<sup>107</sup> Schedule IV prescriptions may be refilled up to five times within six months of the date of the prescription.<sup>108</sup> A Schedule IV drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.<sup>109</sup> Prescriptions for Schedule IV substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

The Board has prohibited physicians from prescribing controlled substances in Schedule IV for their own use.<sup>110</sup>

Some examples of Schedule IV controlled substances include: long-acting barbiturates such as phenobarbital (Luminal®), and mephobarbital (Mebaral®); ultrashort-acting barbiturates such as methohexital (Brevital®); benzodiazepines such as estazolam (ProSom®), flurazepam (Dalmane®), temazepam (Restoril®), triazolam (Halcion®), midazolam (Versed®), alprazolam (Xanax®), diazepam (Valium®), lorazepam (Ativan®), clonazepam (Klonopin®); and dextropropoxyphene forms: Darvon®, Darvocet®, Dolene®, Propacet®, propoxyphene and tramadol (Ultram®).

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<sup>106</sup> 21 U.S.C. § 812(c).

<sup>107</sup> 21 U.S.C. § 812(b)(4); M.G.L. c. 94C, § 3.

<sup>108</sup> 21 U.S.C. § 829(b).

<sup>109</sup> M.G.L. c. 94C, §17(c); M.G.L. c. 94C, §20(c).

<sup>110</sup> 243 CMR 2.07(19).

## Schedule V

Schedule V controlled substances have a low potential for abuse compared to the substances in Schedule IV but may lead to some physical dependence or psychological dependence.<sup>111</sup> A Schedule V drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.<sup>112</sup> Prescriptions for Schedule V substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

Examples of Schedule V controlled substances include: cough preparations of not more than 100 milligrams of codeine per 100 milliliters or per 100 grams Robitussin AC® and Phenergan with Codeine®.

## Schedule VI

Prescription drugs that do not fall within Schedules II through V are considered to be Schedule VI controlled substances in Massachusetts.<sup>113</sup> This is a special Massachusetts schedule. Physicians may dispense up to a 30-day supply of Schedule VI sample medications. Larger supplies of sample medications, up to 90 days, may be dispensed as part of a manufacturer's indigent patient drug program.<sup>114</sup> Physicians must label all sample medications dispensed to patients, including those provided as part of an indigent patient drug program.<sup>115</sup> Physicians who provide samples of Schedule VI drugs to their patients are required to keep a record of such dispensing.<sup>116</sup>

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<sup>111</sup> 21 U.S.C. § 812(b)(5); M.G.L. c. 94C, §3(5)

<sup>112</sup> M.G.L. c. 94C, §17(c); M.G.L. c. 94C, §20(c).

<sup>113</sup> M.G.L. c. 94C, § 2(a); 105 CMR 700.002(F).

<sup>114</sup> 105 CMR 700.010

<sup>115</sup> 105 CMR 700.010

<sup>116</sup> 105 CMR 700.006(F)(5). *See infra* Part II, Section 4, "Dispensing."

As with all controlled substances, there are some Schedule VI drugs that can be misused or abused. Physicians are encouraged to visit the U.S. Department of Justice Diversion Control website at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

### **Prescribing Naloxone**

Opioid overdose is one of the leading causes of death in Massachusetts.<sup>117</sup> According to the Massachusetts Department of Public Health, “the rate of unintentional opioid-related overdose deaths, which includes deaths related to heroin, reached levels in 2013 previously unseen in Massachusetts.”<sup>118</sup>

In an overdose, opioids can slow breathing to the point of death. The drug naloxone (trade name Narcan®) is an opioid antagonist. Naloxone blocks the opioids and restores normal breathing when sprayed in the nose of someone who has overdosed. Naloxone is not an abusable drug.<sup>119</sup>

In 2012, the Massachusetts Legislature passed M.G.L. c. 94C, § 19(d):

Naloxone or other opioid antagonist may lawfully be prescribed and dispensed to a person at risk of experiencing an opiate-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose. For purposes of this chapter and chapter 112, any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

St. 2012, c. 192, § 11

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<sup>117</sup> “Fatalities in Massachusetts related to opioid overdose are projected to have increased by 46% from 2012 to 2013.” Center for Health Information and Analysis, *Access to Substance Use Disorder Treatment in Massachusetts*, (April 2015) page 1.

<sup>118</sup> “The rate of 14.5 deaths per 100,000 residents for 2013 was the highest ever for unintentional opioid overdoses and represents a 273% increase from the rate of 5.3 deaths per 100,000 residents in 2000.” Massachusetts Dept. of Public Health: *Data Brief: Fatal Opioid-related Overdoses among MA Residents*, (April 2015).

<sup>119</sup> Naloxone is a Schedule VI in Massachusetts, a schedule that consists of all prescription drugs that are not included in Schedules II – V.

In 2014, the Board issued a Statement supporting the Massachusetts Pharmacy Rescue Kit Access Program.<sup>120</sup> “The Board encourages its licensees to abide by the protocols of the program and the statute which allows for the prescribing of naloxone to individuals overdosing on opioids in the absence of a physician-patient relationship, and for a Standing Order for naloxone to be provided to pharmacists.” The Board notes that this is an exception to the Board’s long-held policy that prescribing must be done in the context of a physician-patient relationship.

### **3. PRESCRIPTIONS**

#### **The Prescription Slip**

The Massachusetts controlled substances law states:

A practitioner who dispenses a controlled substance by issuing a written prescription shall state on the prescription the name, address and registration number of the practitioner, the date of delivery of the prescription, the name, dosage and strength per dosage unit of the controlled substance, the name and address of the patient unless it is a veterinary prescription, the directions for use and any cautionary statements required, and a statement indicating the number of times to be refilled.<sup>121</sup>

Accordingly, every prescription written in the Commonwealth must be written on a form that contains the following:

- A signature line for the physician’s signature;
- Space in which the physician may write in his or her own handwriting the words “no substitution;”
- The name and address of the physician (or, in the case of a hospital or clinic prescription form, the name and address of the hospital or clinic) must be printed or typed on the form;
- The registration number of the physician;
- The date of issuance of the prescription;
- The name, dosage and strength per dosage unit of the controlled substance prescribed, and the quantity of the dosage units;
- The name and address of the patient;

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<sup>120</sup> Board of Reg. in Medicine, Statement, (Adopted Sept. 10, 2014); accessible at <http://www.mass.gov/eohhs/docs/borim/board-statements/board-statement-naloxone-20140910.pdf>

<sup>121</sup> M.G.L. c. 94C, § 22(a).

- Directions for use, including any cautionary statements required; and
- A statement indicating the number of times the prescription may be refilled.<sup>122</sup>

### **Tamper Resistant Prescription Law**

Federal law requires that all written prescriptions for outpatient drugs that are paid for by Medicaid must be executed on a tamper-resistant prescription.<sup>123</sup> In addition, Massachusetts law requires that all prescriptions for drugs in Schedules II-VI be executed on a tamper-resistant form consistent with the Medicaid requirements even if not written for a Medicaid patient.<sup>124</sup> To be considered tamper-resistant, a prescription pad must contain the following three characteristics:

- 1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form (for example: a high security watermark on the reverse side of blank, or the use of thermochromic ink);
- 2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber (for example: tamper-resistant background ink showing erasures or attempts to change written information); and
- 3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms (for example: sequentially numbered blanks or duplicate or triplicate blanks).<sup>125</sup>

### **Faxing Prescriptions**

For ambulatory patients, Schedule II substances may be faxed to pharmacies, but a hard copy prescription must accompany the patient before the medication can actually be dispensed.<sup>126</sup> However, a hard copy follow-up prescription is not required for residential patients in either long-term care facilities or federally supported or state licensed hospice care

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<sup>122</sup> 105 CMR 721.020.

<sup>123</sup> U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Pub. L. No. 110-28, § 7002 (2008).

<sup>124</sup> M.G.L. c. 94C, § 23(g); 105 CMR 721.020(F).

<sup>125</sup> Centers for Medicare and Medicaid Services, Bureau of Health Care Quality and Safety, *Memorandum to Prescribers and Pharmacists; "Medicaid Tamper Resistant Prescription Law"* (August 7, 2013).

<sup>126</sup> 21 C.F.R. § 1306.11(a)

programs.<sup>127</sup> Nor is a hard copy follow-up prescription required when the facsimile prescription calls for a narcotic to be compounded for direct administration by injection to the patient.<sup>128</sup> Facsimile prescriptions for Schedules III, IV, V, and VI drugs do not require the filing of a hard copy in follow-up with the pharmacy.

### **Electronic Prescribing**

Federal law permits electronically transmitted prescriptions for Schedule II through V controlled substances. The Drug Enforcement Administration (DEA) issued an Interim Final Rule, overturning the federal prohibition on electronically prescribing controlled substances (EPCS), subject to certain restrictions.<sup>129</sup> The effective date of the Final Rule was June 1, 2010. The DEA Rule gives licensed prescribers the option of submitting electronic prescriptions and permits pharmacies to receive, dispense and archive electronic prescriptions with approved EPCS software. When electronically prescribing Schedule II-V controlled substances, there must be independent third party verification of the prescriber and there must be a two-factor authentication on each individual prescription.

Schedule III - VI prescriptions may be electronically transmitted from a physician to a pharmacy.<sup>130</sup> The prescription must be electronically transmitted in a manner that maintains patient confidentiality.<sup>131</sup> Such a prescription must either bear the physician's electronic signature or employ some other secure method of validation.<sup>132</sup>

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<sup>127</sup> 21 C.F.R. § 1306.11(g).

<sup>128</sup> 21 C.F.R. § 1306(11)(e).

<sup>129</sup> 75 Fed. Reg. No. 61 (Wednesday, March 31, 2010); Rules and Regulations, Drug Enforcement Administration, 21 C.F.R. Parts 1300, 1304, 1306 and 1311.

<sup>130</sup> M.G.L. c. 94C, §23(g); 247 CMR 5.02(1); 105 CMR 721.020(A)(3) and 105 CMR 721.030.

<sup>131</sup> 247 CMR 5.02(1).

<sup>132</sup> 105 CMR 721.030.

## **Verbal Authorization**

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations. A verbal prescription for a Schedule II drug must be written and filed with the pharmacy within seven days of being issued, and the prescription should have written on its face, “Authorization for Emergency Dispensing.”<sup>133</sup> Drugs in Schedules III - V may be prescribed by verbal prescription in the absence of an emergency but the prescription must be written and filed with the pharmacy within seven days. Verbal prescriptions may be communicated to a pharmacist by an expressly authorized employee or agent of the physician.<sup>134</sup>

## **4. DISPENSING**

The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery.<sup>135</sup> A physician must have a separate DEA certificate of registration and MCSR number for each location at which he or she dispenses controlled substances.<sup>136</sup>

### **General Requirements**

Federal law permits physicians to dispense Schedule II controlled substances without a prescription only in emergency situations.<sup>137</sup> Under both Federal and Massachusetts law, physicians may dispense controlled substances in Schedules III - V without a prescription, as long as the drug is being delivered or administered directly to the patient for legitimate medical

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<sup>133</sup> 21 C.F.R. § 1306.11(d)(4); M.G.L. c. 94C, §20(c); and 247 CMR 5.03(3).

<sup>134</sup> M.G.L. c. 94C, §20(c).

<sup>135</sup> The Federal and Massachusetts definitions of “dispense” are nearly identical. *See* 21 U.S.C. § 802(10) and M.G.L. c. 94C, § 1.

<sup>136</sup> 21 U.S.C. § 822(e); 105 CMR 700.004(F). *See* Part I, Section 1, “Registration Requirements.”

<sup>137</sup> 21 U.S.C. § 829(a).

purposes.<sup>138</sup> In Massachusetts, the physician must be dispensing the medication for immediate treatment, which is defined as “that quantity of a controlled substance which is necessary for the proper treatment of the patient until it is possible for him to have a prescription filled by a pharmacy.”<sup>139</sup> This includes sample medications in Schedules II - V that have been supplied to the physician by pharmaceutical company representatives.

Massachusetts physicians are permitted to dispense up to a 30-day supply of Schedule VI sample medications.<sup>140</sup> Physicians may dispense larger supplies of sample medications, up to 90 days, as part of a manufacturer's indigent drug program.<sup>141</sup> All sample medications dispensed to patients, including those provided as part of an indigent patient drug program, must be labeled.<sup>142</sup>

Under M.G.L. c. 94C, § 19, physicians may not issue prescriptions for controlled substances for the purpose of dispensing or selling those drugs to patients.<sup>143</sup>

### **Labeling**

When a physician does dispense a controlled substance to a patient (and the substance is not administered by the physician or ingested in the physician's presence) the physician must package the controlled substance in a container and affix a label to the container that includes the following information:

- The physician's name and address;
- The date of dispensing;
- The name of the patient;
- The name, dosage and strength of the drug;
- Directions for use; and
- Any necessary cautionary statements.<sup>144</sup>

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<sup>138</sup> 21 U.S.C. § 829; M.G.L. c. 94C, § 9(b) and 105 CMR 700.010(A)(2).

<sup>139</sup> M.G.L. c. 94C, § 9(b).

<sup>140</sup> 105 CMR 700.010(A)(1).

<sup>141</sup> M.G.L. c. 94C, § 9 and 105 CMR 700.010(A)(1).

<sup>142</sup> M.G.L. c. 94C §22 and 105 CMR 700.010

<sup>143</sup> M.G.L. c. 94C, §19(b).

Physicians who provide samples of Schedule VI drugs to their patients must keep a record of the drug dispensed in the patient's medical record, noting:

- The name, dosage and strength of the substance dispensed;
- The volume of units dispensed;
- The date of the dispensing; and
- The name and address of the person to whom the medication was dispensed.<sup>145</sup>

*See also* Appendix D, DPH Labeling Guidelines for Sample Prescription Drugs.

### **Recordkeeping Requirements**

There are strict record-keeping requirements for physicians who stock controlled substances.<sup>146</sup> Physicians who stock controlled substances in Schedules II and III must maintain records of:

- Their receipt and/or administration, including the names and quantities of the controlled substances,
- The name and address of the patient to whom it is administered or dispensed;
- The name, dosage and strength per dosage unit of each controlled substance; and
- The date of the administration or dispensing.<sup>147</sup>

Inventories and records of Schedules II controlled substances that are dispensed to patients must be maintained in records separate from the inventories and records of other controlled substances dispensed.<sup>148</sup> Inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately, as well.<sup>149</sup> All drug records and inventories must be readily retrievable from the physician's ordinary business records.<sup>150</sup>

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<sup>144</sup> M.G.L. c. 94C, §22(b) and 105 CMR 700.010

<sup>145</sup> 105 CMR 700.006(F)(5).

<sup>146</sup> 21 U.S.C. §§ 331(t), 333(b), and 353(c)-(d); 21 U.S.C. §§ 824, 827; 21 C.F.R. § 1304.21; M.G.L. c. 94C, § 9(d) and 105 CMR 700.006.

<sup>147</sup> 21 C.F.R. § 1304.03(b); 21 C.F.R. § 1304.22 and M.G.L. c. 94C, § 9(d).

<sup>148</sup> 21 U.S.C. § 827(b) and 21 C.F.R. § 1304.04(g).

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

Physicians must take a detailed, initial inventory of all controlled substances on hand for each location at which they dispense, with subsequent inventories done at least every two years.<sup>151</sup> All records related to controlled substances must be maintained at the registered location for at least two years and be available for inspection for a minimum of two years.<sup>152</sup>

Physicians who provide samples of Schedule VI drugs to their patients must keep a record of the drug dispensed (the record may be kept in the patient's medical record), noting:

- The name, dosage and strength of the substance dispensed;
- The volume of units dispensed;
- The date of the dispensing, and
- The name and address of the person to whom the medication was dispensed.<sup>153</sup>

### **Security Requirements**

All physicians who dispense controlled substances must have effective controls and procedures to guard against theft and diversion.<sup>154</sup>

Schedule II through V controlled substances must be in a securely locked, substantially constructed cabinet. Physicians are required to screen all employees or agents who will be working in areas where controlled substances are handled, and are prohibited from knowingly employing anyone who:

- Has been convicted of a felony offense related to controlled substances;
- Has been denied a DEA registration;
- Has had a DEA registration revoked; or
- Has surrendered a DEA registration for cause.<sup>155</sup>

Physicians should notify the DEA when they discover any thefts or significant losses of controlled substances from stock and complete the necessary DEA forms regarding the theft or

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<sup>151</sup> 21 C.F.R. § 1304.11(b); 21 C.F.R. § 1304.11(c) and 105 CMR 700.006.

<sup>152</sup> 21 U.S.C. § 827(c); 21 U.S.C. § 880; 21 C.F.R. § 1304.21 and 105 CMR 700.007.

<sup>153</sup> 105 CMR 700.006(F)(5).

<sup>154</sup> 21 C.F.R. §§ 1301.71(a), 1301.75 and 105 CMR 700.005(A).

<sup>155</sup> 21 C.F.R. § 1301.76(a) and 105 CMR 700.005(B).

loss.<sup>156</sup> Physicians must also report drug theft, loss or any drug discrepancy to the Massachusetts Drug Control Program (DCP) within 24 hours of discovery by:

- Telephoning DCP within 24 hours, then mailing a Drug Incident Report (DIR) to the DCP within 7 days; or
- By visiting the DCP website, downloading a DIR form and faxing that form to DCP with 24 hours.<sup>157</sup>

The submission of the DIR form will satisfy DCP's requirements for both a telephonic and written report. Physicians should submit all subsequent relevant information they discover to the DCP.

Physicians may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. In Massachusetts, the DCP is responsible for drug destruction. Physicians should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

## **5. PRESCRIPTION MONITORING PROGRAM**

The Commonwealth's Prescription Monitoring Program (PMP), which is administered by the Department of Public Health (DPH), is a repository for a patient's prescription history for Schedule II – V prescriptions.<sup>158</sup> All Massachusetts pharmacies and out-of-state pharmacies delivering to people in Massachusetts provide prescription data to the PMP.<sup>159</sup>

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<sup>156</sup> 21 C.F.R. § 1301.76(b).

<sup>157</sup> 105 CMR 700.005(D).

<sup>158</sup> M.G.L. c. 94C, § 24A.

<sup>159</sup> M.G.L. c. 94C, § 24A(2)(c); 105 CMR 700.012(A).

Physicians should note that DPH reviews the PMP information<sup>160</sup> and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, DPH will notify the Board or the appropriate law enforcement agency.<sup>161</sup> DPH will provide the Board with PMP information that the Board requires for an investigation.<sup>162</sup>

All questions about the specific operation of and access to the PMP should be addressed to DPH's Drug Control Program. *See* Appendix A (Contact information).

### **Required and Exempted Usage**

All physicians who have renewed their MCSR on or after January 1, 2013, were automatically granted authority to use the PMP,<sup>163</sup> which provides the physician with a patient's prescription history for the prior 12 months.<sup>164</sup>

All physicians, unless specifically exempted, are required to use the prescription monitoring program in the following circumstances:

- Prior to prescribing a narcotic drug in Schedule II or III to a patient for the first time;<sup>165</sup>
- Each time the prescriber issues a prescription to a patient for any drug in Schedule II or III that "has been determined by the Department of Public Health to be commonly misused or abused and which has been designated as a drug that needs additional safeguards in guidance to be issued by the Department of Public Health;"<sup>166</sup>
- Prior to prescribing a benzodiazepine to a patient for the first time;<sup>167</sup> and
- Prior to prescribing a Schedule IV or V controlled substance, "as designated in guidance to be issued by the Department," to a patient for the first time.<sup>168</sup>

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<sup>160</sup> M.G.L. c. 94C, § 24A(2)(e); 105 CMR 700.012(D)(5).

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> M.G.L. c. 94C, § 7A; 105 CMR 700.012(G).

<sup>164</sup> Mass. Dept. of Public Health, Bureau of Health Care Safety and Quality, Prescription Monitoring and Drug Control Program "*PMP Frequently Asked Questions, November 2014.*"

<sup>165</sup> M.G.L. c. 94C, §24A(2)(c); 105 CMR 700.012(H)(1)(a).

<sup>166</sup> 105 CMR 700.012(H)(2).

<sup>167</sup> M.G.L. c. 94C, §24A(2)(c); 105 CMR 700.012(H)(1)(c).

Physicians are not required to use the PMP in the following circumstances, however:

- If they hold a MCSR that permits them to prescribe, administer, possess, order, or dispense samples of controlled substances only in Schedule VI;<sup>169</sup>
- If they have been granted a waiver by DPH;<sup>170</sup>
- When they are providing medical care to hospice patients;<sup>171</sup>
- When they are treating a patient in an Emergency Department and they *do not*:
  - anticipate writing a prescription for a controlled substance in Schedules II through V during that encounter with the patient;<sup>172</sup> or
  - prescribe more than a five-day supply of a controlled substance in Schedules II through V;<sup>173</sup>
- When emergency care is required and, in their professional opinion, utilization of the prescription monitoring program is likely to result in patient harm;<sup>174</sup>
- When they are providing medical care to hospital inpatients;<sup>175</sup>
- When delivering a controlled substance in a single dose or in a quantity that is essential for the immediate and proper treatment of the patient, until it is possible for the patient to have a prescription filled by a pharmacy;<sup>176</sup>
- When it is not reasonably possible to use the PMP, including when the system is not operational due to temporary technological or electrical failure;<sup>177</sup>
- When they are examining or treating a pediatric patient who is less than 8 years old; or
- Where DPH has articulated another exception.<sup>178</sup>

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<sup>168</sup> *Id.*

<sup>169</sup> 105 CMR 700.012(H)(3)(a).

<sup>170</sup> 105 CMR 700.012(H)(3)(i) and (I).

<sup>171</sup> 105 CMR 700.012(H)(3)(b).

<sup>172</sup> 105 CMR 700.012(H)(3)(c).

<sup>173</sup> *Id.*

<sup>174</sup> 105 CMR 700.012(H)(3)(d).

<sup>175</sup> 105 CMR 700.012(H)(3)(e).

<sup>176</sup> 105 CMR 700.012(H)(3)(f). *See also* M.G.L. c. 94C, § 9(b).

<sup>177</sup> 105 CMR 700.012(H)(3)(g).

<sup>178</sup> 105 CMR 700.012(H)(3)(j).

## **The Use of the PMP by the Physician’s Staff**

Physicians may authorize their support staff members to use the PMP on their behalf (“Delegates”).<sup>179</sup> Note, however, that individuals eligible to be primary PMP account holders (i.e., advanced practice nurses and physicians assistants with their own MCSR) cannot be delegates.<sup>180</sup>

DPH expects that medical offices that use delegates will have “written policies and procedures regarding the management and security of [PMP] data;” physicians are required to provide such written policies and procedures to DPH upon their request.<sup>181</sup>

Physicians are responsible for all delegate use of the PMP and must:

1. Take reasonable steps to ensure that delegates are sufficiently competent in the use of the PMP;<sup>182</sup>
2. Monitor delegates’ use of the PMP;<sup>183</sup>
3. Ensure that delegates comply with the PMP “Sub-account User Terms and Conditions;”<sup>184</sup>
4. Inform DPH when a delegate has violated the Sub-account User Terms and Conditions; and<sup>185</sup>
5. When a delegate is no longer authorized to be a delegate, inform DPH of this action within one business day.<sup>186</sup>

## **Consequences for Misuse of the PMP**

If DPH learns that a physician may have used the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, DPH may immediately

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<sup>179</sup> M.G.L. c. 94C, §24A(2)(c); 105 CMR 700.012(J)(1). *See also* 105 CMR 700.012(D)(2)(a); 105 CMR 700.004(2)(n) through (q), (w).

<sup>180</sup> *Id.*

<sup>181</sup> 105 CMR 700.012(J)(2).

<sup>182</sup> 105 CMR 700.012(J)(3)(c).

<sup>183</sup> 105 CMR 700.012(J)(3)(b).

<sup>184</sup> 105 CMR 700.012(J)(3)(a).

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

restrict electronic access to the prescription monitoring program system;<sup>187</sup> and will contact the prescribing physician to investigate the potential violation.<sup>188</sup>

If the investigation does not reveal a violation, DPH will immediately reinstate electronic access.<sup>189</sup> If the investigation reveals a violation, DPH may, depending on the severity of the violation, take the following actions:

- Issue a warning letter to the physician;<sup>190</sup>
- Require training on the appropriate use of the PMP;<sup>191</sup>
- Temporarily suspend the access to the PMP;<sup>192</sup> and
- Take action pursuant to suspend, revoke, or refuse to renew the physician's MCSR.<sup>193</sup>

The primary account holder is responsible for all delegate use of the PMP and may be referred to the Board if delegate use is inconsistent with the Sub-Account User Terms and Conditions. If a delegate misuses the PMP, DPH may report the primary account holder to the Board.<sup>194</sup> Physicians may contest the DPH's findings, in writing, and request further review.<sup>195</sup>

## **6. MASSACHUSETTS MEDICAL MARIJUANA LAW**

On November 6, 2012, the citizens of Massachusetts voted through the initiative process to pass a medical marijuana law.<sup>196</sup> The law went into effect on January 1, 2013.<sup>197</sup>

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<sup>187</sup> 105 CMR 700.012(K)(1)(a).

<sup>188</sup> 105 CMR 700.012(K)(1)(b).

<sup>189</sup> 105 CMR 700.012(K)(2).

<sup>190</sup> 105 CMR 700.012(K)(3)(a).

<sup>191</sup> 105 CMR 700.012(K)(3)(b).

<sup>192</sup> 105 CMR 700.012(K)(3)(c).

<sup>193</sup> 105 CMR 700.012(K)(3)(d); 105 CMR 700.115.

<sup>194</sup> 105 CMR 700.012(J)(4).

<sup>195</sup> 105 CMR 700.012(K)(4).

<sup>196</sup> The Massachusetts law, St. 2012, c. 369, § 1, reads, "The citizens of Massachusetts intend that there should be no punishment under state law for qualifying patients, physicians and health care professionals, personal caregivers for patients, or medical marijuana treatment center agents for the medical use of marijuana, as defined herein." The federal law on marijuana is different from the Massachusetts law.

<sup>197</sup> St. 2012, c. 369, § 16.

Physicians are now permitted to do the following, without fear of punishment under state law:

- advise a qualifying patient about the risks and benefits of medical use of marijuana; and
- provide a qualifying patient with written certification, based upon a full assessment of the qualifying patient's medical history and condition, that the medical use of marijuana may benefit a particular qualifying patient.<sup>198</sup>

However, it is important to note that Massachusetts law does not grant immunity under federal law,<sup>199</sup> nor does it prevent the federal government from enforcing federal law.<sup>200</sup> Marijuana is a Schedule I controlled substance under federal law.

A physician may decline to prescribe medical marijuana. A physician is not required to authorize the use of medical marijuana for a patient.<sup>201</sup>

### **Physician Registration**

If a physician wants to certify qualifying patients to use medical marijuana, the physician must be registered with the Department of Public Health as a “certifying physician.”<sup>202</sup> In order to register, a physician must have at least one established place of practice in Massachusetts;<sup>203</sup> have an active full license to practice medicine in Massachusetts, without any prescribing restrictions;<sup>204</sup> and have a Massachusetts Controlled Substances Registration.<sup>205</sup> In addition, a certifying physician issuing a written certificate on or after July 1, 2014 must complete a minimum of 2.0 Category 1 continuing professional development (CPD) credits from a program that explains the proper use of marijuana, including side effects, dosage, and contraindications,

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<sup>198</sup> St. 2012, c. 369, § 3 “Protection from State Prosecution and Penalties for Health Care Professionals.”

<sup>199</sup> St. 2012, c. 369, § 7(F).

<sup>200</sup> St. 2012, c. 369, § 7(G).

<sup>201</sup> St. 2012, c. 369, § 7(C).

<sup>202</sup> 105 CMR 725.005.

<sup>203</sup> 105 CMR 725.005(A).

<sup>204</sup> 105 CMR 725.005(A)(1).

<sup>205</sup> 105 CMR 725.005(A)(2).

including with psychotropic drugs, as well as on substance misuse recognition, diagnosis, and treatment related to marijuana.<sup>206</sup>

Physicians need to register only once,<sup>207</sup> but must notify DPH after any changes to their information, within five business days of the change.<sup>208</sup>

### **Patients Who Qualify for the Medical Use of Marijuana**

Physicians may certify only patients who qualify for the medical use of marijuana and with whom they have a bona fide physician-patient relationship.<sup>209</sup> In order to qualify, a patient must be a Massachusetts resident<sup>210</sup> and have one of the following debilitating medical conditions,<sup>211</sup> which is active:<sup>212</sup>

- cancer;
- glaucoma;
- positive status for human immunodeficiency virus (HIV);
- acquired immune deficiency syndrome (AIDS);
- hepatitis C;
- amyotrophic lateral sclerosis (ALS);
- Crohn’s disease;
- Parkinson’s disease;
- multiple sclerosis (MS); or
- other debilitating condition as determined in writing by the physician.

“Debilitating” is defined as causing weakness, cachexia, wasting syndrome, intractable pain or nausea, or impairing strength or ability, and progressing to the extent that one or more of a patient’s major life activities is substantially limited.<sup>213</sup>

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<sup>206</sup> 105 CMR 725.010(A) and 725.005(C)(4).

<sup>207</sup> 105 CMR 725.005(C).

<sup>208</sup> 105 CMR 725.005(D).

<sup>209</sup> St. 2012, c. 369, §§ 2(K), 2(N), and 3; 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”); 105 CMR 725.010(F) and (M).

<sup>210</sup> 105 CMR 725.004 (definition of “Qualifying Patient”).

<sup>211</sup> St. 2012, c. 369, § 2(C); 105 CMR 725.004 (definition of “Debilitating Medical Condition”).

<sup>212</sup> 105 CMR 725.010(F). NOTE: A patient’s debilitating medical condition is still active if it is the medical use of marijuana that has mitigated the patient’s symptoms.

<sup>213</sup> 105 CMR 725.004 (definition of “Debilitating”).

All patients under 18 years of age must also:

- have been diagnosed by two certifying physicians, at least one of whom is a board-certified pediatrician or board-certified pediatric subspecialist,<sup>214</sup> who have a role in the patient’s ongoing care and treatment;<sup>215</sup>
- have a debilitating medical condition that is life-limiting in that it:
  - does not respond to curative treatments; and
  - reasonable estimates of prognosis suggest death may occur within two years;<sup>216</sup>
- have a debilitating medical condition that is not life-limiting, but the two certifying physicians have:
  - determined that the benefits of the medical use of marijuana outweigh the risks;
  - discussed the potential negative impacts on neurological development with the parent or legal guardian of the qualifying patient;
  - obtained written consent of the parent or legal guardian; and
  - documented the rationale in the patient’s medical record and on the written certification.<sup>217</sup>

## **Certifying a Qualified Patient**

### **1. The Physician-Patient Encounter**

Before certifying a qualifying patient, the physician must:

- conduct a clinical visit with the patient, especially before the initial written certification;<sup>218</sup>
- conduct a clinical visit with the qualifying patient no less than once per year;<sup>219</sup>
- complete and document a full assessment of the patient’s medical history and current medical condition;<sup>220</sup>
- explain to the patient the potential benefits and risks of marijuana use;<sup>221</sup>
- have a role in the ongoing care and treatment of the patient;<sup>222</sup>
- review the qualifying patient’s prescription history, using the Massachusetts Prescription Monitoring Program (PMP);<sup>223</sup> and

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<sup>214</sup> 105 CMR 725.004 (definition of “Qualifying Patient”); 105 CMR 725.010(J).

<sup>215</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”).

<sup>216</sup> 105 CMR 725.004 (definitions of “Life-Limiting Illness” and “Qualifying Patient”); 105 CMR 725.010(J).

<sup>217</sup> 105 CMR 725.010(J).

<sup>218</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”) and 725.010(G). The physician may provide a renewal written certification after clinical visit or telephone consultation.

<sup>219</sup> 105 CMR 725.010(G).

<sup>220</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”).

<sup>221</sup> *Id.*

<sup>222</sup> *Id.*

<sup>223</sup> 105 CMR 725.010(E). A physician should be aware of the dangers of combining opioids or benzodiazepines with medical marijuana.

- act in the usual course of their professional practice,<sup>224</sup> complying with the accepted standards of medical practice,<sup>225</sup> and with Board of Registration in Medicine regulations.<sup>226</sup>

If the physician determines that a qualifying patient requires more than 10 ounces as a 60-day supply, he or she must document the amount required and the rationale in the medical record.<sup>227</sup>

Physicians may charge an appropriate fee for a qualifying patient’s clinical visit.<sup>228</sup>

Health insurance providers are not required to reimburse any person for the expenses of the medical use of marijuana.<sup>229</sup>

## 2. **The Written Certification**

The written certification must be issued in a form and manner determined by DPH.<sup>230</sup> Qualifying patients must obtain a registration card from DPH.<sup>231</sup> To obtain a registration card, they must provide the written certification to DPH.<sup>232</sup>

When certifying a qualifying patient, the physician must:

- describe the patient’s pertinent symptoms;<sup>233</sup>
- specify the patient’s debilitating medical condition;<sup>234</sup>
- state that, in his or her professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient;<sup>235</sup>

<sup>224</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”).

<sup>225</sup> 105 CMR 725.010(B).

<sup>226</sup> *Id.*

<sup>227</sup> 105 CMR 725.010(I). NOTE: Qualifying patients may lawfully possess 10 ounces of marijuana for medical use, unless the certifying physician states that 10 ounces is not a sufficient 60-day supply. St. 2012, c. 369, § 4(a); 105 CMR 725.004 (definition of “Sixty-Day Supply”).

<sup>228</sup> 105 CMR 725.010(K)(5).

<sup>229</sup> St. 2012, c. 369, § 7(B). This includes any government agency or authority that provides reimbursement for medical expenses.

<sup>230</sup> 105 CMR 725.010(N).

<sup>231</sup> St. 2012, c. 369, §§ 1(L) and 2(B); 105 CMR 725.015.

<sup>232</sup> 105 CMR 725.015(2) and (3).

<sup>233</sup> 105 CMR 725.004 (definition of “Written Certification”).

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

- indicate the period of time that the written certification is valid; the time period cannot be not less than 15 calendar days or longer than one year;<sup>236</sup> and
- document the amount of marijuana the patient requires if the patient requires more than 10 ounces as a 60-day supply; the physician must also document the rationale for more than 10 ounces.<sup>237</sup>

### **Prohibited Conduct**

Certifying physicians are prohibited from:

- issuing a written certification for himself or herself or for his or her immediate family members;<sup>238</sup>
- delegating to any other health care professional or any other person, authority to diagnose a patient as having a debilitating medical condition;<sup>239</sup>
- examining or counseling a patient at a Registered Marijuana Dispensary (RMD);<sup>240</sup>
- issuing a written certification at a RMD;<sup>241</sup>
- having a direct or indirect financial interest in a RMD;<sup>242</sup>
- offering anything of value, directly or indirectly, to RMD board members, executives, personnel, or any other person associated with an RMD, or from a patient's personal caregiver;<sup>243</sup>
- offering a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular personal caregiver or RMD;<sup>244</sup>
- directly or indirectly benefitting from a patient obtaining a written certification; and<sup>245</sup>

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<sup>236</sup> 105 CMR 725.010(H).

<sup>237</sup> 105 CMR 725.010(I).

<sup>238</sup> 105 CMR 725.010(L).

<sup>239</sup> 105 CMR 725.010(C). *But see* 105 CMR 725.650(C) (citing to M.G.L. c. 112, § 80I, which relates to advanced practice nurses' authority to sign certificates that require the signature of a physician).

<sup>240</sup> 105 CMR 725.010(K)(3). NOTE: The physician's co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>241</sup> *Id.*

<sup>242</sup> 105 CMR 725.010(K)(4). NOTE: The physician's co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>243</sup> 105 CMR 725.010(K)(1). NOTE: The physician's co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>244</sup> 105 CMR 725.010(K)(2). NOTE: The physician's co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>245</sup> 105 CMR 725.010(K)(5) NOTE: The physician's co-workers, employees, and immediate family members are also prohibited from such interactions.

- accepting or soliciting anything of value, directly or indirectly, from RMD board members, executives, personnel, or any other person associated with an RMD, or from a patient’s personal caregiver.<sup>246</sup>

A physician will not retain his or her DPH registration as a certifying physician if one of the following occurs:<sup>247</sup>

- The physician’s license to practice medicine in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts;
- The physician’s Massachusetts Controlled Substances Registration is suspended or revoked;
- The physician has fraudulently issued a written certification of a debilitating medical condition;
- The physician has certified a qualifying patient for a debilitating medical condition on or after July 1, 2014, without appropriate completion of CPD credits; or
- The physician surrenders his or her registration.

## **7. SUPERVISION OF HEALTHCARE PRACTITIONERS WITH PRESCRIPTIVE AUTHORITY**

The term “healthcare practitioner with prescriptive authority” means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he or she practices, to issue orders for a controlled substance in the course of professional practice. Healthcare practitioners with prescriptive authority include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, psychiatric clinical specialists, and physician assistants (PA) who are authorized to issue orders for controlled substances by the state in which

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<sup>246</sup> 105 CMR 725.010(K)(1). NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>247</sup> 105 CMR 725.005(B).

they practice.<sup>248</sup> In Massachusetts, physicians are required to supervise the prescriptive practices of nurse practitioners, certified registered nurse anesthetists, psychiatric clinical nurse specialists and physician assistants.<sup>249</sup> A supervising physician is not required for a certified nurse midwife (CNM); however the CNM must be part of a healthcare system and must be in a clinical relationship with an obstetrician-gynecologist.

### **Advanced Practice Registered Nurses (APRN)**

There are five categories of APRNs in Massachusetts. They include: Certified Registered Nurse Anesthetist (CRNA); Certified Nurse Midwife (CNM); Certified Nurse Practitioner (CNP); Psychiatric Clinical Nurse Specialist (PCNS); and Clinical Nurse Specialist (CNS).<sup>250</sup> Clinical Nurse Specialists, while recognized as APRNs, are not authorized by statute to have a prescriptive practice.

Under the supervision of a licensed physician, CNPs, PCNS, and CRNAs are permitted to issue prescriptions pursuant to guidelines mutually developed and agreed upon by the advanced practice registered nurse and the supervising physician.<sup>251</sup> The guidelines must be in accordance with the regulations of the Board of Registration in Medicine and the Board of Registration in Nursing.<sup>252</sup> The prescriptive practice of advanced practice registered nurses is defined and regulated by the Board of Registration in Nursing.<sup>253</sup>

The supervising physician must have an unrestricted full license in the Commonwealth; have completed training in, be board-certified in or have hospital admitting privileges in a specialty area appropriately related to the advanced practice registered nurse's area of practice;

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<sup>248</sup> 21 C.F.R. § 1200.01(28).

<sup>249</sup> M.G.L. c. 112, §§ 9E, 80B, 80C, 80E and 80G.

<sup>250</sup> 244 CMR 4.06.

<sup>251</sup> Clinical Nurse Midwives are not required to have guidelines for prescriptive practice. 244 CMR 4.07(2).

<sup>252</sup> M.G.L. c. 112, §§ 80E and 80G; 244 CMR 4.00 *et. seq.*, and 243 CMR 2.10.

<sup>253</sup> 244 CMR 4.00 *et. seq.*

and have a valid DEA certificate of registration and MCSR number.<sup>254</sup> In addition, if the physician is supervising a psychiatric clinical nurse specialist, the physician must have completed training in psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada (RCPSC), or be board-certified in psychiatry.<sup>255</sup> A physician who is not an anesthesiologist may supervise a CRNA's prescriptive practice as long as the physician complies with the requirements of a supervising physician.<sup>256</sup>

The supervising physician and advanced practice registered nurse must sign mutually developed and agreed-upon guidelines for prescriptive practice. The supervising physician must review the advanced practice registered nurse's prescriptive practice in accordance with the mutually agreed-upon guidelines, and must provide ongoing direction to the nurse regarding the prescriptive practice.<sup>257</sup>

The Board's regulations set out the minimum requirements for the mutually agreed-upon written guidelines. The Board may request to review the guidelines at any time.<sup>258</sup> The written guidelines must be very specific regarding the types of medications to be prescribed, any limitations on prescriptions, and when referral or physician consultation is required. When appropriate, the guidelines should address the treatment of common medical conditions and should include protocols for managing emergencies. The guidelines must include a mechanism and time frame for the supervising physician to review the APRN's prescriptive practice. In addition, there must be specific protocols for the initiation of intravenous therapies and Schedule

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<sup>254</sup> 244 CMR 4.02.

<sup>255</sup> *Id.*

<sup>256</sup> Mass. Board of Reg. in Medicine, "Board Statement on 243 CMR 2.10," (adopted December 21, 2011).

<sup>257</sup> *Id.*

<sup>258</sup> 243 CMR 2.10 and 244 CMR 4.02.

II drugs.<sup>259</sup> While the regulations permit the physician and the APRN to set the frequency of review of the APRN's prescriptive practice, the physician must review the initial prescription of Schedule II drugs within 96 hours of the prescription.<sup>260</sup>

APRNs who are authorized to prescribe Schedule II drugs may prescribe a hydrocodone-only extended release medication that is not in an abuse deterrent form.<sup>261</sup> Certain APRNs may be authorized to issue written certification for marijuana for medical use.<sup>262</sup> Such prescribing practices shall be completed in accordance with applicable regulations and written guidelines mutually developed and agreed-upon with the APRN and the supervising physician.

Physicians who supervise a CRNA's prescribing practice must be aware that such practice is limited to the immediate perioperative period, which is defined as the time period beginning on the day prior to surgery and ending upon the patient's discharge from post-anesthesia care.<sup>263</sup> The Board urges physicians to remember that they are responsible for the prescriptive activities of the APRNs whom they supervise. Physicians should provide supervision as necessary, taking into account the education, training and experience of the APRN, as well as the nature and scope of their practice. The Board expects that physicians will only enter into supervision agreements with advanced practice registered nurses for whom they are able to provide supervision, practice review, and ongoing direction for the advanced practice registered nurse's prescriptive practice.

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<sup>259</sup> 243 CMR 2.10 and 244 CMR 4.07.

<sup>260</sup> *Id.*

<sup>261</sup> 244 CMR 4.07(3); *See* Part II, Section 2, "Drug Schedules."

<sup>262</sup> 244 CMR 4.06(3)(d).

<sup>263</sup> M.G.L. c. 112, § 80H; 244 CMR 4.02.

## Physician Assistants

Physician assistants are permitted to engage in prescriptive practices under the supervision of a physician.<sup>264</sup> The supervising physician must have an unrestricted full license in the Commonwealth; have completed training in, be board-certified in, or have hospital admitting privileges in a specialty area related to the physician assistant's area of practice; and have a valid DEA certificate of registration and MCSR number.<sup>265</sup>

The physician and physician assistant must sign mutually developed and agreed-upon guidelines; and the physician must review the physician assistant's prescriptive practice at least every three months and provide ongoing direction to the physician assistant.<sup>266</sup>

The Board's regulations set out the minimum requirements for the mutually agreed-upon written guidelines.<sup>267</sup> The guidelines must specify the types of medications to be prescribed, include any limitations on prescriptions, and describe the circumstances in which physician consultation and referral is required. The guidelines must include a mechanism to monitor the prescribing practices, and include protocols for the initiation of intravenous therapies and Schedule II drugs. In addition, the guidelines must specify the frequency of review, and in the case of prescriptions for Schedule II controlled substances, the physician must review the prescription within 96 hours after its issuance.<sup>268</sup> The use of pre-signed prescription blanks or forms is prohibited.<sup>269</sup> Prior to prescribing a hydrocodone-only extended release medication that is not in an abuse-deterrent form, a PA must assess the patient, including an evaluation of the patient's risk factors, substance abuse history, presenting condition(s), current medication(s),

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<sup>264</sup> M.G.L. c. 112, §9E.

<sup>265</sup> 243 CMR 2.08(5)(a).

<sup>266</sup> *Id.*

<sup>267</sup> 243 CMR 2.08(5)(c).

<sup>268</sup> 243 CMR 2.08(5)(c)7.

<sup>269</sup> 243 CMR 2.08(5)(d).

must check the online Prescription Monitoring Program, and must discuss with the patient the risks and benefits of the medication.<sup>270</sup>

On November 4, 2012, the Legislature amended M.G.L. c. 112, § 9E, eliminating a physician assistant-to-supervising physician ratio. According to G.L. c. 112, § 9E and 263 CMR 5.05, there is no prescribed limit on the number of physician assistants that a supervising physician may supervise. The Board urges physicians to remember that they are responsible for the prescriptive activities of the PAs whom they supervise. The Board expects that physicians will only enter into supervision agreements with PAs for whom they are able to provide supervision, practice review, and ongoing direction for the physician assistant's prescriptive practice.

## **Pharmacists**

### **Collaborative Drug Therapy Management**

In January, 2009, the Commonwealth enacted the Collaborative Drug Therapy Management (CDTM) Act.<sup>271</sup> This law permits certain pharmacists and physicians to enter into a collaborative practice agreement, under which the pharmacist may then initiate, monitor, modify and discontinue a patient's drug therapy. Collaborative practice agreements must be in accord with the regulations of the Board of Registration in Medicine and the Board of Registration in Pharmacy.<sup>272</sup> The pharmacist must have advanced training and the scope of the collaborative practice must be within the scope of practice of the supervising physician.<sup>273</sup> Supervising physicians must have an unrestricted full license in the Commonwealth and must be

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<sup>270</sup> 263 CMR 5.07

<sup>271</sup> St. 2008, c. 528.

<sup>272</sup> 243 CMR 2.12 and 247 CMR 16.00.

<sup>273</sup> M.G.L. c. 112, §24B½.

engaged in the clinical practice of medicine in an area appropriately related to the scope of the collaborative practice.<sup>274</sup>

Collaborative practice agreements are allowed only in the following settings:

- Hospitals;
- Long Term Care facilities;
- Licensed inpatient or outpatient hospice settings;
- Ambulatory care clinics with onsite supervising by the attending physician and with a collaborating pharmacist who has no connection to any retail pharmacy; or
- Community retail drug businesses, with supervision by a physician according to the terms of the collaborative practice agreement and limited to the following: patients 18 years of age or older; an extension by 30 days of current drug therapy prescribed by the supervising physician; and administration of vaccines or the modification of dosages of medications prescribed by the supervising physician for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS and osteoporosis.

The collaborative practice agreement must specifically name each disease being co-managed by the pharmacist and physician. The agreement must detail the pharmacist's prescribing authority and practice protocols. A patient must be referred by a supervising physician to that physician's collaborating pharmacist, must be given notice of the collaboration and must, as appropriate to the setting of the agreement, consent to the collaboration.

Any collaborative practice agreement in the retail drug business setting may only permit the prescription of Schedule VI controlled substances. Any collaborative practice agreement in such a setting, which allows the pharmacist to initiate prescriptions for referred patients of the supervising physician, must state that the pharmacist may only issue prescriptions for Schedule VI controlled substances for a patient diagnosis specified in the supervising physician's individual referral of that patient. A copy of such a prescription shall be sent to the supervising physician within 24 hours.

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<sup>274</sup> 243 CMR 2.12(3).

A physician or physician group may hire pharmacists for the purpose of practicing collaborative drug therapy management under a collaborative practice agreement for the benefit of a patient of that physician or physician group. No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a physician.<sup>275</sup> The Board urges physicians to remember that, when entering into a collaborative practice agreement with a pharmacist, the physician must provide reasonable and safe supervision and the physician retains responsibility for the care of the patient.

### **Epinephrine**

A prescriber may order and a physician may sell stock supply of non-patient specific epinephrine by auto-injector (EpiPen® and EpiPen Jr.® auto-injectors) for use at a Massachusetts public or private school for emergency treatment of severe allergic reactions (anaphylaxis).<sup>276</sup>

### **Vaccines**

The Massachusetts Department of Public Health has enacted regulations permitting qualified pharmacists who have completed an accredited training course to administer vaccines as designated by the MDPH.<sup>277</sup> The MDPH and the Board of Registration in Pharmacy adopted a policy on Pharmacist and Pharmacist Interns Administration of Vaccines, which authorizes qualified pharmacists to administer vaccines included in the CDC's Recommended Adult

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<sup>275</sup> M.G.L. c. 112, §24B ½, 243 CMR 2.12 and 247 CMR 16.00.

<sup>276</sup> 105 CMR 210.000. Additional information on epinephrine administration in Massachusetts schools can be obtained from the MDPH, Bureau of Community Health Access and Prevention - School Health Services.

<sup>277</sup> 105 CMR 700.004(B)(6).

Immunization Schedule to adults 18 years of age and older.<sup>278</sup> In order to administer a vaccine, a qualified pharmacist must have a prescription, a physician directive or a standing order.

## **8. GIFTS OR INDUCEMENTS FROM THE PHARMACEUTICAL INDUSTRY**

The Board takes seriously the potential for impropriety or the appearance of impropriety which may occur when pharmaceutical companies or medical device manufacturers give gifts to physicians.

The AMA has issued an ethical opinion regarding gifts to physicians from representatives of the pharmaceutical and medical device manufacturing industry.<sup>279</sup> The AMA opinion recommends that physicians avoid accepting inappropriate gifts by focusing on whether the gifts primarily entail a benefit to patients, and ensuring that the gifts do not come with a *quid pro quo*, such as providing gifts in relation to the physician's prescribing practices.

In Massachusetts, there are specific prohibitions related to the giving of gifts to physicians by pharmaceutical and medical device manufacturing companies.<sup>280</sup> Of particular relevance to physicians are the standards regarding financial inducements to physicians by pharmaceutical or medical device manufacturing companies. Similar to the AMA Opinion, these prohibitions are aimed at limiting the possibility of entangling the physician's practice of medicine with an expectation of *quid pro quo* from the pharmaceutical or medical device manufacturing company.

The rules prohibit or restrict many incentives previously provided by pharmaceutical or medical device manufacturing companies. Among the restrictions are the following:

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<sup>278</sup> MDPH, Drug Control Program, Immunization Program and Board of Registration in Pharmacy, *2015-01 Joint Policy Pharmacist and Pharmacy Intern Administration of Vaccines and FAQs*. The Joint Policy is at Appendix E.

<sup>279</sup> American Medical Assn., *Opinion 8.061 "Gifts to Physicians From Industry."* The entire opinion can be found online at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>

<sup>280</sup> M.G.L. c. 111N and 105 CMR 970.000 *et. seq.*

- Pharmaceutical or medical device manufacturing companies may only provide or pay for meals for physicians that are modest and occasional in nature, and are directly related to an informational presentation;
- No pharmaceutical or medical device manufacturing companies may provide or pay for meals for a physician's spouse or other guest;
- No pharmaceutical or medical device manufacturing company may provide physicians with financial support related to the costs of attending CME events, conferences, or professional meetings;
- No pharmaceutical or medical device manufacturing companies may provide inducements or gifts or provide or pay for any entertainment or recreational items of any value, including but not limited to tickets, vacations or supporting equipment, to any physician who is not a salaried employee of the company.<sup>281</sup>

Benefit of \$50 Value or Greater

As of July 1, 2010, and annually thereafter, every pharmaceutical or medical device manufacturing company must disclose to the Department of Public Health the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any covered recipient, including physicians, in connection with the company's sales and marketing activities.<sup>282</sup> A person who knowingly and willfully violates these rules can be punished by a fine of up to \$5,000 for each violation.<sup>283</sup>

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<sup>281</sup> M.G.L. c. 111N and 105 CMR 970.000 *et. seq.*

<sup>282</sup> M.G.L. c. 111N.

<sup>283</sup> *Id.*

# MICHIGAN

## Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain

### Section I: Preamble

The Michigan Boards of Medicine and Osteopathic Medicine & Surgery recognize that principles of quality medical practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Boards' position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute<sup>1</sup> and cancer-related pain<sup>2</sup>. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Boards are obligated under the laws of the State of Michigan to protect the public health and safety. The Boards recognize that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline*. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.
2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9*. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.

The Boards will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Boards consider to be within the boundaries of professional practice.

## Section II: Guidelines

The Boards have adopted the following guidelines when evaluating the use of controlled substances for pain control:

### 1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

### 2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

### 3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- o urine/serum medication levels screening when requested;
- o number and frequency of all prescription refills; and
- o reasons for which drug therapy may be discontinued (i.e., violation of agreement).

#### 4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

#### 5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

#### 6. Medical Records

The physician should keep accurate and complete records to include

- o the medical history and physical examination;
- o diagnostic, therapeutic and laboratory results;
- o evaluations and consultations;
- o treatment objectives;
- o discussion of risks and benefits;
- o treatments;
- o medications (including date, type, dosage and quantity prescribed);
- o instructions and agreements; and
- o periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

## 7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

### **Section III: Definitions**

For the purposes of these guidelines, the following terms are defined as follows:

#### Acute Pain

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

#### Addiction

Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

#### Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

#### Chronic Pain

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

## Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

## Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

## Pseudoaddiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

## Substance Abuse

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

## Tolerance

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.



# MINNESOTA

## Guidelines for the use of controlled substances

### The patient, the physician and pain control

The Minnesota Board of Medical Practice continues to be active in the education of physicians about pain management.

The Board has in the past provided educational seminars and guidelines about the proper use of controlled substances. The Board has emphasized that physicians should **not** be afraid to prescribe controlled substances. Physicians however have been reluctant to prescribe controlled substances due to fear of reprisals in the form of hostile scrutiny or regulatory action against their licenses.

The Board wants to emphasize that proper use of controlled substances will **not** result in any action against the physician. It is in the best interest of the patient to have proper pain control.

**Therefore, the Board wants to make physicians aware of the updated version of the Model Guidelines for pain control published by the Federation of Medical Boards. These guidelines are linked below.**

Physicians should not avoid the prescribing of controlled substances provided that they have done a thorough work-up as well as the appropriate follow up. The physician needs to have complete documentation of each step.

The Federation guidelines for pain management are a guidelines for physicians. They are not rules or laws. They should be used as a way to improve pain management for our patients. These guidelines are not used as part of an enforcement process.

The Board wants the physician to use these guidelines as a way to improve pain management of our patients. The Board hopes that you find the guidelines useful.

Burt Schwartz, MD, F.A.C.P.  
Board President

[Model Policy for the Use of Controlled Substances for the Treatment of Pain \(PDF\)](https://mn.gov/boards/assets/2004_grpol_Controlled_Substances.pdf_tcm21-36687.pdf)  
([https://mn.gov/boards/assets/2004\\_grpol\\_Controlled\\_Substances.pdf\\_tcm21-36687.pdf](https://mn.gov/boards/assets/2004_grpol_Controlled_Substances.pdf_tcm21-36687.pdf))

# MISSOURI

## Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

Effective January 2007, the Board of Healing Arts appointed a Task Force to review the current statutes, rules and guidelines regarding the treatment of pain. This Task Force consisted of both staff and Board members, with input from the Governor's Council on Pain and Symptom Management. They were charged with gathering information and to draft language for the Board to review.

In the report, the committee members made recommendations that included:

- ✓ Developing a pain and symptom management website for healthcare professionals and the general public.
- ✓ Encouraging hospitals to increase their medical and nursing staff's knowledge by providing guidelines for required curricula in pain and symptom management in their educational programs.
- ✓ Encouraging pharmacies within communities or among pharmacy chains to share information and stock adequate supplies of Schedule II medications to meet the needs of patients.
- ✓ Evaluating patients with complete history and physicals and adding previous pain physician(s) records with their current medical records.
- ✓ Documenting any pain agreements between the patients and the physician and add this along with an informed consent to the medical records.
- ✓ Making appropriate referrals.

The Missouri Guidelines are not intended to define complete or best practice but rather to communicate what the Board considers to be within the boundaries of professional practice. The guidelines state that patients should have access to appropriate and effective pain relief that will serve to improve the quality of life for those who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

The Missouri guidelines have been broken down into the following sections:

- Section I: Preamble
- Section II: Guidelines (Evaluation of the Patient; Treatment Plan; Informed Consent and Agreement for Treatment; Periodic Review; Consultation; Medical Records; Compliance with Controlled Substances Laws and Regulations)
- Section III: Definitions (Acute Pain; Addiction; Analgesic Tolerance; Chronic Pain; Pain; Physical Dependence; Pseudoaddiction; Substance Abuse; Tolerance)

To view and/or print a complete copy of the Missouri guidelines, please go to our website at [www.pr.mo.gov/healingarts.asp](http://www.pr.mo.gov/healingarts.asp)

## The Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

### Section I: Preamble

The Missouri Board of Healing Arts recognizes that the people of the State of Missouri have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

These guidelines have been developed to clarify the Boards' position on pain control, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Food and Drug Administration Consumer Magazine the March/April 2004 Issue Publication number FDA04-1336C entitled "Managing Chronic Pain", for a sound approach to the management of chronic pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. During the treatment of pain the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics are not synonymous with addiction.

The Board is obligated under the laws of the State of Missouri to protect the public health and safety. The Board recognizes that prescribing of controlled substances, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be aware of the methods for preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory enforcement agencies for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and based on sound clinical grounds. Sound clinical grounds include a working diagnosis for the etiology of the pain. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be accompanied by clear documentation in

the medical record of the treatment and in compliance with applicable state or federal law with the Board of Healing Arts § 334 RSMo; §334.105 RSMo; and §195 RSMo and with the Bureau of Narcotic and Dangerous Drugs and the Drug Enforcement Agency §21 USC.

Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within boundaries of professional practice.

## Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

### 1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of controlled substances.

### 2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

### 3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

### 4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

### 5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

## 6. Medical Records

The physician should keep accurate records including complete medical history and physical examination;

- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

## 7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations. The Physician's Manual can be found at the DEA Diversion website at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov) . The State guidelines can be found under Chapter 195.070 RSMo and 334.105 RSMo.

### Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

#### **Acute Pain**

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

**Addiction**

Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

**Analgesic Tolerance**

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

**Chronic Pain**

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

**Pain**

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

**Physical Dependence**

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

**Pseudoaddiction**

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

**Substance Abuse**

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

**Tolerance**

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

### Section I: Preamble

**“Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States.”**

Centers for Disease Control and Prevention (CDC) “Unintentional Drug Poisoning in the United States”, July, 2010.  
<http://www.cdc.gov/homeandrecreationalafety/pdf/poison-issue-brief.pdf>

The Nebraska Board of Medicine and Surgery recognizes that principles of quality medical practice dictate that the people of the State of Nebraska have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can improve the quality of life for those patients who suffer from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes non-treatment, under-treatment, over-treatment, or the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board’s position on pain control, particularly as related to the use of controlled substances, as well as to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment can result from a lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies can also result in inappropriate treatment of pain. Appropriate pain management is the treating physician’s responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances, including opioid analgesics, are essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Nebraska Board of Medicine and Surgery is obligated under the laws of the State of Nebraska to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, can lead to drug diversion and abuse by individuals who seek them for other than legitimate medical uses. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a medical diagnosis and the documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in the patient's functioning and/or quality of life.

## **Section II: Guidelines**

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

**Evaluation of the Patient**—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

**Treatment Plan**—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program could be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

**Informed Consent and Agreement for Treatment**—The physician should discuss the risks and benefits of the use of controlled substances with the patient, with persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining the patient's responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy can be discontinued (e.g., violation of agreement).

**Periodic Review**—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment can be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

**Consultation**—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder usually requires extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

**Medical Records**—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic, and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage, and quantity prescribed),
9. instructions and agreements,
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

**Compliance With Controlled Substances Laws and Regulations**—To prescribe, dispense, or administer controlled substances, the physician must be licensed in the State of Nebraska and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and to any relevant documents issued by the Nebraska Board of Medicine and Surgery and the Nebraska Department of Health and Human Services for specific rules governing controlled substances as well as applicable state statutes and regulations. The Federation of State Medical Boards (FSMB) has published and makes available a book entitled “Responsible Opioid Prescribing – A Clinician’s Guide” by Scott M. Fishman, M.D.

### **Section III: Definitions**

For the purposes of these guidelines, the following terms are defined as follows:

**Acute Pain**—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

**Addiction**—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

**Chronic Pain**—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that can or cannot be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

**Pain**—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

**Physical Dependence**—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of a pharmacologic antagonist. Physical dependence, by itself, does not equate with addiction.

**Pseudoaddiction**—The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are the drug-seeking behaviors commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

**Substance Abuse**—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

**Tolerance**—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance can or cannot be evident during opioid treatment and does not equate with addiction.



# NEW HAMPSHIRE

Thursday, April 21,  
2016 Wednesday, April 20, 2016

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## Frequently Asked Questions

### Pain Guidelines

Dear Physician:

The New Hampshire Board of Medicine has adopted guidelines for pain management in hopes of fostering the best pain treatment for the citizens of this State. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, be it acute or chronic, due to either malignant or benign disease, and particularly when associated with terminal illness. For many physicians, fear of investigation or sanction for dispensing large or prolonged narcotic prescriptions has impeded effective and appropriate treatment. Accordingly, these guidelines have been developed to clarify the Board's position of pain control specifically as related to the use of controlled substances, to alleviate physician uncertainty, and to encourage better pain management. This format was derived from many sources including N.H. Physicians specializing in pain management, the N.H. State Medical Society, and the Federation of State Medical Boards.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing or administering controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board has concern in those cases where inadequate pain control results from either lack of current knowledge of pain management or inappropriate fear of investigation for providing narcotics where indicated.

The N.H. Board remains obligated under the laws of the State of New Hampshire to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Improper prescribing or documentation will continue to be investigated.

The guidelines are not rigid rules. They serve as a model for physician practice, and to communicate what the Board considers to be within the boundaries of professional practice. While the Board will likely not take disciplinary action against a physician for failing to adhere strictly to the provisions of this protocol, "significant deviation" from the guidelines will likely result in investigation and/or sanction of a physician practice. Key features of the guidelines include accurate documentation, some form of a treatment plan, acceptance of the plan by the patient, and appropriate evaluations and/or consultations. Compliance with all controlled substances laws and regulations is mandatory.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work related factors. This Board hopes to encourage superior pain management by physicians, and clarify appropriate pain relieving practice with the institution of these guidelines.

Sincerely,

The New Hampshire Board of Medicine

### GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES IN THE MANAGEMENT OF CHRONIC PAIN

#### 1. Evaluation of the Patient

An accurate and complete medical history and physical examination must be documented in the medical record. The medical record should document the nature and intensity of the pain and relevant co-existing condition (including current or past substance abuse.) The results of relevant diagnostic studies, other evaluations and consults should be part of the record.

#### 2. Treatment Plan

A treatment plan should state objectives that will be used to determine treatment success, such as pain relief, and/or improved physical or psycho social function. The record should indicate if any further diagnostic evaluations or treatments are planned. Other treatment modalities might include a rehabilitation program, physical therapy or the like, or other treatment plan deemed appropriate for the patient's treatment objectives. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient.

#### 3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, appropriate significant other, and/or guardian. The patient should receive prescriptions

from one physician and one pharmacy when chronic narcotic use is adopted, and should authorize communication between both parties. Frequently, the physician may elect to use a written agreement with the patient, especially where risk of medication abuse is a concern. A written agreement may; (1) indicate a specific pharmacy and prescribing physician; (2) give permission for communication between care providers; (3) detail amount and frequency of medication and prescription refills; (4) define expected follow-up and participation in any other pain treatment activities; (5) provide reasons for which opioid therapy may be discontinued; (6) include an agreement to have urine/serum medication or drug levels/screens when requested; and (7) document other inclusions appropriate for management of the individual patient.

#### 4. Periodic Review

At reasonable intervals, the physician should review the course of opioid treatment and any new information about the etiology and impact of the pain. Continuation or modification of opioid therapy should depend on the physician's evaluation of progress toward stated treatment objectives. If reasonable treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued opioid treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

#### 5. Consultation

The physician should refer the patient for additional evaluation and treatment as necessary and reasonable in order to achieve adequate control of pain and any other treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse, or with comorbid psychiatric disorder, requires extra care in structuring, monitoring, and documentation. When indicated and available, consultation with, or referral to, an expert in the management of chronic pain is advised.

#### 6. Medical Records

The physician should keep accurate and complete records to include documentation of; (1) medical history and physical examination; (2) relevant diagnostic, therapeutic and laboratory results; (3) results of evaluation and consultation; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments and treatment responses; (7) medications (including date, type, dosage, refills, and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current, be maintained in an accessible manner and be readily available for review.

#### 7. Compliance with Controlled Substances Law and Regulations

To prescribe controlled substances the physician must be licensed in the State of New Hampshire, have a valid controlled substances registration and comply with federal and state regulation for issuing controlled substances prescription. Physicians should refer to federal, state and local regulatory agencies for guidance, by writing the Board of Medicine, 2 Industrial Park Drive, Concord, New Hampshire 03301.

**Pain related law of interest** - [www.gencourt.state.nh.us/legislation/2000/SB0424.html](http://www.gencourt.state.nh.us/legislation/2000/SB0424.html)

# PRACTITIONER'S MANUAL

## An Informational Outline For New Mexico

New Mexico Board of Pharmacy  
5200 Oakland NE Suite A  
Albuquerque, New Mexico 87113  
505-222-9830  
800-565-9102

E-Mail: [Debra.wilhite@state.nm.us](mailto:Debra.wilhite@state.nm.us)

[www.rld.state.nm.us/pharmacy](http://www.rld.state.nm.us/pharmacy)

### **The Prescription Monitoring Program Data Center**

NEW! Prescribers, Pharmacists, and other authorized users may now make requests for data from the Prescription Monitoring Program via a secure web page. This web page will assist authorized users in organizing their requests and the reports that are generated by the program. To access the [PMP Data Center click here](#). Or <https://www.pmp.state.nm.us/pmpwebcenter>. If you are not already a registered user of the **PMP Data Center** click on the "Not a User? Register to become a User" link on the login screen, fill out the information form and click submit. Your User Name and Password will be emailed to the address listed on your registration. For questions about the PMP Data Center please call 505-222-9830. Access the [PMP Data Center](#). <https://www.pmp.state.nm.us/pmpwebcenter>.

Revised 6/2010

All statutes and regulations administered and enforced by the NM Board of Pharmacy are available on our web site.

## ***I. CONTROLLED SUBSTANCES***

### **Registration Requirements**

Practitioners must obtain a controlled substance registration in order to prescribe and/or order controlled substances. A state controlled substance registration is required (annually) from the New Mexico Board of Pharmacy for each location that controlled substances will be stored, dispensed, distributed, administered, and in which the practitioner practices, performs research, or uses in teaching or chemical analysis. Practitioners who prescribe or order controlled substances, but do not administer or dispense them, at locations other than their principle place of business may do so under the authority of their state controlled substance registration obtained to prescribe controlled substances.

[http://www.rld.state.nm.us/pharmacy/PDFs/Applications/Prac%20CS%20App%209-07%20\\_2\\_.pdf](http://www.rld.state.nm.us/pharmacy/PDFs/Applications/Prac%20CS%20App%209-07%20_2_.pdf)

Practitioners must obtain a DEA registration for their principle place of business and for each location as described above (renewed every three years). The DEA will not issue a registration until the Board of Pharmacy has issued a controlled substance registration.

<https://www.deadiversion.usdoj.gov/webforms/app224Login.jsp>

### **Modification, Transfer, and/or Change of Address of Registration**

Modification of a registration to authorize additional controlled substances may be made by filing an application in the same number as an application for a new registration.

In the event of a change in name or address the registrant shall file an application in the same number as an application for modification of a registration, a legal document indicating the change must be submitted. The old registration shall be returned to the Board of Pharmacy. A renewal application for registration will only be sent to the registered address on file with the Board of Pharmacy. It will not be forwarded.

A practitioner who moves to a new physical location must request a modification of the federal registration. A modification of registration can be requested on-line at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) or in writing to the DEA field office responsible for that state. If the change in address involves a change in state, the proper state issued license and controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new Schedule II order forms (DEA Form-222, Official Order Form). A Renewal Application for Registration (DEA Form-224a) will only be sent to the registered address on file with DEA. It will not be forwarded.

Registration under the Controlled Substances Act shall not be transferable.

### **Termination of Registration**

Registration shall terminate if and when a registrant dies, discontinues business or professional practice, has his/her professional license revoked or suspended, no longer possesses a DEA registration, and/or has had his/her DEA registration revoked or suspended, or changes his/her name or address as shown on the registration without notifying the Board of Pharmacy and local DEA office prior to change. In such instances, the registrant or his/her estate shall notify the Board of Pharmacy promptly of such fact and return certificate of registration to the Board within 30 days.

Any practitioner desiring to discontinue business activities with respect to controlled substances must notify the DEA field office (See last page) in writing. Along with the notification of termination of registration, the practitioner should send the DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222) to the nearest DEA field office.

### **Order Forms**

Practitioners must use a DEA form 222 (a triplicate form) in order to obtain Schedule II drugs for office use.

### **Inventory and Records**

Practitioners must inventory all controlled substances, including samples, under their control on May 1<sup>st</sup> of each year ( $\pm$  4 days). Practitioners may inventory controlled substances within six months before or after May 1<sup>st</sup> if they notify the Board of Pharmacy in writing of such date. The specific information required on an inventory is available on the DEA web site listed on the last page.

This site lists the requirements specific for New Mexico.

<http://www.nmcpr.state.nm.us/nmac/parts/title16/16.019.0020.htm>

Every registrant shall maintain the following records:

- A complete and accurate record of each substance (including samples) manufactured, received, sold or delivered.
- Separate records for drugs under Schedules I & II.
- Records of all controlled substances dispensed other than by prescribing or administering.
- All records must be maintained for at least 3 years.

Proper receipt records include the invoices or packing slips from the supplier on which you must record the day received and confirm the order is accurate. These receipts must be maintained in a readily retrievable form.

Typical receipt records include:

- The date received (DEA requires the actual date received to be documented on the distributor/wholesaler's invoice).
- Drug name, strength, dosage form, and amount received.
- Distributor's name, address and telephone number.

Keep dispensing records showing at least the following:

- Date dispensed.
- Name and address of the patient.
- Drug name, strength, and quantity dispensed.

### **Dispensing Container Label**

Practitioners must label the container of a prescription drug, including sample drugs (Provided by Drug Manufacturers) with the following:

- Date of dispensing
- Prescription number, if applicable
- Name and address of dispenser
- Name of patient
- Name and strength of drug
- Name of practitioner
- Directions for use and cautionary statements, if any
- The label affixed to the dispensing container of a drug listed in Schedule II, III or IV when dispensed to, or for a patient, shall contain a clear concise warning that it is a crime to transfer the drug to any person other than the patient.

All official compendium requirements for the preservation, packaging, labeling and storage of dangerous drug are applicable.

### Sample Drugs

Sample drugs that are prescription drugs (i.e. have the logo “Caution: Federal Law Prohibits Dispensing Without a Prescription” or “Rx Only”) are subject to all the record keeping, storage and labeling requirements for prescription drugs.

### Disposal of Unwanted or Expired Drugs

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as “Reverse Distributors.” The practitioner should contact the local DEA field office (See last page) for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of three years.

### Security

Practitioners must provide effective controls and procedures to guard against theft and diversion of controlled substances. Items for consideration include:

- The quantity of controlled substances handled.
- The extent of unsupervised public access to the facility.
- The adequacy of supervision over employees having access to storage or distribution areas.
- The procedures for handling business guests, visitors, maintenance personnel and non-employee service personnel.
- The adequacy of the registrant’s or applicant’s system for monitoring the receipt, manufacture, distribution and disposition of controlled substances in its’ operation.
- Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
- Use prescription blanks only for writing a prescription order and not for notes.
- Never sign prescription blanks in advance.
- Assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
- Contact the nearest DEA field office (See last page) to obtain or to furnish information regarding suspicious prescription activities.
- Use tamper-resistant prescription pads.

### Theft or Loss Reporting

Report of loss or theft of a controlled substance must be reported to the NM Board of Pharmacy within five days and DEA within one day of becoming aware of that loss. DEA form 106 must be completed by the registrant and forwarded to the NM Board of Pharmacy and DEA.

The Drug Enforcement Administration web site is [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

Theft or Loss forms and other reporting forms, required by federal law, are available at that site.

#### **DEA Albuquerque District Office**

301 Martin Luther King Ave NE  
Albuquerque, New Mexico 87102  
(505) 346-7419

Please report prescription forgeries and all thefts or unexplained losses of controlled substances to the **New Mexico Board of Pharmacy Drug Diversion Unit**.  
Albuquerque 222-9830, In-State 1-800-565-9102, Fax 505-222-9845.

## New Mexico Controlled Substances

In addition to those substances listed in schedules by the DEA, the following drugs, by Board Regulation, are listed in the New Mexico Controlled Substances Act:

Substance	Schedule
Flunitrazepam (Rohypnol)	C-I
Butalbital (Fioricet)	C-III
Carisoprodol (Soma)	C-IV
Dezocine (Dalgan)	C-IV
Nalbuphine (Nubain)	C-IV
Pseudoephedrine (Sudafed)	C-V

A listing of controlled substances is available on the DEA web site [www.dea diversion.usdoj.gov](http://www.dea diversion.usdoj.gov) or from the Board of Pharmacy web site [www.rld.state.nm.us/pharmacy](http://www.rld.state.nm.us/pharmacy)

## ***II. Prescription Orders***

Practitioners may NOT obtain controlled substances for “office use” by prescription. Pharmacies or drug wholesalers must provide you with an invoice that you must file with your controlled substance records.

Every prescription shall contain on its face:

- Name, address, and DEA registration number of the prescriber
- Name and address of the patient
- Name, strength, and dosage form of the drug
- Quantity prescribed
- Directions for use
- Date of issue
- Number of refills (if any)
- Practitioners license classification
- Signature of practitioner (written prescriptions only)

Prescriptions may be transmitted directly from the practitioner to the pharmacist or indirectly by a written, signed order. Prescriptions may be faxed to the pharmacy. Prescriptions transmitted through intermediary sources (i.e. nursing agencies, discharge planner, institutional staff) require the pharmacist to contact the prescriber to verify the order. Practitioners may electronically transmit a prescription to the patient’s pharmacy of choice if such transmission complies with Board of Pharmacy Regulation 16 NMAC 19.6.23F. The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

Prescriptions for a controlled substances listed in Schedule II shall be written in ink, indelible pencil, or typewritten, zero refills permitted, and manually signed by the practitioner. Exceptions include only:

- Practitioners may not prescribe Schedule II drugs verbally except for emergencies. In such cases, it is the practitioner’s responsibility to provide the pharmacy with a written prescription within 7 days. The quantity prescribed is to be only the amount necessary to cover the emergency period.
- A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner’s agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance.
- A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, or subcutaneous infusion may be transmitted by the practitioner or the practitioner’s agent to the Parenteral Products Pharmacy by facsimile.
- The facsimile serves as the original written prescription.

- A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription.
- A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II narcotic substance for a patient enrolled in a hospice program certified by Medicare under Title XVIII or licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription.

Prescriptions for controlled substances listed in Schedules III or IV may have a maximum of 5 refills within 6 months, and be dispensed only pursuant to:

- A written prescription signed by a practitioner.
- A facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy.
- An oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist containing all information required for a prescription except the signature of the practitioner.

You may NOT issue a prescription for narcotic drugs listed in any schedule to a narcotic dependent person for the sole purpose of continuing dependence upon such a drug. An individual practitioner acting in the usual course of his professional practice may issue a prescription for a controlled substance for a legitimate medical reason. The responsibility of the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

### ***III. PAIN CARE***

#### **Pain Care Bill of Rights**

As a person with pain, you have the right to:

- have your report of pain taken seriously and to be treated with dignity and respect by doctors, nurses, pharmacists, and other healthcare professionals.
- have your pain thoroughly assessed and promptly treated.
- be informed by your healthcare provider about what may be causing your pain, possible treatments, and the benefits, risks and costs of each.
- participate actively in decisions about how to manage your pain.
- have your pain reassessed regularly and your treatment adjusted if your pain has not been eased.
- be referred to a pain specialist if your pain persists.
- get clear and prompt answers to your questions, take time to make decisions, and refuse a particular type of treatment if you choose.

*Although not always required by law, these are the rights you should expect, and if necessary demand, for your pain care.*

## How do I talk with my healthcare provider about pain?

- Speak up! Tell your doctor, nurse or social worker that you're in pain.
- Tell your doctor, nurse or social worker where it hurts. Do you have pain in one place or several places? Does the pain seem to move around?
- Describe how much your pain hurts. On a scale from 0 to 10, zero means no pain at all and 10 means the worst pain you can imagine.
- Describe what makes your pain better or worse. Is the pain always there, or does it go away sometimes? Does the pain get worse when you move in certain ways? Do other things make it better or worse?
- Describe what your pain feels like. Use specific words like sharp, stabbing, dull, aching, burning, shock-like, tingling, throbbing, deep or pressing.
- Explain how the pain affects your daily life. Can you sleep? Work? Exercise? Participate in social activities? Concentrate? How is your mood?
- Tell your doctor, nurse or social worker about past treatments for pain. Have you taken medication or had surgery? Tried massage or meditation? Applied heat or cold? Exercised? Explain what worked and what didn't.

American Pain Foundation  
201 N. Charles Street, Suite 710  
Baltimore, MD 21201-4111

Toll-free information line: 888-615-7246

[www.painfoundation.org](http://www.painfoundation.org)

**New Mexico Boards of Medical Practice, Nursing, and Pharmacy Approved: May 5, 2005**

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### Joint Statement on the Management of Chronic Pain

Pain management is a significant issue in health care today. Estimates of Americans experiencing pain range from 50-75 million persons annually. Thirty to fifty percent of patients undergoing cancer treatment experience pain. The effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines on pain management state, "Patients have the *right* to appropriate assessment and management of pain." (Emphasis added). It is, therefore, incumbent upon New Mexico physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the New Mexico Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of chronic pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If the patient reports untreated or inadequately treated chronic pain, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize the risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

#### ***IV. MONITORING PATIENT CONTROLLED SUBSTANCE USE***

New Mexico offers practitioners' possessing DEA and NM controlled substance registrations a secure web based program to access controlled substance prescriptions information on their patients. By registering on-line with the program a practitioner can submit requests for patient reports containing all controlled substance prescriptions dispensed by pharmacies to that patient. These reports can be used to evaluate therapies, identify possible "doctor shoppers", monitor compliance with patient treatment agreements (contracts), and identify possible altered prescriptions.

Registration information is available at: [HTTPS://WWW.PMP.STATE.NM.US/PMPWEBCENTER](https://www.pmp.state.nm.us/pmpwebcenter)

Read the goals of prescription monitoring programs at:

<http://www.rld.state.nm.us/pharmacy/PDFs/PrescriptionMonitoring/goalsofpmp.pdf>

**TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING**  
**CHAPTER 10 MEDICINE AND SURGERY PRACTITIONERS**  
**PART 14 MANAGEMENT OF PAIN WITH CONTROLLED SUBSTANCES**

**16.10.14.1 ISSUING AGENCY:** New Mexico Medical Board, hereafter called the board.  
[16.10.14.1 NMAC - N, 1/20/03; A, 4/3/05]

**16.10.14.2 SCOPE:** This part applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration.  
[16.10.14.2 NMAC - N, 1/20/03; A, 9/28/12]

**16.10.14.3 STATUTORY AUTHORITY:** These rules are promulgated pursuant to and in accordance with the Medical Practice Act, Sections 61-6-1 through 61-6-35 NMSA 1978 and the Pain Relief Act, Sections 24-2D-1 NMSA through 24-2D-6.  
[16.10.14.3 NMAC - N, 1/20/03; A, 9/28/12]

**16.10.14.4 DURATION:** Permanent  
[16.10.14.4 NMAC - N, 1/20/03]

**16.10.14.5 EFFECTIVE DATE:** January 20, 2003, unless a later date is cited at the end of a section.  
[16.10.14.5 NMAC - N, 1/20/03]

**16.10.14.6 OBJECTIVE:** It is the position of the board that practitioners have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed for that purpose. When such medicines and drugs are used, they should be prescribed in adequate doses and for appropriate lengths of time after a thorough medical evaluation has been completed.  
[16.10.14.6 NMAC - N, 1/20/03; A, 4/3/05]

**16.10.14.7 DEFINITIONS:**

**A.** “Addiction” is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and, craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

**B.** “Acute pain” means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and is generally time-limited.

**C.** “Chronic pain” means pain that persists after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. “Chronic pain” does not, for purpose of the Pain Relief Act requirements, include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

**D.** “Clinical expert” means a person who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

**E.** “Drug abuser” means a person who takes a drug or drugs for other than legitimate medical purposes.

**F.** “Pain” means acute or chronic pain or both.

**G.** “Physical dependence” means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

**H.** “Prescription monitoring program” means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.

**I.** “Therapeutic purpose” means the use of pharmaceutical and non-pharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

**J.** “Tolerance” means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.  
[16.10.14.7 NMAC - N, 1/20/03; A, 9/28/12]

**16.10.14.8 REGULATIONS:** The following regulations shall be used by the board to determine whether a health care practitioner’s prescriptive practices are consistent with the appropriate treatment of pain.

**A.** The treatment of pain with various medicines or controlled substances is a legitimate medical practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

**B.** The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substance abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A practitioner shall be familiar with and employ screening tools as appropriate, as well as the spectrum of available modalities, in the evaluation and management of pain. The practitioner shall consider an integrative approach to pain management.

(3) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan shall include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(4) The practitioner shall discuss the risks and benefits of using controlled substances with the patient or surrogate or guardian, and shall document this discussion in the record.

(5) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized shall be recorded. Prescriptions for opioids shall include indications for use. For chronic pain patients treated with controlled substance analgesic(s), the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. As part of a written agreement, chronic pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.

(6) The management of patients needing chronic pain control requires monitoring by the attending or the consulting practitioner. The practitioner shall periodically review the course of treatment for chronic pain, the patient’s state of health, and any new information about the etiology of the chronic pain at least every six months. In addition, a practitioner shall consult, when indicated by the patient’s condition, with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control.

(7) If, in a practitioner’s medical opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

**C.** Pain management for patients with substance use disorders shall include:

- (1) a contractual agreement;
- (2) appropriate consultation;
- (3) drug screening when other factors suggest an elevated risk of misuse or diversion; and
- (4) a schedule for re-evaluation at appropriate time intervals at least every six months.

**D.** The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medical indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner’s treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient’s pain for its duration while effectively addressing other aspects of the patient’s functioning, including physical, psychological, social, and work-related factors.

**E.** The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection.

**F.** A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Medical Practice Act or board rules.

[16.10.14.8 NMAC - N, 1/20/03; A, 4/3/05; A, 9/28/12; A, 2/14/13]

**16.10.14.9 PHYSICIAN, PHYSICIAN ASSISTANTS AND ANESTHESIOLOGIST ASSISTANTS**

**TREATED WITH OPIATES:** Physicians, physician assistants or anesthesiologist assistants who have chronic pain and are being treated with opiates shall be evaluated by a pain clinic or, by an M.D. or D.O. pain specialist, and must have a complete, independent neuropsychological evaluation, as well as clearance from their physician, before returning to or continuing in practice. In addition, they must remain under the care of a physician for as long as they remain on opiates while continuing to practice.

[16.10.14.9 NMAC - N, 4/3/05; A, 9/28/12]

**16.10.14.10 PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS:** The intent of the New Mexico medical board in requiring participation in the PMP is to assist practitioners in balancing the safe use of controlled substances with the need to impede illegal and harmful activities involving these pharmaceuticals.

**A.** A health care practitioner who holds a federal drug enforcement administration registration and a New Mexico controlled substance registration shall register with the board of pharmacy to become a regular participant in PMP inquiry and reporting.

**B.** A health care practitioner shall, before prescribing, ordering, administering or dispensing a controlled substance listed in Schedule II, III or IV, obtain a patient PMP report for the preceding 12 months when one of the following situations exists:

(1) the patient is a new patient of the practitioner, in which situation a patient PMP report for the previous 12 months shall only be required when Schedules II, III, and IV drugs are prescribed for a period greater than 10 days; and

(2) during the continuous use of opioids by established patients a PMP shall be requested and reviewed a minimum of once every six months.

[16.10.14.10 NMAC - N, 9/28/12; A, 2/14/13]

**16.10.14.11 PAIN MANAGEMENT CONTINUING EDUCATION:** This section applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids. Pursuant to the Pain Relief Act, in order to ensure that all such health care practitioners safely prescribe for pain management and harm reduction, the following rules shall apply.

**A. Immediate requirements effective November 1, 2012.** Between November 1, 2012 and no later than June 30, 2014, all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids, shall complete no less than five continuing medical education hours in appropriate courses that shall include:

- (1) an understanding of the pharmacology and risks of controlled substances,
- (2) a basic awareness of the problems of abuse, addiction and diversion,
- (3) awareness of state and federal regulations for the prescription of controlled substances,
- (4) management of the treatment of pain, and

(5) courses may also include a review of this rule (16.10.14 NMAC) the applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval.

Practitioners who have taken continuing medical education hours in these educational elements between July 1, 2011 and November 1, 2012, may apply those hours toward the required five continuing medical education hours described in this subsection.

**B. Triennial requirements for physicians.** Beginning with the July 1, 2014 triennial renewal date, as part of the 75 continuing medical education hours required during each triennial renewal cycle, all New Mexico medical board physician licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit five continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the three-year period immediately preceding the triennial renewal date. The five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of the required continuing medical education hours in pain management in either

the triennial cycle in which these hours are completed, or the triennial cycle immediately thereafter.

**C. Biennial requirements for physician assistants.** Beginning with the July 1, 2014 biennial renewal date, in addition to the NCCPA certification required during each biennial renewal cycle pursuant to 16.10.15.16 NMAC, all New Mexico medical board physician assistant licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit three continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the two-year period immediately preceding the renewal date. Three of the five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of these required three continuing medical education hours in pain management in either the biennial cycle in which these hours are completed, or the biennial cycle immediately thereafter. Any or all three of these hours may also be applied to satisfy NCCPA requirements for certification.

**D. Biennial requirements for anesthesiologist assistants.** Beginning with the July 1, 2014 biennial renewal date, all New Mexico medical board anesthesiologist assistant licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit three continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the two-year period immediately preceding the renewal date. Three of the five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of these required three continuing medical education hours in pain management in either the biennial cycle in which these hours are completed, or the biennial cycle immediately thereafter.

**E. Requirements for new licensees.** All New Mexico medical board licensees, whether or not the New Mexico license is their first license, who hold a federal drug enforcement administration registration and license to prescribe opioids, shall complete five continuing medical education hours in pain management during the first year of licensure. These five continuing medical education hours completed prior to the first renewal may be included as part of the hours required in Subsections B, C or D, above.

**F.** The continuing medical education requirements of this section may be included in the total continuing medical education requirements set forth at 16.10.4.8 NMAC, 16.10.15.16 NMAC and 16.10.19.15 NMAC.

[16.10.14.11 NMAC - N, 9/28/12; A, 2/14/13]

**16.10.14.12 NOTIFICATION:** In addition to the notice of procedures set forth in the State Rules Act, Section 14-4-1 et seq NMSA 1978, the board shall separately notify the following persons of the Pain Relief Act and Part 14 of the New Mexico medical board rule, 16.10.14 NMAC;

**A.** health care practitioners under its jurisdiction; and

**B.** a health care practitioner being investigated by the board in relation to the practitioner's pain management services.

[16.10.14.12 NMAC - N, 9/28/12]

**HISTORY OF 16.10.14 NMAC:** [RESERVED]

**NEW YORK**

**What Every  
Practitioner Needs  
to Know About  
Controlled  
Substance  
Prescribing**

**New York State Department of Health**



## **Use of Controlled Substances**

Controlled substances can be effective in the treatment of illness, pain, and disease and must, therefore, be accessible to persons who medically need them. These same drugs, however, have the capacity to cause addiction, injury, impairment, and death when abused, misused or diverted to illegal use.

## **Prescribing Controlled Substances**

Practitioners in good faith and in the course of their professional practice are encouraged to prescribe controlled substances for legitimate medical purposes, including pain management, when appropriate. Practitioners are expected to regulate the dosage and prescribe a quantity of such drugs that ordinarily are recognized by members of their profession as sufficient for the proper treatment or medical purpose.

## **Record Keeping**

Practitioners must maintain a written record of the prescribing of all controlled substances. The patient record must contain sufficient information to justify the diagnosis that warrants controlled substance treatment. The record shall include, among other information, the drug name, amount, strength, and directions for use of the controlled substance.

## **Practitioner Notification of “Doctor Shopping”**

Under the Official Prescription Program, the Department of Health will notify a practitioner when prescription data analysis indicates that a patient under his or her treatment with a controlled substance is also obtaining controlled substances from other practitioners, which is unlawful unless the patient informs each practitioner. The Department’s notification will include a drug utilization review and information on rehabilitation treatment if the practitioner deems it necessary for the patient.

## Test Your Knowledge of Controlled Substance Prescribing

- 1 A practitioner must examine a patient every time he/she prescribes controlled substances.**

**FALSE:** Once the initial examination has been made, the necessity for future examinations, and their frequency, is a matter of clinical judgment based on generally accepted medical standards.

- 2 A practitioner can mail an official prescription to the patient or to the patient's pharmacy.**

**TRUE:** The patient does not have to physically pick up the prescription at the practitioner's office.

- 3 When a practitioner prescribes a large quantity of controlled substances, the practitioner's name is flagged in the state's monitoring system.**

**FALSE:** The state does not monitor controlled substance prescribing solely based upon the quantity prescribed. A practitioner should utilize sound professional judgment when prescribing controlled substances and must maintain a patient record containing sufficient information to justify the diagnosis and warrant the treatment. Such information shall include at least:

- patient identification data;
- chief complaint;
- patient condition; and
- the prescribed amount, strength and directions for use.

The record need not be distinct from the patient's medical record.

**4 Controlled substances may only be prescribed in a maximum thirty-day supply.**

**FALSE:** A practitioner may issue a prescription for up to a three-month supply of a controlled substance, including chorionic gonadotropin, or up to a six-month supply of an anabolic steroid by writing on the face of the prescription either the diagnosis or code for the treatment of the following conditions:

**Code    Diagnosis**

- A**    Panic Disorder
- B**    Attention Deficit Disorder
- C**    Chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity
- D**    Relief of pain in patients suffering from conditions or diseases known to be chronic or incurable
- E**    Narcolepsy
- F**    Hormone deficiency states in males; gynecologic conditions that are responsive with anabolic steroids or chorionic gonadotropin; metastatic breast cancer in women; anemia and angioedema

- 5 If a practitioner would like to obtain a stock of controlled substances for office administration he/she can write a prescription labeled “For Office Use” and have the prescription filled at a pharmacy.**

**FALSE:** Controlled substance prescriptions must be patient-specific. Prescriptions for office use are prohibited. Practitioners must order controlled substances intended for office administration directly from a licensed distributor or manufacturer.

- 6 If a practitioner makes a mistake on an official prescription form, he/she can cross out and initial the error.**

**TRUE:** The practitioner is not required to issue a new official prescription form if he/she makes an error when writing the prescription. The practitioner should be aware that, in most situations, the pharmacist will call the practitioner to verify the alteration. Should the situation arise, a practitioner can authorize the pharmacist to change all prescription information except for practitioner signature, date written, patient name, drug name and strength. A practitioner may authorize a pharmacist to change the prescribed quantity, but may not authorize a pharmacist to add a quantity if it is missing from the prescription.

- 7 Long-term opioid use is limited to the treatment of cancer pain.**

**FALSE:** There are no such limits to long-term opioid prescribing. Current statutory amendments are meant to encourage the use of controlled substances in treating patients with a legitimate complaint of pain. A practitioner should utilize generally accepted medical standards and his or her professional judgment when treating any patient with controlled substances.

**8 An official New York State prescription is required only when a practitioner writes a prescription for a controlled substance.**

**FALSE:** Effective April 19, 2006, an official prescription is required for **every** prescription written in New York, for both controlled **and** non-controlled substances.

**9 Physician assistants are authorized to prescribe Schedule II controlled substances in an outpatient setting.**

**TRUE:** Under the Public Health Law, physician assistants are authorized to prescribe Schedule II controlled substances in an outpatient setting beginning December 13, 2007. (Physician assistants' prescribing authority previously extended only to Schedule III, IV, and V controlled substances.) The law also requires the prescribing of controlled substances to be:

- In good faith and in the physician assistant's lawful scope of practice;
- Authorized by the physician assistant's supervising physician;
- For patients under the care of a supervising physician.

Physician assistants also must be authorized by the DEA to prescribe controlled substances. Physician assistants wishing to prescribe Schedule II controlled substances must contact DEA to amend their registration to include Schedule II prescribing authority, if necessary.

**10 A practitioner may phone in a controlled substance prescription to the patient's pharmacy.**

**TRUE:** A practitioner may orally prescribe up to a five-day supply of Schedule II, III and V controlled substances, as well as benzodiazepines. Practitioners may orally prescribe up to a 30-day supply or 100 dosage units, whichever is less, of Schedule IV (non-benzodiazepines) controlled substances.

**NOTE:** The controlled substance law and regulations authorize a practitioner to orally prescribe a controlled substance to a pharmacist. To be valid for dispensing, oral prescriptions for controlled substances must be phoned in by the prescribing practitioner him or herself. Nurses or other office personnel are not authorized to phone in a controlled substance prescription to a pharmacist.

Within 72 hours after authorizing an oral prescription for controlled substances, the practitioner must furnish the pharmacist with the written follow-up prescription. Prescriptions for Schedule II controlled substances and benzodiazepines may only be orally prescribed in an emergency situation. These follow-up prescriptions must also have written or typed on the face the words: "Authorization for Emergency Dispensing," in addition to the information otherwise required.

**11 Practitioners must date controlled substance prescriptions on the day that they sign the prescription.**

**TRUE:** The date on a controlled substance prescription must be the date the prescription was actually signed by the practitioner. Controlled substance prescriptions can not be pre-dated or post-dated.

**12 Official prescriptions for controlled substances must indicate the drug quantity and refills in numerical and written word form.**

**TRUE:** Regulations require official prescriptions for controlled substances to indicate the quantity of drug prescribed and the number of refills authorized by the practitioner in both **numerical and written word form**. Because drug-seekers often alter these numbers in an attempt to divert controlled substances, this requirement helps detect and prevent such illegal activity.

**13 Only prescriptions for Schedule II controlled substances and benzodiazepines must indicate the maximum daily dose of the prescribed drug.**

**FALSE:** In addition to containing the specific directions for use and all other information required by the controlled substance law and regulations, all prescriptions for controlled substances must indicate the maximum daily dose (MDD) of the prescribed drug.

**14 Anabolic steroids, including testosterone, are Schedule III controlled substances and may have refills.**

**FALSE:** New York State Public Health Law, Section 3306, classifies all anabolic steroids, including testosterone, as Schedule II controlled substances. As with all Schedule II controlled substances, prescriptions for anabolic steroids cannot be refilled.

**15 All staff practitioners in hospitals, clinics, and residential healthcare facilities can use the institution official New York State prescription forms when prescribing for outpatient use.**

**TRUE:** In addition to information required by controlled substance law and regulations, institution official prescriptions must also contain the practitioner's stamped or typed name, and his or her personal DEA registration number.

Only unlicensed interns, residents, and foreign physicians may prescribe under a hospital's DEA registration, provided they are authorized by the hospital to do so and are assigned a suffix that must be indicated on the prescription.

**16 Practitioners must safeguard their official New York State prescription forms.**

**TRUE:** Practitioners are required to undertake adequate security measures to safeguard official prescriptions against loss, destruction, theft, or unauthorized use. Practitioners are also required to maintain a sufficient but not excessive supply of official prescriptions in reserve.



## How To Reach Us

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State of New York  
Department of Health

## New York City Emergency Department Discharge Opioid Prescribing Guidelines

*Note: These guidelines do not replace clinical judgment in the appropriate care of patients nor are they intended to provide guidance on the management of patients while in the ED.*

### **In the management of patients with acute or chronic non-cancer pain discharged from an emergency department,**

1. Consider short-acting opioid analgesics for the treatment of acute pain only when the severity of the pain is reasonably assumed to warrant their use.
2. Start with the lowest possible effective dose if opioid analgesics are considered for the management of pain.
3. Prescribe no more than a short course of opioid analgesics for acute pain. Most patients require no more than three days.
4. To assess for opioid misuse or addiction, use targeted history or validated screening tools. Prescribers can also access the New York State Controlled Substance Information (CSI) on Dispensed Prescriptions Program for information on patients' controlled substance prescription history.
5. Avoid initiating treatment with long-acting or extended-release opioid analgesics.
6. Address exacerbations of chronic or recurrent pain conditions with non-opioid analgesics, non-pharmacological therapies, and/or referral to specialists for follow-up, all as clinically appropriate.
7. Avoid when possible prescribing opioid analgesics to patients currently taking benzodiazepines and/or other opioids. Consider other risk factors for consequential respiratory depression.
8. Attempt to confirm with the treating physician the validity of lost, stolen, or destroyed prescriptions. If considered appropriate, replace the prescription only with a one-to two-day supply.
9. Provide information about opioid analgesics to patients receiving a prescription, such as the risks of overdose and dependence/addiction, as well as safe storage and proper disposal of unused medications.

## Background

With increased use of prescription opioid analgesics for the treatment of pain, misuse also has increased, as have the use of medical services and deaths associated with opioid analgesics. From 2002-2003 to 2008-2009, self-reported, non-medical prescription opioid use increased by 40% with four % of New Yorkers aged 12 and older (263,000) reporting misuse. Between 2004 and 2009, the rate of opioid analgesic-related emergency department (ED) visits in New York City doubled, rising from 55 to 110 visits for every 100,000 New Yorkers. In 2009, one in every four unintentional drug poisoning (overdose) deaths (158) in New York City involved prescription opioid analgesics, a 20% increase from 2005.<sup>1</sup>

The New York City Department of Health and Mental Hygiene created these guidelines to help reduce the misuse of prescription opioid analgesics by establishing standards for prescribing from the ED. In developing the guidelines, the Health Department was cognizant of the need to preserve the vital role of the ED in treating patients with painful medical conditions. These guidelines are consistent with the City Health Information bulletin on Opioid Prescribing, "Preventing Misuse of Prescription Opioid Drugs,"<sup>2</sup> and were informed by opioid prescribing guidelines in other jurisdictions.<sup>3,4</sup> They also incorporate input from a panel of New York City ED providers. The guidelines are not meant for patients in palliative care programs or with cancer pain. They do not replace clinical judgment in the appropriate care of patients nor are they intended to provide guidance on the management of patients while they are in the ED.

## Recommendations

### In the management of patients discharged from an emergency department,

1. **Consider short-acting opioid analgesics for the treatment of acute pain only when the severity of the pain is reasonably assumed to warrant their use.**

Opioid analgesics should not be considered as the primary approach to pain management in discharge planning for patients. Alternative and effective pharmacological interventions for acute pain exist, including non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and nerve blocks (e.g., for dental pain). Non-pharmacological therapies, such as fracture immobilization, may obviate the need for additional pain medications. Short-acting opioid analgesics such as hydrocodone, immediate-release oxycodone, and hydromorphone may be prescribed as adjuncts to relieve acute pain when the severity of the pain warrants their use. They also may be prescribed when non-opioid therapies have not or are reasonably presumed to not provide adequate relief from pain.<sup>4</sup> When prescribing combination preparations of prescription opioid analgesics and acetaminophen, caution the patient about the maximum dose of acetaminophen they should take to avoid toxicity.

The federal Emergency Medical Treatment and Active Labor Act (EMTALA) requires hospitals to provide a medical screening examination to determine whether an individual presenting at an ED has an emergency medical condition. If the hospital determines that a patient has an emergency medical condition, the hospital must provide treatment as may be required to stabilize the patient's medical condition.<sup>5</sup> EMTALA, however, **does not** require the use of opioid analgesics to treat pain. ED prescribers may apply their professional judgment to determine whether prescribing opioid analgesics for pain is the appropriate course of treatment.

**2. Start with the lowest possible effective dose if opioid analgesics are considered for the management of pain.**

If opioid analgesics are considered for the management of pain after patient discharge from the ED, start with the lowest possible effective dose. Higher doses increase the risk of adverse events such as respiratory depression and overdose.<sup>6,7,8</sup> These risks are especially pronounced for opioid-naïve patients.

**3. Prescribe no more than a short course of opioid medication for acute pain. Most patients require no more than three days.**

Excessive quantities of opioid analgesics increase the risk of misuse, abuse, or diversion. In addition, initiation of opioid analgesic therapy in opioid-naïve patients may lead to inappropriate long term use.<sup>9</sup> For most patients with acute pain, a three-day supply is generally sufficient. When considering the quantity of pills prescribed, it is important to take as-needed dosing into account. For example, a patient taking opioid analgesics “every six hours as needed for pain” may need only one or two doses a day. There may be some acute conditions, e.g. rib fractures, for which severe pain is expected to last more than three days and for which risks of inadequate pain control may exceed risks of a longer supply of opioids. However, if the patient’s acutely painful condition outlasts a three-day supply of opioid medication a re-evaluation of the condition is likely to be beneficial. Consider expediting follow-up care if the patient’s condition is expected to require more than a three-day supply of opioid analgesics.

**4. To assess for opioid misuse or addiction, use targeted history or validated screening tools. Prescribers can also access the New York State Controlled Substance Information (CSI) on Dispensed Prescriptions Program for information on patients’ recent controlled substance prescription history before prescribing controlled substances.**

Patients with histories of substance use disorders are at increased risk of developing opioid addiction when prescribed opioid analgesics for acute pain.<sup>10,11</sup> Validated screening tools include the 10-item Drug Abuse Screening Test (DAST-10).<sup>12</sup> Alternatively, the single question “How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?” (with an answer of one or more considered positive) was found to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview.<sup>12</sup> A history of substance use disorder should not exclude an ED patient from being prescribed opioid analgesics for acute pain. It should, however, prompt a discussion with the patient about the increased risk for addiction. If necessary, refer for treatment of opioid dependence or addiction.

Prescription databases such as the CSI contain information on patients’ controlled substance prescription history that can inform prescribing decisions. Emergency Department physicians using the Ohio Automated Rx Reporting System for patients presenting with painful conditions changed their opioid prescription plan for 41% of patients after reviewing the patients’ prescription history. Among patients whose prescriptions were changed, 61% received fewer and 39% received more opioids than originally planned.<sup>13</sup>

The New York State CSI on Dispensed Prescriptions program is a database accessible via the Internet that contains information on patients’ controlled substance prescriptions.<sup>14</sup> Changes to New York State law in 2012 will make a patient’s entire controlled substance history (rather than only history meeting

specific criteria) available to prescribers through the CSI. The law also will require New York State prescribers, including ED prescribers writing controlled substance prescriptions for more than five days, to check the patient's history in the CSI before issuing a controlled substance prescription.<sup>15</sup> Prescribers should register with the [New York State \(NYS\) Health Commerce System health.ny.gov/professionals/narcotic/practitioners/online\\_notification\\_program/](http://www.health.ny.gov/professionals/narcotic/practitioners/online_notification_program/) ) to gain access. Consider the possibility that a patient is misusing opioid analgesics if the system indicates that the patient has multiple prescriptions for opioid analgesics by multiple providers or filled at multiple pharmacies.

**5. Avoid initiating treatment with long-acting or extended-release opioid analgesics.**

Long-acting and extended-release opioid analgesics are not indicated in the management of acute or intermittent pain. This class of opioid analgesics may cause fatal respiratory depression when administered to patients not previously exposed to opioids, even when used as directed. Patients being treated with long-acting and sustained or extended-release opioid analgesics for the treatment of pain require close follow-up that cannot reasonably be provided by ED prescribers.

**TABLE 1. Prescription Opioid analgesics: Short Acting and Long Acting or Extended Release\*<sup>16</sup>**

<b>Short Acting</b>	<b>Long Acting/Extended Release</b>
<b>Codeine</b>	<b>Oxycodone</b> (Sustained Release) OxyContin <sup>®</sup>
<b>Oxycodone</b> (Immediate Release) Percocet <sup>®</sup> Percodan <sup>®</sup>	<b>Methadone</b> Dolophine <sup>®</sup>
<b>Hydrocodone</b> Vicodin <sup>®</sup> Lorcet <sup>®</sup> Lortab <sup>®</sup> Norco <sup>®</sup>	<b>Morphine</b> (Sustained Release) MS Contin <sup>®</sup> Avinza <sup>®</sup> Kadian <sup>®</sup> Oramorph SR <sup>®</sup>
<b>Morphine</b> (Immediate Release)	<b>Fentanyl transdermal</b> Duragesic <sup>®</sup>
<b>Hydromorphone</b> Dilaudid <sup>®</sup>	<b>Oxymorphone</b> (Extended Release) Opana ER <sup>®</sup>
<b>Oxymorphone</b> (Immediate Release)	<b>Hydromorphone</b> (Extended Release) Exalgo ER <sup>®</sup>

\*This is not a comprehensive list of all available products.

**6. Address exacerbations of chronic or recurrent pain conditions with non-opioid analgesics, non-pharmacological therapies, and/or referral to specialists for follow-up, all as clinically appropriate.**

Opioid prescriptions from the ED for exacerbation or progression of chronic pain not associated with palliative/end of life care are discouraged in general. Patients with chronic pain who require opioid analgesics should obtain opioid prescriptions from a single prescriber who monitors the patient's pain relief and function. Prescribing, and particularly initiating, sustained-release or long-acting opioid analgesics from the ED for chronic pain is a form of unmonitored opioid therapy that is not optimal for patient care. In exceptional circumstances, the ED prescriber may consider prescribing short-acting opioid analgesics for patients with acute worsening of chronic pain. Similarly, changing the opioid a patient is using chronically in an effort to improve pain relief (i.e., opioid rotation) is complicated and generally should not be done in the ED.<sup>17</sup>

**7. Avoid when possible prescribing opioid analgesics to patients currently taking benzodiazepines and/or other opioids. Consider other risk factors for consequential respiratory depression.**

Opioid analgesics, when combined with other central nervous system depressants or given to patients with certain underlying medical conditions, can increase the risk for overdose,<sup>18</sup> especially in older patients. Avoid the combination of benzodiazepines and opioid analgesics as much as possible. In New York City, about half of unintentional opioid drug poisoning overdose deaths involve a benzodiazepine; most commonly alprazolam (Xanax®).<sup>19</sup> In addition, patients taking higher doses of opioids, including cumulative doses from more than one source, are at higher risk for respiratory depression. The CDC estimates that the 20% of patients receiving opioids who were prescribed a combination of 100 or more morphine equivalents per day account for 80% of opioid overdoses, with half of these among patients with opioids from more than one prescriber.<sup>20</sup> Opioid analgesics should be used with caution in older patients and those with sleep-disordered breathing, such as obstructive sleep apnea, obesity, or congestive heart failure.<sup>21</sup> Doses may have to be adjusted in patients with renal or liver disease due to decreased clearance of the drug.

**8. Attempt to confirm with the treating physician the validity of lost, stolen, or destroyed prescriptions. If considered appropriate, replace the prescription only with a one to two day supply.**

Patients misusing controlled substances may report their prescriptions as having been lost or stolen in an attempt to obtain more pills. The American Pain Society's Agreement for Long-term Controlled Substances Therapy for Chronic Pain stipulates that "medications may not be replaced if they are lost, get wet, are destroyed, ... etc."<sup>6</sup> EDs should institute a policy to not replace prescriptions for opioid analgesics that are requested on the basis of having been lost, stolen, or destroyed. On-site dispensing of a single dose may be a reasonable option. In those rare instances where this may be warranted, ED providers should document that they confirmed the need directly with the patient's physician. ED providers should not replace these prescriptions if they are unable to obtain this confirmation.

**9. Provide information about opioid analgesics to patients receiving a prescription, such as the risks of overdose and dependence/addiction, as well as safe storage and proper disposal of unused medications.**

Patients should be informed of the risks of taking opioid analgesics and be reminded to take them as prescribed, not more frequently or in greater quantities. Risks of opioid analgesics include, but are not limited to: overdose that can slow or stop their breathing and even lead to death; fractures from falls in patients aged 60 years and older; drowsiness leading to injury; tolerance; and dependence. Respiratory depression is more common with use of alcohol, benzodiazepines, antihistamines, and barbiturates. Patients should be reminded to avoid medications that are not part of their treatment plan because they may worsen side effects and increase the risk of overdose.

Nearly three quarters (71%) of people aged 12 and older who have used opioid analgesics for nonmedical purposes reported obtaining them free or buying them from family or friends.<sup>22</sup> Patients should be told how to minimize risks to others by keeping the medication in a secure location, preferably locked, not sharing medication with anyone, and promptly disposing of unused opioid analgesics by flushing them down the toilet.

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These guidelines are to provide a general approach in the prescribing of OOCs. They are not intended to take the place of clinical judgment, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient.

1. OOCs for acute pain, chronic pain and acute exacerbations of chronic pain will be prescribed in emergency/acute care facilities only when appropriate based on the patient's presenting symptoms, overall condition, clinical examination and risk for addiction.
  - a. Doses of OOCs for routine chronic pain or acute exacerbations of chronic pain will typically NOT be given in injection (IM or IV) form.
  - b. Prescriptions for chronic pain will typically NOT be provided if the patient has either previously presented with the same problem or received an OOCs prescription from another provider within the last month.
  - c. IV Demerol (Meperidine) for acute or chronic pain is discouraged.
2. Emergency medical clinicians will not routinely provide:
  - a. Replacement prescriptions for OOCs that were lost, destroyed or stolen.
  - b. Replacement doses of Suboxone, Subutex or Methadone for patients in a treatment program.
  - c. Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches, and methadone).
3. Prior to making a final determination regarding whether a patient will be provided a prescription for OOCs, the emergency clinician or facility:
  - a. Should search the Ohio Automated Rx Reporting System (OARRS) database (<https://www.ohiopmp.gov/portal/Default.aspx>) or other prescription monitoring programs, per state rules.
  - b. Reserves the right to request a photo ID to confirm the identity of the patient. If no photo ID is available, the emergency or other acute care facility should photograph the patient for inclusion in the facility medical record.
  - c. Reserves the right to perform a urine drug screen or other drug screening.
4. Emergency/acute care facilities should maintain an updated list of clinics that provide primary care and/or pain management services for patients, as needed.
5. Prior to making a final determination regarding whether a patient will be provided a prescription for an OOCs, the emergency clinician should consider the following options:
  - a. Contact the patient's routine provider who usually prescribes their OOCs.
  - b. Request a consultation from their hospital's palliative or pain service (if available), or an appropriate sub-specialty service.
  - c. Perform case review or case management for patients who frequently visit the emergency/acute care facilities with pain-related complaints.
  - d. Request medical and prescription records from other hospitals, provider's offices, etc.
  - e. Request that the patient sign a pain agreement that outlines the expectations of the emergency clinician with regard to appropriate use of prescriptions for OOCs.
6. Emergency/acute care facilities should use available electronic medical resources to coordinate the care of patients who frequently visit the facility, allowing information exchange between emergency/acute care facilities and other community-care providers.
7. Except in rare circumstances, prescriptions for OOCs should be limited to a three-day supply. Most conditions seen in the emergency/acute care facility should resolve or improve within a few days. Continued pain needs referral to the primary care physician or appropriate specialist for re-evaluation.
8. Each patient leaving the emergency/acute care facility with a prescription for OOCs should be provided with detailed information about the addictive nature of these medications, the potential dangers of misuse and the appropriate storage and disposal of these medications at home. This information may be included in the Discharge Instructions or another handout.
9. Following the medical screening, emergency/acute care facilities should provide a patient handout that reflects the above guidelines and clearly states the facility position regarding the prescribing of opioids and other controlled substances.

Endorsed by:



Facilitated by:

**Ohio**

Department of Health  
Department of Aging

## Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office-Based Setting

*Note: These guidelines do not replace clinical judgment in the appropriate care of patients. They are not intended as standards of care or as templates for legislation, nor are they meant for patients in palliative care programs or with cancer pain. The recommendations are an educational tool based on the expert opinion of numerous physicians and other health care providers, medical/nursing boards, mental and public health officials, and law enforcement personnel in Oklahoma and throughout the United States. The guidelines are available at <http://poison.health.ok.gov>.*

### Opioid Treatment for Acute Pain

1. Opioids should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.
2. Providers should query the Oklahoma Prescription Monitoring Program (PMP) for patients presenting with acute pain, prior to prescribing an opioid medication. In circumstances where a patient's pain is resulting from an objectively diagnosed disease process or injury, a provider may prudently opt not to review the Oklahoma PMP.
3. When opioids are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.
4. When opioids are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.
5. Long duration-of-action opioids (e.g., methadone, buprenorphine, fentanyl, extended release oxycodone, and morphine) are rarely indicated for treatment of acute pain.
6. The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistent pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition. Health care providers should query the Oklahoma PMP as part of this re-evaluation process.
7. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

### Opioid Treatment for Chronic Pain

1. Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment.
2. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. For chronic pain patients transferring their care to new health care providers, new opioid prescriptions should generally not be written until the previous provider's records have been reviewed or the previous health care provider has been notified of the transfer of care.
3. The health care provider should screen for risk of abuse or addiction before initiating opioid treatment.
4. Prior to the initial prescribing of opioid medications, health care providers should query the Oklahoma Prescription Monitoring Program (PMP).
5. When opioids are used for the treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function. One health care provider should coordinate a patient's comprehensive pain care plan and provide all opioid prescriptions required for the plan.

6. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement.
7. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.
8. Regular visits for evaluation of progress toward goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma PMP more frequently.
9. Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. The Oklahoma PMP should be queried at least once per year for patients receiving opioid treatment for chronic pain.
10. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, weaning whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.
11. Opioid treatment should be discontinued if adverse effects outweigh benefits or if aberrant, dangerous, or illegal behaviors are demonstrated.
12. Health care providers treating chronic pain patients with opioids should maintain records, in accordance with state and federal law, documenting patient evaluation, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.
13. Health care providers should consider consultation for patients with complex pain conditions, serious comorbidities and mental illness, a history or evidence of current drug addiction or abuse, or when the provider is not confident of his/her ability to manage the treatment.
14. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.
15. The administration of intravenous and intramuscular opioids for the relief of exacerbations of chronic pain is discouraged, except in special circumstances.
16. Long-acting opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.
17. When opioids are prescribed for treatment of chronic pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.



## Background

Prescription drug abuse is Oklahoma's fastest growing drug problem. Of the nearly 3,200 unintentional poisoning deaths in Oklahoma from 2007-2011, 81% involved at least one prescription drug.<sup>1</sup> In 2010, Oklahoma had the fourth highest unintentional poisoning death rate in the nation (17.9 deaths per 100,000 population).<sup>2</sup> Prescription painkillers (opioids) are now the most common class of drug involved in overdose deaths in Oklahoma (involved in 87% of prescription drug-related deaths, with 417 opioid-involved overdose deaths in 2011).<sup>1</sup> In a 2010 National Survey on Drug Use and Health report, Oklahoma led the nation in non-medical use of painkillers, with more than 8% of the population age 12 and older abusing/misusing painkillers.<sup>3</sup> Oklahoma is also one of the leading states in prescription painkiller sales per capita.<sup>4</sup>

These guidelines were primarily adapted from the Utah Clinical Guidelines on Prescribing Opioids.<sup>5</sup> The Opioid Prescribing Guidelines for Oklahoma Workgroup also studied other state and national recommendations in an effort to prepare guidelines most relevant to the practice of medicine in Oklahoma. The Workgroup created these guidelines in an effort to help reduce the misuse of prescription opioid analgesics while preserving patient access to needed medical treatment.

## Guidelines for Acute Pain

**1. Opioids should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.**<sup>6</sup>

Most acute pain is better treated with non-opioid medications [e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs)] or physical modalities such as therapeutic exercises or stretching. Opioid medications have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that opioid treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. Non-medical use of opioids is more common among younger people, and these risks should be considered when prescribing to an adolescent.

**2. Providers should query the Oklahoma Prescription Monitoring Program (PMP) for patients presenting with acute pain, prior to prescribing an opioid medication. In circumstances where a patient's pain is resulting from an objectively diagnosed disease process or injury, a provider may prudently opt not to review the Oklahoma PMP.**

The Oklahoma PMP is a real-time database of scheduled prescriptions written to persons who filled a prescription in Oklahoma. The Oklahoma PMP can be accessed at:  
[http://www.ok.gov/obnnd/Prescription\\_Monitoring\\_Program/](http://www.ok.gov/obnnd/Prescription_Monitoring_Program/).

Patients with a history of or current substance abuse are at increased risk of misusing opioids when prescribed.<sup>7,8</sup> Medical providers should ask the patient about a history of substance abuse prior to prescribing an opioid medication for the treatment of acute pain. A non-opioid regimen is preferred for patients presenting with a history of substance abuse who have acute pain. Although this should not exclude a patient from being prescribed opioids for acute pain, it should prompt a discussion with the patient about the potential for addiction. When a patient with a history of opioid addiction presents with acute pain due to an objectively diagnosed clinical or traumatic condition requiring the use of opioids for pain control, very close follow-up is indicated.

**3. When opioids are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.**

Prescribing more medications than necessary can lead to non-medical use, abuse, and diversion of unused medications. Opioid pain medications should be discontinued when the pain severity no longer requires opioid medications.

**4. When opioids are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.**

It is important that patients understand the need to store medications securely. Health care providers should encourage patients to keep medications in a locked environment rather than in easily accessible locations, such as the bathroom or kitchen cabinet, where medications are accessible to children and can be a target for theft. After recovery from pain, leftover medications should be properly disposed of immediately to help protect the medications from being diverted.

Tools to accompany *Recommendation 4*:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf>
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations <http://www.ok.gov/obnnd/documents/TakeBackBoxes.pdf>

**5. Long duration-of-action opioids (e.g., methadone, buprenorphine, fentanyl, extended release oxycodone, and morphine) are rarely indicated for treatment of acute pain.**

Given the epidemiological data showing a significant increase in mortality associated with long-acting opioids, the inherent difficulty in titrating these medications, and the availability of alternative medications and/or treatment modalities, health care providers are advised to refrain from the routine use of long-acting opioids in the acute pain setting.<sup>5,9</sup>

**6. The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistent pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition. Health care providers should query the Oklahoma PMP as part of this re-evaluation process.**

Patients with acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course for their diagnosis should be carefully re-evaluated. The continuation of opioid treatment for acute pain in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such. At this time, the diagnosis and appropriateness of the treatment plan should be re-evaluated and the patient's medical history should be reviewed for factors that could interfere with treatment and pose a risk for complications during opioid treatment, including substance abuse or history of substance abuse.

Tools to accompany *Recommendation 6*:

- Oklahoma Prescription Monitoring Program [http://www.ok.gov/obnnd/Prescription\\_Monitoring\\_Program/](http://www.ok.gov/obnnd/Prescription_Monitoring_Program/)

**7. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.**

Patients misusing controlled substances frequently report their opioid medications as having been lost or stolen. Pain specialists routinely stipulate in pain agreements with patients that lost or stolen controlled substances will not be replaced. Most written agreements between chronic pain patients and pain management physicians, including the Health Resources and Services Administration (HRSA) toolkit sample pain agreement, state that prescriptions for opioids will not be replaced.<sup>10</sup>

The diversion of prescribed opioids is common. One study looked at completed patient surveys, and found that 45% of respondents reported some form of drug diversion at least once. Stolen medication was the most prevalent method of drug diversion, with 30% of respondents reporting at least one incident of stolen medication.<sup>11</sup> In another survey study, among persons 12 years and older who abused opioid pain medications

(2009-2010), 71.2% came from friends or relatives; 55% were given to the abuser, 11.4% were purchased, and 4.8% were stolen.<sup>12,13</sup>

## **Guidelines for Chronic Pain**

### **1. Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment.**<sup>6,9,13,14,15</sup>

Opioid medications are usually not the most appropriate first line of treatment for patients with chronic pain. Other measures, such as non-opioid pain medications, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., therapeutic exercise, physical therapy), should be tried first and the outcomes of those therapies documented. Opioid therapy should be considered only when other potentially safer and more effective therapies prove inadequate. This approach is consistent with the World Health Organization's (WHO) *Pain Relief Ladder*.<sup>16</sup>

**1.1** Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany *Recommendation 1*:

- Non-opioid Pain Management Tool  
<http://health.utah.gov/prescription/tools.html> (see *Informational Tools* on website)

### **2. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. For chronic pain patients transferring their care to new health care providers, new opioid prescriptions should generally not be written until the previous provider's records have been reviewed or the previous health care provider has been notified of the transfer of care.**<sup>13,14,15,17</sup>

There are many reasons to prescribe cautiously when initiating opioid therapy; therefore a comprehensive initial evaluation is necessary to identify patients at high risk for adverse outcomes. The major goal should be to provide the greatest functional benefit while minimizing the potential for harm to patients. The potential for serious harm, including death, exists due either to overdose or to dangerous behaviors that may occur while taking opioids. The patient may be directly harmed, but others may also be harmed through diversion or by acts performed by a person taking opioids.

Initiating opioid treatment often results in short-term relief, which may not be sustainable. Safe long-term use of opioid medications requires the commitment of adequate resources. Patients need to be monitored regularly to evaluate outcomes and identify aberrant behavior or adverse side effects.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, and to evaluate how the pain is affecting the patient's function and quality of life. The provider should attempt to identify other conditions or circumstances that could adversely affect the treatment plan or the approach to managing the patient's treatment plan. The provider should also re-assess and re-evaluate prior approaches to the patient's pain management to provide a basis for establishing an effective ongoing plan of care.

The evaluation should specifically assess:

A. The character and potential cause(s) of pain, as well as prior treatments.

- The duration of the pain should be considered.
- The character of the pain should be considered. Since certain types of pain, such as neuropathic pain, might not be best treated with opioids. It is important for the clinician to consider the type and character of pain when prescribing a medication.

B. Social factors and medical or mental health conditions might influence treatment, especially those that might interfere with appropriate and safe use of opioid therapy.<sup>14</sup>

- Obtain a history of substance use, addiction, or dependence. (If present, refer to *Recommendations 13.2*

and 13.3.)

- Consider potential psychiatric conditions, including personality disorders that may affect pain or the treatment of pain. (If present, refer to *Recommendation 13.4.*)
- Identify use of alcohol and other medications that might interact with opioid medications used to treat pain. Particular attention and caution should be given to alcohol, benzodiazepines, and other sedative medications.
- Assess the presence of medical conditions that might complicate the treatment of pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea.
- Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher dosages. Some experts recommend that all patients who are considered for long-term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered.<sup>14</sup>

### C. Effects of pain on the patient's life and function.

- Assess the patient's baseline severity of pain, functional status, and quality of life using a valid, reliable method/instrument that can be used later to evaluate treatment effectiveness.

Tools to accompany *Recommendation 2*:

- Sheehan Disability Tool  
<http://health.utah.gov/prescription/pdf/guidelines/SheehanDisabilityScale.pdf>
- Pain Management Evaluation Tool  
<http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf>

## **3. The health care provider should screen for risk of abuse or addiction before initiating opioid treatment.**

**3.1** Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication for chronic pain.<sup>6</sup>

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. The screening tools are intended to assist the health care provider in determining whether opioid treatment is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

**3.2** Consider performing drug screening before initiating long term opioid treatment for chronic pain.

Drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., potential diversion), undisclosed use of alcohol, or the use of illicit substances, not identified without testing.

Health care providers should use a urine drug screen or another laboratory test that can detect the presence of illegal drugs, unreported prescription medications, and/or unreported alcohol use. It is recommended that drug testing be strongly considered and conducted, especially when other factors suggest caution. When screening is limited to situations when there is suspicion of substance misuse, some opportunities may be missed. In one study, testing results upon first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most discrepancies involved substances not reported by the patient; a small minority reported taking medications that were not found on testing.<sup>18</sup>

A positive drug screen indicates the need for caution, but does not preclude opioid use for the treatment of pain. However, consideration should be given to referral for substance abuse counseling and/or a pain management specialist. If an opioid medication is subsequently prescribed, the patient should be more carefully monitored and the conditions under which opioids are being prescribed should be well documented in the treatment plan. (See *Recommendations 5, 6, 8, 12.*)

Inexpensive immunoassays can be performed in the office. These tests can rapidly determine if opioids are

present but they do not identify specific substances. When necessary, specific substances can be identified by ordering confirmatory laboratory testing. However, in many cases, candidly going over the results of the initial in-office test with the patient can eliminate the need for confirmatory testing. It is extremely important to keep in mind that immunoassays have both false-positive and false-negative results. Certain over-the-counter medications may cause a positive result. The prescriber should consider confirmatory gas chromatography or mass spectrometry testing or consultation with a certified Medical Review Officer if drug test results are unclear or confirmation is clinically necessary.<sup>9</sup>

Tools to accompany *Recommendation 3*:

- Urine Drug Testing Devices  
<http://health.utah.gov/prescription/pdf/guidelines/CLIADrugTestlist.pdf>
- Current Opioid Misuse Measure  
<http://health.utah.gov/prescription/tools.html> (see *Tools to Screen for Risk of Complications* on website)
- SOAPP-R  
<http://health.utah.gov/prescription/tools.html> (see *Tools to Screen for Risk of Complications* on website)
- Opioid Risk Tool  
[http://health.utah.gov/prescription/pdf/guidelines/ORTwithout\\_scoring.pdf](http://health.utah.gov/prescription/pdf/guidelines/ORTwithout_scoring.pdf)
- Signs of Substance Misuse  
[http://health.utah.gov/prescription/pdf/guidelines/signs\\_substance\\_misuse.pdf](http://health.utah.gov/prescription/pdf/guidelines/signs_substance_misuse.pdf)
- Checklist for Adverse Effects, Function, and Opioid Dependence  
<http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf>

#### **4. Prior to the initial prescribing of opioid medications, health care providers should query the Oklahoma Prescription Monitoring Program (PMP).**

Most patients who request treatment for pain are legitimately seeking relief of pain. However, subsets of patients seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of controlled substance prescriptions filled by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to potential problems.

The Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDDC) maintains the Oklahoma Prescription Monitoring Program, a real time, searchable database of all controlled substance prescriptions filled in the state. The PMP is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. Access to the data is provided to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and potential abuse of controlled substances throughout the state. This database is accessible online to all controlled substance prescribers.

Tools to accompany *Recommendation 4*:

- Oklahoma Prescription Monitoring Program  
[http://www.ok.gov/obndd/Prescription\\_Monitoring\\_Program/](http://www.ok.gov/obndd/Prescription_Monitoring_Program/)

#### **5. When opioids are used for the treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function. One health care provider should coordinate a patient's comprehensive pain care plan and provide all opioid prescriptions required for the plan.**

**5.1** The treatment plan should be tailored to the patient's circumstances and the characteristics and pathophysiology of the pain. The pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function, and should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan, whenever possible, to maximize the likelihood of

achieving treatment goals.

**5.2** Goals for the treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.<sup>6,9,14</sup>

For most chronic pain conditions, complete elimination of pain is an unreasonable goal. Goals for treatment of chronic pain should include improvement in the tolerability of pain and function.<sup>15</sup> The clinician should counsel the patient on reasonable expectations for treatment outcomes so that agreement is achieved on the goals of addressing pain, function, and quality of life.

The pathophysiologic basis of the pain can help establish a prognosis for future improvement (or worsening) in function and pain and should influence the goals of treatment. Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcomes.<sup>6,14</sup> These include:

- Objective physical findings obtained by the examining health care provider (e.g., improved strength, range of motion, aerobic capacity);
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions); and
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living, and frequency and intensity of conditioning).

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale;
- Psychosocial status (e.g., increased social engagement or decreased emotional distress);
- Familial status (e.g., improved relationships with, or decreased burden, on family members); and
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Health care providers should consider cultural differences in assessing function, quality of life, and pain intensity (see <http://prc.coh.org/culture.asp> for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient's condition with these persons should have been previously obtained and documented.

**5.3** Treatment goals should be developed jointly by the patient and health care provider.<sup>15</sup>

Engage patients in their own health care. Health care providers have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the health care provider should focus not just on pain control, but also on treating the patient's underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany *Recommendation 5*:

- Pain Management Evaluation Tool  
<http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf>
- Patient Pain and Medication Tracking Chart  
<http://health.utah.gov/prescription/pdf/guidelines/PatientPain-FunctionTracking.pdf>
- Sheehan Disability Scale  
<http://health.utah.gov/prescription/pdf/guidelines/SheehanDisabilityScale.pdf>
- Brief Pain Inventory Form  
<http://health.utah.gov/prescription/pdf/guidelines/BriefPainInvNPEC.pdf>

- Sample Treatment Plan for Prescription Opioids  
[http://health.utah.gov/prescription/pdf/guidelines/treatment\\_plan.pdf](http://health.utah.gov/prescription/pdf/guidelines/treatment_plan.pdf)
- Cultural considerations in assessing function, quality of life, and pain intensity  
<http://prc.coh.org/culture.asp>

**6. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement.<sup>13</sup>**

**6.1** Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long-term complete pain relief. Without careful guidance, this may lead the patient to disappointment and to seek excessive doses of opioids.

The patient should be counseled about the appropriate use of opioid medications, possible adverse effects, and the risks of developing tolerance, physical and/or psychological dependence, and withdrawal symptoms.<sup>9,19</sup> Adverse effects can include opioid-induced hyperalgesia, allodynia, abnormal pain sensitivity, and depression.<sup>6,9,20</sup>

Sedation and cognitive impairment may occur when patients are taking opioid medications. Therefore, discuss with patients the need for caution in operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.<sup>11</sup>

Ensure the patient does not have any absolute contraindications, and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent);
- Co-administration of a drug capable of inducing life-threatening drug-drug interaction; and
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed).

More detail about absolute contraindications is contained in the *Guidelines Tools* section.

Consider co-prescribing naloxone for high risk patients, and providing training to family/caregivers to reverse potential life-threatening depression of the respiratory and central nervous system. Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

- Snoring heavily and cannot be awakened;
- Periods of ataxic (irregular) or other sleep disordered breathing;
- Trouble breathing;
- Exhibiting extreme drowsiness and slow breathing;
- Slow, shallow breathing with little chest movement;
- Increased or decreased heartbeat; and
- Feeling faint, very dizzy, confused or has heart palpitations.

**6.2** The patient and, when applicable, the family or caregiver should be involved in the education process.<sup>14</sup>

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver.<sup>14</sup> Educating the family or caregiver about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is important to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information about the patient can be disclosed to others, such as

family members, and under what conditions discussions about the patient with others are allowed.

**6.3** The treatment plan, which defines the responsibilities of both the patient and health care provider, should be documented.<sup>6,9,13,14,15</sup>

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. Patient responsibilities also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber.<sup>14</sup>

The prescribing health care provider may consider requiring that the treatment plan be documented in the form of a treatment agreement signed by the patient. Patients should be encouraged to store opioid medications in a secure location to keep the medication away from others who should not have access to them.

**6.4** The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum screening upon request, and reasons for possible discontinuation of drug therapy.<sup>9,13,14,15,17</sup>

The treatment plan (sometimes referred to as a treatment agreement) should contain the items developed jointly by the patient and health care provider, such as follow-up appointments, the pharmacy and health care provider to be used, as well as any non-negotiable demands or limitations the health care provider wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the agreement and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications or obtaining them from multiple providers as documented by Oklahoma's Prescription Monitoring Program.<sup>14,20</sup>

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use;<sup>14,19</sup>
- Prohibition of use with alcohol or certain other medications;<sup>14</sup>
- Documentation of counseling regarding driving or operating heavy machinery; and<sup>6,14</sup>
- Specific frequencies of urine testing.

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only.<sup>14,17,19</sup>

It is not necessary to include specific consequences for specific non-compliant behaviors, but it should be documented in the treatment agreement that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship and of opioid prescribing by that clinician.

**6.5** Discuss involvement of family members in the patient's care and request that the patient give written permission to talk with family members about the patient's care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the health care provider may want to consider a family conference to help assess the patient's integrity.<sup>19</sup> Consultation with others, however, must be done within the constraints of HIPAA, as noted above. (See *Recommendation 6.2.*)

Tools to accompany *Recommendation 6:*

- Absolute Contraindications to Opioid Prescribing  
[http://health.utah.gov/prescription/pdf/guidelines/absolute\\_contraindications.pdf](http://health.utah.gov/prescription/pdf/guidelines/absolute_contraindications.pdf)
- Sample Treatment Plan for Prescribing Opioids  
[http://health.utah.gov/prescription/pdf/guidelines/treatment\\_plan.pdf](http://health.utah.gov/prescription/pdf/guidelines/treatment_plan.pdf)
- Signs of Substance Misuse  
[http://health.utah.gov/prescription/pdf/guidelines/signs\\_substance\\_misuse.pdf](http://health.utah.gov/prescription/pdf/guidelines/signs_substance_misuse.pdf)
- Guidance on HIPAA

- Prescription Drug Overdose in Oklahoma Brochure  
[http://www.ok.gov/health2/documents/DrugOverDoseBrochure\\_2013.pdf](http://www.ok.gov/health2/documents/DrugOverDoseBrochure_2013.pdf)

## Initiating, Monitoring, and Discontinuing Opioid Treatment

### **7. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.**

**7.1** The health care provider should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid medication treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to *Recommendation 11* for more information on discontinuation of treatment.

**7.2** Short-acting opioid medications are, in general, safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the health care provider may consider switching the patient to a long-acting or sustained-release formulation. The patient's individual situation should influence whether the patient is switched from a short-acting medication. Treatment with a long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

Tools to accompany *Recommendation 7*:

- Dosing Guidelines  
[http://health.utah.gov/prescription/pdf/guidelines/dosing\\_guidelines.pdf](http://health.utah.gov/prescription/pdf/guidelines/dosing_guidelines.pdf)
- Current Opioid Misuse Measure (COMM)  
<http://health.utah.gov/prescription/tools.html> (see *Tools to Screen for Risk of Complications* on website)

## Titration Phase of Opioid Treatment

### **8. Regular visits for evaluation of progress toward goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma PMP more frequently.<sup>14</sup>**

**8.1** Face-to-face follow-up visits should occur at least every 2-4 weeks during the titration period. More frequent follow-up visits may be advisable and caution should be used when prescribing an opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused).<sup>15</sup>

**8.2** When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered.<sup>14,15</sup>

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than necessary by increasing too slowly with the risk of causing harm, including fatal overdose, by increasing too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient.<sup>14</sup> Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of

opioid measured in morphine milligram equivalents (MMEs). It is likely that the risk-benefit ratio is less favorable at higher doses. Clinical vigilance is needed at all dosage levels of opioids, but is even more important at higher doses. Health care providers who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. No clear threshold for a high dose has been established based on evidence. The Washington State guidelines suggest a threshold of 120 MME per day. It is important to increase clinical vigilance at doses exceeding 120 MME per day. Patients receiving 100 MME or more per day had a 9-fold increase in overdose risk. Most overdoses were medically serious, 12% were fatal.<sup>9</sup>

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to use medication only as directed, that is, not to change doses or frequency of administration without specific instructions from the health care provider.

**8.3** During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma Prescription Monitoring Program more frequently, such as monthly or quarterly.

Tools to accompany *Recommendation 8*:

- Dosing Guidelines  
[http://health.utah.gov/prescription/pdf/guidelines/dosing\\_guidelines.pdf](http://health.utah.gov/prescription/pdf/guidelines/dosing_guidelines.pdf)
- Electronic MME Dosing Calculator  
<http://agencymeddirectors.wa.gov/mobile.html>
- Prescription Monitoring Program  
[http://www.ok.gov/obnndd/Prescription\\_Monitoring\\_Program/](http://www.ok.gov/obnndd/Prescription_Monitoring_Program/)

## Maintenance of Opioid Treatment

**9. Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. The Oklahoma PMP should be queried at least once per year for patients receiving opioid treatment for chronic pain.**<sup>13,15</sup>

**9.1** The health care provider is advised to consider baseline drug testing at the initiation of opioid treatment, compliance monitoring one to three months later, and random monitoring every 6-12 months. In the event of unexpected drug screens or suspicious patient behavior, additional monitoring can be performed. Health care providers may consider each of the following four areas of concern at each visit: Analgesia, Activity, Adverse effects, and Aberrant behavior. These assessments can be remembered as the “four A’s”:<sup>21</sup>

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess the patient’s function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: evaluate for possible drug abuse-related behavior

**9.2** During the maintenance period, the Oklahoma Prescription Monitoring Program should be checked at least annually.

After the titration period is complete and the maintenance period is underway, the frequency of checks of the Oklahoma PMP can be based on clinical judgment, but should be done no less than annually. The Oklahoma PMP should be checked more often for high risk patients and patients exhibiting aberrant behavior.

**9.3** Continuation or modification of treatment should depend on the health care provider’s evaluation of progress towards stated treatment goals.<sup>13</sup>

Treatment goals include reduction in a patient’s pain scores and improved physical, psychological, and social

function. If patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the health care provider should re-evaluate the appropriateness of continued treatment with the current medications.<sup>9,17</sup>

A frequent need for dose adjustments after a reasonable time interval of titration is an indication to re-evaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

**9.4** Adjustments to previously stable maintenance treatment may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.<sup>14</sup>

Options for adjustment include reducing the medication or rotating opioid medications. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., the addition of supplemental short-acting medications for control of break-through pain (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success.<sup>22</sup> If rotating among different opioid medications, refer to a standard dosing equivalence table, taking into account the current drug's half-life and potency.

If the patient's situation has changed permanently and consideration is given to the increased risk of adverse events, it is reasonable to consider an ongoing increase in maintenance dosing. In general, if the patient's underlying medical condition is chronic and unchanging, and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level.<sup>14</sup>

**9.5** Dosing changes should generally be made during a clinic visit.<sup>14</sup>

If the patient's underlying, pain-producing, chronic medical condition improves, it is expected that the health care provider will begin tapering the patient off the opioid medication. (See *Recommendation 11* for guidelines on discontinuation.)

Tapering an opioid medication with or without the goal of discontinuation may be performed as described below (*Recommendation 11*) or as described in the *Strategies for Tapering and Weaning Tool*.

Tools to accompany *Recommendation 9*:

- Checklist for Adverse Effects, Function, and Opioid Dependence  
<http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf>
- Signs of Substance Misuse  
[http://health.utah.gov/prescription/pdf/guidelines/signs\\_substance\\_misuse.pdf](http://health.utah.gov/prescription/pdf/guidelines/signs_substance_misuse.pdf)
- Pain Management Evaluation Tool  
<http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf>
- Dosing Guidelines  
[http://health.utah.gov/prescription/pdf/guidelines/dosing\\_guidelines.pdf](http://health.utah.gov/prescription/pdf/guidelines/dosing_guidelines.pdf)
- Strategies for Tapering and Weaning  
[http://health.utah.gov/prescription/pdf/guidelines/Strategies\\_tapering\\_weaning.pdf](http://health.utah.gov/prescription/pdf/guidelines/Strategies_tapering_weaning.pdf)

## Evaluating the Opioid Treatment Trial

**10. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, weaning**

**whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.**

The health care provider should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. A second opinion or consult may be useful in making the decision to continue or discontinue opioids after the treatment trial.

## **Discontinuing Opioid Treatment**

**11. Opioid treatment should be discontinued if adverse effects outweigh benefits, or if aberrant, dangerous, or illegal behaviors are demonstrated.<sup>9</sup>**

**11.1** Discontinuation of opioid treatment is recommended if any of the following occurs:

- Dangerous or illegal behaviors are identified;
- Patient claims or exhibits a lack of effectiveness;
- Pain problem resolves;
- Patient expresses a desire to discontinue therapy; and
- Opioid treatment appears to be causing harm to the patient, particularly if harm exceeds benefit.<sup>14</sup>

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver.<sup>17</sup> This decision should include careful consideration of the outcomes of ongoing monitoring.

**11.2** When possible, offer to assist patients in safely discontinuing medications, even if they have withdrawn from treatment or been discharged for agreement violations.<sup>14</sup>

The goal is to taper all patients off opioid medications safely. If the patient is discharged, the health care provider is obliged to offer continued monitoring for 30 days post-discharge. Possible complications of opioid withdrawal should be taken into consideration when discontinuing or tapering opioid medications.

Tools to accompany *Recommendation 11*:

- Strategies for Tapering and Weaning  
[http://health.utah.gov/prescription/pdf/guidelines/Strategies\\_tapering\\_weaning.pdf](http://health.utah.gov/prescription/pdf/guidelines/Strategies_tapering_weaning.pdf)

## **Documentation and Medical Records**

**12. Health care providers treating chronic pain patients with opioids should maintain records, in accordance with state and federal law, documenting patient evaluation, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.<sup>9,13,14,15,17</sup>**

**12.1** A written treatment plan should document objectives that will be used to evaluate treatment success.<sup>9,13,14,15,17</sup>

**12.2** Opioid prescriptions should be written on tamper-resistant prescription paper to help reduce the likelihood of prescription fraud or misuse.<sup>15</sup>

To reduce the chance of tampering with the prescription, write legibly, and keep a copy.<sup>15</sup>

**12.3** Assessment of treatment effectiveness should be documented in the medical record.<sup>9,13,15</sup>

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may

affect the efficacy of treatment or risks of adverse events should be assessed and documented at every visit.

Health care providers should consider utilizing a standardized approach such as “The Four A’s” or “The SAFE Tool” for medical documentation. The Four A’s considers four areas of concern: Analgesia, Activity, Adverse effects, and Aberrant behavior.<sup>21</sup> The SAFE Tool is a numerical five point scoring system that helps to guide the health care provider toward broader views of treatment options.<sup>23</sup> It considers four areas of concern: social functioning (S), analgesia (A), physical function (F), and emotional functioning (E).

The Four A’s can be remembered as:

- Analgesia: inquire about level of pain (current, recent, trends, etc.);
- Activity: assess both the patient’s function and overall quality of life;
- Adverse events: determine whether the patient is having medication side effects; and
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior.

The SAFE Tool can be remembered as:

- Social functioning: inquire about family and employment relationships;
- Analgesia: inquire about level of pain (current, recent, trends, etc.);
- Physical functioning: inquire about how well the patient is meeting goals; and
- Emotional functioning: ask about changes in the patient’s mental health status.

**12.4** Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record.<sup>14</sup>

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics; and
- Follow-up referrals, tests, and other therapies.

Health care providers are encouraged to make use of resources designed to assist them in managing the care of patients with aberrant behavior. Serious non-adherence issues (e.g., illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid treatment.

Tools to accompany *Recommendation 12*:

- Checklist for Adverse Effects, Function, and Opioid Dependence  
<http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf>
- Signs of Substance Misuse  
[http://health.utah.gov/prescription/pdf/guidelines/signs\\_substance\\_misuse.pdf](http://health.utah.gov/prescription/pdf/guidelines/signs_substance_misuse.pdf)
- Federal Laws on Prescribing Controlled Substances (21 CFR 1306 et. seq.)  
<http://www.deadiversion.usdoj.gov/21cfr/cfr/>
- Osteopathic Rules on Prescribing for Intractable Pain (OAC 510:5-9-1 et. seq.)  
<http://www.ok.gov/osboe/documents/RULES.pdf>
- Medical Board Rules on Prescribing for Intractable Pain (OAC 435:10-7-11 et. seq.)  
<http://www.okmedicalboard.org/download/457/MDRULES.pdf>

## **Consultation and Management of Complex Patients**

**13. Health care providers should consider consultation for patients with complex pain conditions, serious co-morbidities and mental illness, a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her ability to manage the treatment.**<sup>9,13</sup>

**13.1** Prescribers may wish to consider referring patients if any of the following conditions or situations are

present, or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis;
- The patient has significant co-morbidities, including psychiatric illness;
- The patient is at high risk of aberrant behavior or addiction; or
- The clinician suspects the development of significant tolerance, particularly at higher doses.

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

**13.2** Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be closely monitored (e.g., more frequent random drug screens, random pill counts) or considered for referral to an addiction specialist for evaluation of recurrent risk and for assistance with treatment.<sup>9,13,14</sup>

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Oklahoma where there is a shortage of readily available addiction specialists.

**13.3** Pain patients addicted to medications/drugs should be referred to a pain management and/or mental health/substance use disorder specialist, if available, for recommendations on the treatment plan and assistance in management.

The health care provider may consider prescribing opioid medications for pain even if the patient has a self-reported or documented previous opioid abuse problem, as long as monitoring is performed during the titration and maintenance phase.

**13.4** Patients with a coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving an opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation.<sup>17,19</sup> Consultation can be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric condition(s).

Tools to accompany *Recommendation 13*:

- Strategies for Tapering and Weaning  
[http://health.utah.gov/prescription/pdf/guidelines/Strategies\\_tapering\\_weaning.pdf](http://health.utah.gov/prescription/pdf/guidelines/Strategies_tapering_weaning.pdf)

#### **14. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.**

Patients misusing controlled substances frequently report their opioid medications as having been lost or stolen. Pain specialists routinely stipulate in pain agreements with patients that lost or stolen controlled substances will not be replaced. Most written agreements between chronic pain patients and pain management physicians, including the Health Resources and Services Administration (HRSA) toolkit sample pain agreement, state that prescriptions for opioids will not be replaced.<sup>10</sup>

The diversion of prescribed opioids is common. One study looked at completed patient surveys and determined that 45% of respondents reported some form of drug diversion at least once. Stolen medication was the most prevalent method of drug diversion, and 30% of respondents reported at least one incident of stolen medication.<sup>11</sup> Another survey study found that among persons 12 years and older who abused opioid pain medications (2009-2010), 71.2% came from friends or relatives; 55% were given to the abuser, while 11.4% were purchased, and 4.8% were stolen.<sup>12,13</sup>

#### **15. The administration of intravenous and intramuscular opioids for the relief of exacerbations of chronic pain is discouraged, except in special circumstances.**

Parenteral opioids should be generally avoided for the treatment of chronic pain because of their short duration and potential for addictive euphoria. For chronic pain, oral opioids are superior to parenteral opioids in duration of action and provide a gradual decrease in the level of pain control. When there is evidence or reasonable suspicion of an acute pathological process causing the acute exacerbation of chronic pain, parenteral opioids may be appropriate.

Tools to accompany *Recommendation 15*:

- Dosing Guidelines  
[http://health.utah.gov/prescription/pdf/guidelines/dosing\\_guidelines.pdf](http://health.utah.gov/prescription/pdf/guidelines/dosing_guidelines.pdf)
- Current Opioid Misuse Measure (COMM)  
<http://health.utah.gov/prescription/tools.html> (see *Tools to Screen for Risk of Complications*)

## **Methadone and Extended Release/Long-Acting Opioids**

**16. Long-acting opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.**

**16.1** The prescription use of methadone remains controversial due to concerns about its efficacy and safety. During the past two decades methadone-related death rates increased in Oklahoma and the U.S. From 2007-2011, methadone was listed in the cause of death in 21% of prescription drug-related unintentional poisoning deaths in Oklahoma.<sup>1</sup>

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect. Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone metabolism is complicated and varies among individuals. Methadone interacts with several other medications that can alter its metabolism, changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in a patient taking other medications, and before starting any medication in a patient taking methadone.

Methadone can prolong the rate-corrected QT interval (QTc), increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias or cardiac conduction abnormalities and in patients taking another medication associated with QTc interval prolongation.<sup>24</sup> An online reference of such medications is available at: <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>.

Health care providers should consider obtaining an electrocardiogram (ECG) to measure the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline recommended that an ECG be performed before prescribing methadone, within the first 30 days, and annually. Additional ECG examinations were recommended if the methadone dose exceeds 100 mg per day or if a patient on methadone has unexplained syncope or seizure. Guidance was provided for actions to be taken at two levels of QTc prolongation (450-500 ms and greater than 500 ms).<sup>25</sup>

Methadone and other opioids have been associated with worsening obstructive sleep apnea and new onset of central sleep apnea. Clinicians should question patients about symptoms and signs of sleep apnea and consider obtaining a sleep study in patients treated with opioids if they develop any signs of sleep-disordered breathing or respiratory depression. This is particularly important for patients receiving higher doses of opioid medications. In a recent study, 92% of patients on opioid doses at or above 200 MMEs had developed ataxic or irregular breathing.<sup>25</sup>

**16.2** If extended release/long-acting opioids are prescribed, consideration should be given to the increased risk of overdose with these medications. Prescribers should consider the current risk evaluation and implement mitigation strategies and close monitoring to reduce the possibility of adverse events.

Tools to accompany *Recommendation 16*:

- Dosing Guidelines  
[http://health.utah.gov/prescription/pdf/guidelines/dosing\\_guidelines.pdf](http://health.utah.gov/prescription/pdf/guidelines/dosing_guidelines.pdf)
- The Role of Methadone in the Management of Chronic Non-Malignant Pain  
[http://health.utah.gov/prescription/pdf/guidelines/role\\_of\\_methadone.pdf](http://health.utah.gov/prescription/pdf/guidelines/role_of_methadone.pdf)
- Electronic MME Dosing Calculator  
<http://agencymeddirectors.wa.gov/mobile.html>

## **Education of Chronic Pain Patients on Using Opioids**

**17. When opioids are prescribed for treatment of chronic pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.**

It is important that patients understand the need to store medications securely. Health care providers should encourage patients to keep medications in a locked environment rather than in easily accessible locations, such as the bathroom or kitchen cabinet, where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medications after they have recovered, they should dispose of their medications immediately to help protect them from being a target for theft as well as protect others from getting into the medications.

Tools to accompany *Recommendation 17*:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs  
<http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf>
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations  
<http://www.ok.gov/obnndd/documents/TakeBackBoxes.pdf>

## Guidelines Tools

### Tools to use in evaluation and monitoring:

- Pain Management Evaluation Tool  
<http://health.utah.gov/prescription/pdf/guidelines/PainManagementWorksheet.pdf>
- Patient Pain and Medication Tracking  
<http://health.utah.gov/prescription/pdf/guidelines/PatientPain-FunctionTracking.pdf>
- Sheehan Disability Scale  
<http://health.utah.gov/prescription/pdf/guidelines/SheehanDisabilityScale.pdf>
- Brief Pain Inventory Form  
<http://health.utah.gov/prescription/pdf/guidelines/BriefPainInvNPEC.pdf>
- Treatment Plan for Prescribing  
[http://health.utah.gov/prescription/pdf/guidelines/treatment\\_plan.pdf](http://health.utah.gov/prescription/pdf/guidelines/treatment_plan.pdf)
- SF-12  
<http://health.utah.gov/prescription/pdf/guidelines/SF-12v2Standard-Sample.pdf>

### Tools to screen for risk of complications:

- Oklahoma Prescription Monitoring Program  
[http://www.ok.gov/obnnd/Prescription\\_Monitoring\\_Program/](http://www.ok.gov/obnnd/Prescription_Monitoring_Program/)
- Current Opioid Misuse Measure (COMM)  
<http://health.utah.gov/prescription/tools.html>
- SOAPP-R  
<http://health.utah.gov/prescription/tools.html>
- Opioid Risk Tool  
[http://health.utah.gov/prescription/pdf/guidelines/ORTwithout\\_scoring.pdf](http://health.utah.gov/prescription/pdf/guidelines/ORTwithout_scoring.pdf)
- Urine Drug Testing Devices  
<http://health.utah.gov/prescription/pdf/guidelines/CLIADrugTestlist.pdf>
- Signs of Substance Misuse  
[http://health.utah.gov/prescription/pdf/guidelines/signs\\_substance\\_misuse.pdf](http://health.utah.gov/prescription/pdf/guidelines/signs_substance_misuse.pdf)
- Checklist for Adverse Effects, Function, and Opioid Dependence  
<http://health.utah.gov/prescription/pdf/guidelines/checklist%20for%20adverse%20effects.pdf>

### Informational tools:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs  
<http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf>
- Non-opioid Pain Management Tool  
<http://health.utah.gov/prescription/tools.html>
- Absolute Contraindications to Opioid Prescribing  
[http://health.utah.gov/prescription/pdf/guidelines/absolute\\_contraindications.pdf](http://health.utah.gov/prescription/pdf/guidelines/absolute_contraindications.pdf)
- Strategies for Tapering and Weaning  
[http://health.utah.gov/prescription/pdf/guidelines/Strategies\\_tapering\\_weaning.pdf](http://health.utah.gov/prescription/pdf/guidelines/Strategies_tapering_weaning.pdf)
- Information for Patients-Opioid Analgesics for Non-cancer Pain  
[http://health.utah.gov/prescription/pdf/guidelines/Information\\_for\\_patients.Opioid\\_analgesics\\_for\\_non-cancer\\_pain.pdf](http://health.utah.gov/prescription/pdf/guidelines/Information_for_patients.Opioid_analgesics_for_non-cancer_pain.pdf)
- The Role of Methadone in the Management of Chronic Non-Malignant Pain  
[http://health.utah.gov/prescription/pdf/guidelines/role\\_of\\_methadone.pdf](http://health.utah.gov/prescription/pdf/guidelines/role_of_methadone.pdf)
- Dosing Guidelines  
[http://health.utah.gov/prescription/pdf/guidelines/dosing\\_guidelines.pdf](http://health.utah.gov/prescription/pdf/guidelines/dosing_guidelines.pdf)

- Prescription Drug Overdose in Oklahoma Brochure  
[http://www.ok.gov/health2/documents/DrugOverDoseBrochure\\_2013.pdf](http://www.ok.gov/health2/documents/DrugOverDoseBrochure_2013.pdf)
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations  
<http://www.ok.gov/obnnd/documents/TakeBackBoxes.pdf>
- Electronic MME Dosing Calculator  
<http://agencymeddirectors.wa.gov/mobile.html>
- Federal Laws on Prescribing Controlled Substances (21 CFR 1306 et. seq.)  
<http://www.dea.gov/diversion.usdoj.gov/21cfr/cfr/>
- Osteopathic Rules on Prescribing for Intractable Pain (OAC 510:5-9-1 et. seq.)  
<http://www.ok.gov/osboe/documents/RULES.pdf>
- Medical Board Rules on Prescribing for Intractable Pain (OAC 435:10-7-11 et. seq.)  
<http://www.okmedicalboard.org/download/457/MDRULES.pdf>

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***Disclaimer:*** This document should not be used to establish any standard of care. No legal proceeding, including medical malpractice proceedings or disciplinary hearings, should reference a deviation from any part of this document as constituting a breach of professional conduct. These guidelines are only an educational tool. Clinicians should use their own clinical judgment and not base clinical decisions solely on this document. The recommendations are based on evidence-based research, promising interventions, and expert opinion. Additional research is needed to understand the impact of these interventions on decreasing unintentional drug poisoning and on health care costs. These guidelines should be considered by clinicians, hospitals, administrators, public health entities, and other relevant stakeholders.

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# Statements of Philosophy

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## Pain Management

The OMB urges the skillful use of effective pain control for all patients. Providers are encouraged to treat pain within the scope of their practice and refer patients to the appropriate specialists when indicated. In all cases of pain management, practitioners should maintain records to track prescriptions and coordinate care with other treating practitioners. Health care providers are encouraged to use the Oregon Prescription Drug Monitoring Program (PDMP), a division of the Oregon Health Authority, to help guide treatment plans. The PDMP is a database that allows prescribers of controlled substances to access a patient's name, the controlled substance prescribed, the dosage, and the name and contact information of the prescriber.

The National Transportation Safety Board recommends that health care providers discuss with patients the effect their medical condition and medication may have on their ability to safely operate a vehicle in any mode of transportation.

It is important for providers to be well-informed on relevant pain management techniques and hone their skills for the optimal treatment of their patients, taking into account the etiology of the pain. Types of pain include, but are not limited to, acute, post-operative or traumatic pain, chronic non-cancer pain, chronic pain caused by malignancies and pain associated with terminal illness.

### Acute Pain

Effective treatment of acute pain promotes recovery and return to normal function. The potential for addiction is low when short courses of opioids are used to treat acute pain and discontinued as the patient recovers. Inadequately managed acute pain may result in chronic pain. Patients who are not recovering as expected must be carefully assessed. Skillful pain management techniques including oral, parenteral and, when available, regional pain management techniques, can achieve maximum patient comfort and may reduce the need for opioids.

### Chronic Pain

Patients with chronic pain require complex care and treatment decisions for multi-faceted problems. Providers have a responsibility to diagnose and manage chronic pain while maximizing the benefits and minimizing the potential adverse effects of treatment. Opioids are not always required or effective for the treatment of chronic pain, and they should be discontinued if the patient's pain control or function does not improve with their use.

Pain management treatment must be evidence-based and individualized to the patient. Oregon statute protects providers from disciplinary action by the Board when prescribing or administering controlled substances as part of a treatment plan for pain with the goal of controlling the patient's pain for the duration of the pain. However, prescribing controlled substances without a legitimate medical purpose is prohibited.

Patient safety should be a key factor in determining a treatment plan for pain management. When the provider prescribes opioids as part of the treatment plan, the provider must consider drug safety, efficacy and treatment goals for the patient. Safe opioid prescribing requires knowledge of the pharmacology of various opioid classes, and of potential drug interactions. Opioids are most likely to be successful in reducing pain and restoring function when they are combined with other pain management approaches such as physical therapy and psychological techniques.

When prescribing opioids for chronic pain, Oregon law requires practitioners to provide careful assessment and documentation of the medical condition causing pain as well as co-morbid medical and mental health conditions. Goals for treatment should be established with the patient before prescribing opioids. The provider's assessment, diagnosis and discussion must be documented in the patient record. The diagnosis, drugs used, goals, alternatives, and side effects must be included in a signed document demonstrating consent and understanding of the treatment plan and its risks. A sample document may be found here (</omb/OMBForms1/material-risk-notice.pdf>). In addition to the signed informed consent document, a written patient-provider agreement is recommended for patients requiring opioids for chronic pain.

## Terminal Illness

The OMB believes that physicians should make every effort to relieve the pain and suffering of their terminally ill patients. Patients nearing the end of their lives should receive sufficient opioid dosages to produce comfort. The physician should acknowledge that the natural dying process usually involves declining blood pressures, decreasing respirations and altered levels of consciousness. Opioids should not be withheld on the basis of physiologic parameters when patients continue to experience pain.

Some physicians express concerns that the use of opioids in these patients may hasten death through pneumonia or respiratory depression. For these reasons, at times physicians may have limited the use of opioids in dying patients out of fear that they may be investigated for inappropriate prescribing or allegations of euthanasia.

The OMB is concerned that such fear on the part of physicians may result in inadequate pain control and unnecessary suffering in terminally ill patients. The OMB encourages physicians to employ skillful and compassionate pain control for patients near the end of life and believes that relief from suffering remains the physician's primary obligation to these patients.

*- Adopted January 1993*

*- Amended April 1999*

*- Amended July 2004*

*- Amended April 2011*

*- Amended January 2013*

*- Amended April 2016*

# RHODE ISLAND



## Rhode Island Department of Health Safe Opioid Prescribing

When prescribing opioid medications for patients, it is important that both the healthcare provider and the patient be aware of their responsibilities in prescribing and using these medications. An opioid treatment agreement between patient and provider will clarify expectations.

These guidelines are not meant to replace individual provider judgment. The treating provider is in the best position to make treatment decisions for the individual patient.

When appropriate, providers will follow the guidelines below regarding the use and prescribing of opioid pain medications for chronic intermittent, non-cancer related pain:

### What we do

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- **Monitor** trends in opioid prescribing
- **Provide** advice and guidelines to healthcare providers to encourage responsible prescribing of pain medications

**Take a Medical History and Physical Examination:** This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance.

**Screening Brief Intervention and Referral to Treatment (SBIRT):** Consider screening all patients annually or upon entry to your practice to assess potential risk for substance abuse. Tools such as the [Opioid Risk Tool](#) (ORT) as well as [DAST 10 \(Drug and Alcohol Screening Tools 10\)](#) and several more tools available from [Substance Abuse and Mental Health Services Administration \(SAMHSA\)](#)

**Make a Treatment Plan:** The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The prescriber should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

**Prescribe Proportionately:** Only prescribe the amount of pain medicine reasonably expected to be needed. If you expect 3 days of severe pain prescribe only 3 days worth of medication. Acute Pain (< 5days) can often be managed without opioids.

**Start an Opioid trial:** Advise your patient to try the medication for a specified period of time and re-assess. Agree that if are not making reasonable progress, to consider stopping and trying a different approach.

**Electronically Prescribe Controlled Substances:** Make sure you upgrade your electronic health record system, get 2 identification tokens, and get approval from surescripts®. [MORE](#)

**Obtain Informed Consent:** The prescriber should discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative. This discussion should be documented and signed by the patient, guardian or authorized representative. [SAMPLE](#)

**Enter Into a Prescriber-Patient Agreement:** [The agreement](#) will help you and your patient share information about medications and comply with controlled substance regulations. [Violations of the agreement](#) should be discussed with your patient.

**Co-prescribe Naloxone:** If your patient is at-risk for overdose. [SAMPLE FORM](#)

**Monitor your patients opioid utilization:** Use the [Prescription Monitoring Program](#) before each appointment. [ENROLLLOGIN Positive Prescription Monitoring Reports should be reviewed with the patient](#). Additionally, it is important to conduct random urine drug screens as well as have patients bring back pill bottles to monitor supply remaining.

**Periodically Review Treatment:** The prescriber should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the prescriber's evaluation of progress toward treatment objectives. If the patient has not improved, the prescriber should assess the appropriateness of continued opioid treatment or trial of other modalities.

**Make Consultations:** The prescriber should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, prescribers should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

**Keep Accurate Records:** The prescriber should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

**Be Compliant with Controlled Substances Laws & Regulations:** To prescribe controlled substances, the prescriber must be licensed appropriately in Rhode Island, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions.

Addiction is a disease, chronic and relapsing. Patients with any chronic disease deserve appropriate treatment. There are [many places](#) to find treatment for addiction and substance abuse. [partial list](#).

# SOUTH CAROLINA

# South Carolina Board of Medical Examiners

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LLR-Board of Medical Examiners

Approved by the Board: July 2009 Board meeting

Service Area: Medical

Subject: Pain Management Guidelines

POLICY:

## Section I: Preamble

The State Board of Medical Examiners of S. C. recognizes that principles of quality medical practice dictate that the people of the State of South Carolina have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The State Board of Medical Examiners of S. C. is obligated under the laws of the State of South Carolina to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

## **Section II: Guidelines**

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

**Evaluation of the Patient** ♦ A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

**Treatment Plan** ♦ The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

**Informed Consent and Agreement for Treatment**◆The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

**Periodic Review**◆The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

**Consultation**◆The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients

**Medical Records**◆The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews

Records should remain current and be maintained in an accessible manner and readily available for review.

**Compliance With Controlled Substances Laws and Regulations**◆To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

**Section III: Definitions** For the purposes of these guidelines, the following terms are defined as follows:

**Acute Pain** ♦ Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

**Addiction** ♦ Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

**Chronic Pain** ♦ Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

**Pain** ♦ An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

**Physical Dependence** ♦ Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

**Pseudoaddiction** ♦ The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

**Substance Abuse** ♦ Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

**Tolerance** ♦ Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

TENNESSEE

# Tennessee Chronic Pain Guidelines

Clinical Practice Guidelines for  
Outpatient Management of  
Chronic Non-Malignant Pain





STATE OF TENNESSEE  
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH  
COMMISSIONER

BILL HASLAM  
GOVERNOR

September 24, 2014

Dear Friends and Colleagues:

I would like to thank the General Assembly for their leadership in addressing prescription drug abuse through Public Chapter 430 that required the development of treatment guidelines for chronic pain patient care. These guidelines represent the dedicated, important and indeed bold efforts of many in our state to identify the appropriate, necessary balance between relief of chronic pain and prevention of misuse, abuse, addiction and death. While the guidelines will evolve as the evidence, principles and judgment we employ every day as clinicians continues to develop, these guidelines provide rational approaches today to help address our state's ongoing challenges associated with prescription drugs.

More than a decade after we began to see a substantial increase in prescriptions and, even as some were finding relief and returning to function, others experienced misuse, suffering and untimely overdose death. While it was remarkable that 12 years ago the Legislature established the Controlled Substance Monitoring Database, our nation now clearly recognizes the epidemic of substance abuse and misuse driven by prescription opioids. Today, there are many more people, communities and organizations working passionately and creatively to make a positive difference.

As scientific and clinical knowledge increases and evolves, our journey to prevent prescription drug-related problems will move forward at a more brisk pace. We have made significant progress as a society and culture in accelerating our understanding the disease of addiction is not primarily a moral failing but a preventable and treatable medical condition.

We know treatment or exposure to these powerful drugs that stimulate our dopaminergic reward system can do both great good and great harm. As we gain a better understanding of how to best treat acute and chronic pain, as well as addiction, employing strategies tailored to individual patients and their historical and genomic profile of risk and protective factors, needs and preferences, we can be optimistic our epidemic will subside. As many know, this is not the first such epidemic in our nation's history. We have our best chance this time however, to make it the last.

I recommend these guidelines to you and I invite your participation and comment as they are refined in the months and years ahead. Thank you for your partnership as we work together to protect, promote and improve the health and prosperity of people in Tennessee.

Sincerely yours,

John J. Dreyzehner, MD, MPH, FACOEM  
Commissioner

JJD/DR/WM/VN/pll

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## **TENNESSEE CLINICAL PRACTICE GUIDELINES FOR OUTPATIENT MANAGEMENT OF CHRONIC NON-MALIGNANT PAIN**

The purpose of these guidelines is to define appropriate treatment of chronic pain, a common and often serious condition. We want to foster timely and appropriate treatment for pain, which improves both the ability to function and quality of life. These guidelines are intended to be used to support clinicians in their treatment of patients with chronic pain with particular reference to the prescribing of opioid medications. We want to avoid addiction and adverse outcomes. Optimal treatment of chronic pain, defined as pain lasting longer than 90 days, is an interdisciplinary process that includes many interventions which do not always involve opioid pain medications.

The method used to formulate these guidelines included a review of national expert panel recommendations and state practice guidelines, multiple listening sessions with clinicians in Tennessee, oversight by a multidisciplinary steering committee and recommendations from an advisory committee with strong representation by clinicians with specialty training in pain medicine. Draft clinical guidelines were also circulated to a broader group of professional associations within Tennessee, including but not limited to mental health and substance abuse and workers' compensation programs.

The importance of management of chronic pain is apparent by the following facts:

- In 2011, Tennessee had the second highest per capita prescription rate for opioids in the US.
- Unintentional overdose deaths increased more than 250% from 2001 to 2011, exceeding deaths due to motor vehicle accidents, homicide or suicide in 2010.
- The number of babies born dependent to drugs who suffered from Neonatal Abstinence Syndrome (NAS) grew ten-fold from 2001 to 2011.
- Worker's compensation programs have seen the number of people treated for substance abuse increase five-fold in ten years.
- In the midst of this substance abuse epidemic, chronic pain is likewise a significant public health problem. At least 116 million US adults—more than the number affected by heart disease, diabetes and cancer combined—suffer from common chronic pain conditions.
- Acute and chronic pain are among the most common reasons for physician visits, for taking medications and are major causes of work disability. Severe chronic pain affects physical and mental functioning, quality of life and productivity.

The long term goals of appropriate pain management are to improve symptoms, function and overall quality of life while minimizing adverse effects, addiction, overdose deaths and NAS. These guidelines can help providers reduce problems associated with prescription opiates while maintaining access to compassionate care and appropriate medications for patients living with chronic pain. These guidelines are organized into three sections and appendices contain additional tools and guidance.

***These guidelines are not applicable to end-of-life care, emergency room care or acute pain management. The guidelines apply to all healthcare providers. These guidelines would not apply to patients in a hospice program or in a palliative care setting with a life expectancy of six months or less. These guidelines do not apply to patients admitted to a hospital. These guidelines are not meant to dictate medical decision making. They are guidelines of generally accepted medical practice rather than absolutes. Providers still have flexibility to deal with exceptional cases. Occasional deviation from these guidelines for appropriate medical reasons is to be expected and documented.***

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# SECTION I:

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## Prior to Initiating Opioid Therapy for Chronic Non-Malignant Pain

# SECTION I: PRIOR TO INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

## A. Key Principles Prior to Initiating Opioid Therapy

1. A patient having been prescribed opioids by a previous provider is not, in and of itself, a reason to continue opioids.
2. Reasonable non-opioid treatments should be tried before opioids are initiated. Opioids should be initiated only after other reasonable, appropriate and available treatments for the pain condition have been considered.
3. All newly pregnant women should have a urine drug test administered by the appropriate women's health provider.
4. The provider should discuss a birth control plan to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity when opioids are initiated.
5. The patient's medical history, physical examination, laboratory tests, imaging results, electro-physiologic testing, and other elements supporting the plan of care, should be documented in the medical record prior to initiating opioid therapy.
6. Chronic pain shall not be treated by the use of controlled substances through telemedicine.

## B. Initial Evaluation: Steps Prior to Initiating Trial of Opioid Therapy

1. A specific evaluation and history of the patient's pain condition should be obtained. The examination should include the nature and intensity of the pain, past and current treatments for pain, any co-occurring disorders and the effect of the pain on the patient's life functioning, including but not limited to work, relationships, recreation and sleep.
2. The presence of important co-morbid medical conditions should be assessed and considered when deciding whether to initiate opioids. This includes age of the patient and medical conditions such as chronic obstructive pulmonary disease, sleep apnea, diabetes or congestive heart failure.
3. An initial, condition-appropriate physical examination of the patient should be conducted. A systems review shall be conducted as well.
4. The possible presence of co-occurring mental health disorders should be considered when deciding whether to initiate a trial of opioids. Screening should occur for disorders such as depression, anxiety and current or past substance abuse and, if present, these should be addressed in the creation of a treatment plan **(See Mental Health Appendix)**.
5. A review of prior records directly related to the patient's chronic pain condition is encouraged before opioids are prescribed.
6. Women of child-bearing age who have reproductive capacity should be asked about the possibility of pregnancy at each visit. For women who wish to avoid unintended pregnancy, use of long-acting reversible contraceptives should be discussed, or referral to appropriate high-risk obstetrician made **(See Women of Child Bearing Age Appendix and Pregnant Women Appendix)**.

## SECTION I: PRIOR TO INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

### C. Establishing a Diagnosis

There shall be the establishment of a current diagnosis that justifies a need for opioid medications.

### D. Assessment of Risk for Abuse

1. The prescriber shall assess the patient's risk for misuse, abuse, diversion and addiction using a validated risk assessment tool prior to initiating opioid therapy. **(See Risk Assessment Tools Appendix)**
2. The prescriber should obtain a Urine Drug Test (UDT) (or a comparable test on oral fluids) prior to initiating opioid therapy. **(See Urine Drug Testing Appendix)**
3. Based on the combined information of the validated risk assessment results, the Controlled Substances Monitoring Database (CSMD) results and the UDT results and past records, an initial assessment should be made about a patient's risk of misuse, abuse or diversion of medications. The prescribing of opioids, if medically indicated, shall take this risk assessment information into account in the prescribing of opioids and the patient's treatment plan. **(See CSMD Appendix)**

### E. Goals for Treatment

1. The primary goal of treatment should be clinically significant improvement in function.
2. A treatment plan is expected to include other treatments or modalities beyond opioids, both non-pharmacological and pharmacological. The provider should make reasonable attempts to implement this treatment plan, allowing for barriers such as finances, accessibility and resource distribution.
3. The patient should be counseled that the goal of chronic opioid therapy is to increase function and reduce pain, not to eliminate pain. Documentation of this discussion shall be included in the medical record.

## SECTION II:

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# Initiating Opioid Therapy for Chronic Non-Malignant Pain

## SECTION II: INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

### A. Key Principles When Considering Prescribing Opioids.

1. A patient should be prescribed a maximum of four doses of a short-acting opioid per day. If a provider deems it necessary to do otherwise then he/she shall clearly document the medical reasons for this decision.
2. Prescribers who are not pain medicine specialists shall not prescribe methadone for a chronic pain condition. **(See Pain Medicine Specialist Appendix)**
3. Prescribers shall not prescribe buprenorphine in the form of oral or sublingual buprenorphine for chronic pain condition.
4. Benzodiazepines should be generally avoided in combination with chronic opioid therapy. When the opioid dose reaches 120mg MEDD and the benzodiazepines are being used for mental health purposes, the provider shall refer to a mental health professional to assess necessity of benzodiazepine medication.
5. Buprenorphine/naloxone combinations shall be avoided for the treatment of chronic pain.
6. Should treatment deviate from recommended guidelines, the reasons shall be documented in the medical record.

### B. Upon Initiating Opioid Therapy

1. The initiation of opioids should be presented to the patient as a therapeutic trial.
2. When initiating opioid therapy, the lowest dose of opioids should be given to an opioid-naïve patient and then titrated to effect.
3. Informed consent for the use of opioids in treating pain must be obtained prior to initiating treatment. Informed consent documents typically cover: potential risks and anticipated benefits of opioid therapy, potential side effects, likelihood of physical dependence, risk of over-sedation, pregnancy, risk of impaired motor skills, risk of addiction and death. **(See Sample Informed Consent Appendix)**
4. A written treatment agreement should be used with the patient at the time opioids are first prescribed for chronic pain. Treatment agreements typically cover reasons, for which opioids may be discontinued, the practice policy on early refills, policy on lost prescriptions or medications, expectation for safe storage of medications, use of one pharmacy and expectations about periodic drug testing. The treatment agreement shall include an expectation that a female patient will tell the provider if she wishes to avoid unintended pregnancy and if she becomes pregnant. **(See Sample Patient Agreement Appendix)**
5. As these new guidelines are implemented, practitioners may provide a bridge of opioids for up to six months while the assessment process is carried out. During this time a patient may be continued on a trial of opioids without a fully completed assessment. No provider is obligated to continue opioid therapy that has been initiated by another provider. If the initial evaluation of the patient does not support the need for opioids, a discussion about risks and possible treatment of withdrawal shall be included in the documentation of clinical reasoning for opioid cessation.

## SECTION II: INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

6. Providers must continually monitor the patient for signs of abuse, misuse or diversion. An unannounced UDT (or a comparable oral fluids test) should be done twice a year at a minimum. **(See Urine Drug Testing Appendix)**

### C. Women's Health

1. The provider should discuss a method to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity before opioids are initiated.
2. The practitioner should obtain a signature indicating that any woman who wishes to become or is at risk to become pregnant has been educated about the risks and benefits of opioid treatment during her pregnancy.
3. Women of child-bearing age who have reproductive capacity shall undergo a pregnancy test prior to the initiation of opioids.
4. Women of child-bearing age who have reproductive capacity should be asked about the possibility of pregnancy at each visit. For women who wish to avoid unintended pregnancy, use of long acting reversible contraceptives should be discussed, or referral to appropriate high risk obstetrician made. **(See Women of Child Bearing Age Appendix and Pregnant Women Appendix)**

## **SECTION III:**

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### **Ongoing Opioid Therapy for Chronic Non-Malignant Pain**

## SECTION III: ONGOING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

### A. Key Principles

1. All chronic opioid therapy should be handled by a single provider or practice and all prescriptions should be filled in a single pharmacy, unless the provider is informed and agrees that the patient can go to another pharmacy for a specific reason.
2. Opioids should be used at the lowest effective dose.
3. A provider should not use more than one short-acting opiate concurrently. If a provider deems it necessary to do so then the medical reasons shall be clearly documented.

Documentation of the discussion of the five A's (analgesia, activities of daily living, adverse side effects, aberrant drug-taking behaviors and affect) at initiation of chronic opioid therapy and at follow up visits shall be included in the medical record

### B. Ongoing Therapy

1. Patients on opioid doses of 120mg MEDD or greater should be referred to a pain specialist for a consultation and/or management. If a provider cannot make the required consultation as outlined above, then he/she shall clearly document why not.
2. Providers must continually monitor the patient for signs of abuse, misuse or diversion. A UDT (or a comparable oral fluids screen or test) should be done twice a year at a minimum. **(See Urine Drug Testing Appendices)**
3. Based on the combined information of patient behavior, collateral information, the CSMD results, the UDT (or OFT) results and past records, an ongoing risk assessment should be made about a patient's risk of misuse, abuse or diversion of medications. The prescribing of opioids, if medically indicated, shall take this risk assessment information into account on an ongoing basis. Adjustments to the patient's treatment should occur in a timely manner based on this information
4. Emergency department physicians should keep the specialist and the primary care provider informed about changes in a patient's condition and any emergent incidents or conditions.
5. Opioids are to be discontinued when the risks, side effects, lack of efficacy or presence of medication or aberrant behavior outweigh the benefits. Opioids sometimes have to be discontinued due to financial or third-party coverage issues. A taper of opioids may or may not be indicated, depending on the clinical situation. **(see Tapering Protocol Appendix)**
6. Appropriate documentation of CSMD query should be included in the medical record. **(see CSMD Appendix)**

### C. Women's Health

1. The provider should discuss a method to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity when opioids are initiated. **(See Women of Child Bearing Age Appendix and Pregnant Women Appendix)**
2. The provider shall advise every woman of child-bearing potential on opioids that she be on a method to prevent unintended pregnancy specifically considering long acting contraceptive methods.
3. The treatment agreement shall include an expectation that a female patient will tell the

### SECTION III: ONGOING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

provider if she becomes pregnant or plans to become pregnant.

4. If she plans to become or becomes pregnant, she shall be referred to a high risk obstetrician.
5. When a UDT is performed, results must be documented in the medical record.

*The appendices that follow contain specific references from the guidelines as well as other pertinent information about the resources available in the State of Tennessee concerning substance abuse, the efforts to curb overdose death and other support systems centered around these topics.*

# APPENDICES

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## APPENDICES

### PAIN MEDICINE SPECIALIST

Pain Medicine is the medical specialty dedicated to the prevention, evaluation and treatment of people with chronic pain. While most Physicians, Advanced Practice Nurses, and Physicians Assistants have training and experience in the management of chronic pain, Pain Medicine Specialists have fellowship training from ABMS, AOA, or additional training in pain medicine sufficient to obtain ABPM diplomat status. Current protocols regarding the delineation of prescribing authority to and supervision of Advanced Practice Nurses with certificate of fitness for prescribing and Physicians Assistants for prescribing to treat chronic pain continue to apply. Pain Medicine Specialists deal with patients being treated with more than 120 milligram morphine equivalents daily dose **because they are at least eleven times more likely to suffer an adverse effect including overdose death.**

The American Board of Medical Specialties (ABMS) and the American Osteopathic Association (AOA) are the primary physician certification organizations in the United States. The ABMS and the AOA assist 24 boards in granting certificates in 124 specialty and subspecialty areas. The AOA assists 18 boards in granting certificates in 57 specialty and subspecialty areas. The ABMS certifies pain medicine fellowship programs that result in subspecialty certification in Pain Medicine are under the Boards of Anesthesiology, Physical Medicine & Rehabilitation, Psychiatry and Neurology.

The American Board of Pain Medicine (ABPM) is not affiliated with the ABMS or the AOA and does not oversee fellowship training programs. The ABPM administers practice-related examination for Pain Medicine to qualified candidates who have achieved specified requirements in graduate medical education, licensure and controlled substances authorization, ABMS board certification (not necessarily in pain management), practice experience, continuing medical education, and adherence to ethical and professional standards. Diplomats of ABPM have certification in Pain Medicine.

### **The State of Tennessee sets forth two tiers for the treatment of pain management:**

#### **Tier 1 Non-Pain Medicine Specialist:**

1. All providers who wish to treat patients requiring less than 120 milligram morphine equivalent daily dose (MEDD) shall:
  - a. Hold a valid Tennessee license issued by their respective board through the Department of Health and a current DEA certification.
  - b. Attend Continuing Education pertinent to pain management as directed by their governing board.
  - c. We recommend, but do not require, that providers have completed three years of residency training and be ABMS or AOA board eligible or board certified.
2. All providers wishing to treat patients requiring 120 MEDD or more shall consult with a Pain Medicine Specialist.
3. Providers treating patients with ongoing opioid therapy (prescribing of 120MEDD for more than six months in any calendar year) shall obtain at least one annual consultation with a Pain Medicine Specialist. Patients with more complicated cases may require more frequent consultation.

## APPENDICES

### Tier 2 Pain Medicine Specialists:

A Pain Medicine Specialist shall hold:

1. ABMS or AOA subspecialty certification in Pain Medicine under the boards of, Anesthesia, Neurology, Psychiatry and Physical Medicine & Rehabilitation and:
  - a. An unencumbered Tennessee license and,
  - b. The minimum number of CME hours in pain management to satisfy retention of ABMS or AOA certification.
  - c. Any exceptions to this must be approved by the respective regulatory board; OR
2. ABPM diplomate status by 7/1/2016 and:
  - a. Unencumbered Tennessee license and,
  - b. The minimum number of CME hours in pain management to satisfy retention of ABPM diplomat status.
  - c. Any exceptions to this must be approved by the respective health related licensing and regulatory board.
  - d. Current pain medicine specialists who are qualified to take the ABPM exam may continue to practice as a pain medicine specialist until 7/1/16, when diplomate status will be required.

## APPENDICES

### MENTAL HEALTH ASSESSMENT TOOLS

There are several validated mental health screening and assessment tools available for use by physicians and healthcare professionals. Below are some names and links to these.

1. Patient Health Questionnaire – 2 (PHQ-2). This is a simple two-item screening tool. If it is positive on either item, the clinician should offer another more detailed questionnaire to better assess the presence or absence of a depressive disorder. One link to this screening tool: [http://www.cqaimh.org/pdf/tool\\_phq2.pdf](http://www.cqaimh.org/pdf/tool_phq2.pdf).
2. Patient Health Questionnaire – 9 (PHQ-9). This nine-item tool screens for a depressive disorder, and often is used as a follow-up to the PHQ-2. It's easy to score and use. Here's one link to a copy: <http://www.integration.samhsa.gov/images/res/PHQ%20-%20Questions.pdf>.
3. Zung Self-Rating Depression Scale (Zung). This is a 20-item written questionnaire. One copy is at <http://healthnet.umassmed.edu/mhealth/ZungSelfRatedDepressionScale.pdf>.
4. Hamilton Depression Rating Scale (Ham-D). This is 21-item screening questionnaire. Cutoff scores is <7 is normal. <http://img.medscape.com/pi/emed/ckb/psychiatry/79926-1889862-1859039-2124408.pdf>
5. A fairly comprehensive article on screening for depression in medical settings is <http://emedicine.medscape.com/article/1859039-overview>. This article reviews several scales.
6. Generalized Anxiety Disorder 7-item Scale (GAD-7). This is a 7-item scale to screen for generalized anxiety. One link is: <http://www.integration.samhsa.gov/clinical-practice/GAD708.19.08Cartwright.pdf>.
7. Primary Care PTSD (PC-PTSD). This is a four item screening test for Post-Traumatic Stress Disorder. One link is: <http://www.integration.samhsa.gov/clinical-practice/PC-PTSD.pdf>.
8. One excellent source for a number of screening tools for various mental health disorders is from the Substance Abuse and Mental Health Services Administration (SAMHSA), which is a branch of the U.S. Department of Health and Human Services. A link to a site that lists a number of tools is: <http://www.integration.samhsa.gov/clinical-practice/screening-tools>.
9. CAGE Questionnaire for Drug Use
  - a. Have you ever felt you ought to cut down on your drinking or drug use?
  - b. Have people annoyed you by criticizing your drinking or drug use?
  - c. Have you felt bad or guilty about your drinking or drug use?
  - d. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover (eye-opener)?

Scoring: Item responses on the CAGE questions are scored 0 for "no" and 1 for "yes" answers, with a higher score being an indication of alcohol problems. A total score of two or greater is considered clinically significant.

## APPENDICES

### MEDICATION ASSISTED TREATMENT PROGRAM

Methadone has been used in the treatment of opioid dependence for over 30 years. It has been found to be both effective and safe in long term administration. Medication Assisted Treatment (MAT) is the continual administering and dispensing of Methadone and other federally approved medications at relatively stable dosage levels, in conjunction with the provision of appropriate social, clinical, and medical services for an individual who is dependent on an opiate or morphine-like substance. An adequate individualized daily dose of methadone eliminates drug craving, prevents the onset of withdrawal, and blocks (through opiate cross-tolerance) the effects typical of other opiates, such as heroin or morphine. Efficacy of treatment is based on elimination of or reduction in illicit/inappropriate drug use, elimination or marked reduction in illegal activities, improved employment, pro-social behavior and improved general health. Patients taking stable doses of methadone are able to drive and operate heavy machinery in the same manner as individuals not taking methadone. Also methadone can be utilized when patients are pregnant (it is also monitored as needed and/or during every trimester). MAT is designed for an unknown and possibly indefinite period, according to the need of the individual. The only appropriate measure of time in treatment is how long it takes the individual to overcome a life of addiction.

All programmatic decisions regarding eligibility and admission criteria for MAT conform to regulations from the Dept. of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration (SAMHSA), and Tn. State Methadone Authority. Clinics offering MAT are accredited through CARF (Commission for Accreditation of Rehabilitation Facilities) or similar bodies.

Most patients are self-referred and must agree to coordination of care with their primary care physician and/or mental health practitioner. Dual enrollment in pain management is inappropriate and not allowed. Patients are subject to random bottle checks. Initially, all patients are required to visit the clinic daily for dosing. As patients establish a reliable track record (counseling, licit drug screens, absence of behavioral problems/criminal activity, gainful vocational, educational, or employment activity, safeguarding of medication), they gradually earn "take home" medication for self-administration. The most trustworthy patients come to the clinic once every 28 days. Typical methadone doses range from 60-120 mg daily.

Longstanding opiate abusers with high tolerance often do best staying on MAT with the supportive environment of the clinic staff. Younger patients or those with shorter abuse histories are more likely to be able to wean off methadone entirely.

## APPENDICES

### WOMEN'S ISSUES: WOMEN OF CHILD BEARING AGE

All women with reproductive capacity receiving a prescription for an opiate shall be educated about the risks of opiate use during pregnancy including the risk of physical dependence and addiction in the woman, the potential of physical dependence and withdrawal in the newborn, and possible long term consequences to the child.

1. Upon initiation of opioid therapy, the provider shall recommend reliable contraception such as long term reversible contraceptives and appropriate referrals should be made.
2. Any woman with reproductive capacity, who is presently under physician care for chronic pain management or medical replacement therapy, shall be counseled on the importance of reliable contraception such as long term reversible contraceptives. Appropriate referrals should be made.
3. The treatment plan shall include an expectation that a female patient will notify the provider if she becomes, or plans to become, pregnant.
4. The possibility of pregnancy should be assessed prior to initiation and continuation of any opioid or opioid replacement therapy. This risk should be assessed at each visit and prior to any refill for long-term therapies. A pregnancy test should be performed if there is any possibility of pregnancy. This should be documented in the medical record.
5. A woman who desires to become pregnant and is under physician treatment for chronic pain management and/or opioid replacement therapy shall be counseled on the potential risks of Intra-Uterine Drug Exposure. A referral for prenatal counseling should be made. Alternative treatment modalities should be discussed. Informed consent should be obtained prior to continuation of opioid or opioid replacement therapy.
6. Education shall include the potential risks of stopping her medications on her own during her pregnancy which include: the risk of relapse, risk of preterm delivery, intrauterine withdrawal, fetal distress, and fetal demise.
7. A woman on opioid therapy who becomes pregnant or desires to become pregnant shall be referred to or consult with an Obstetrician and appropriate Pain Management Specialist or Medical Replacement Treatment program.

## APPENDICES

### PREGNANT WOMEN

1. The OB and medical treatment physician should work together to encourage compliance with both chronic pain management or medical replacement therapy plan, and prenatal care.
2. A risk assessment, UDT, and CSMD check should be performed before initiating any opiate or benzodiazepine during pregnancy.
3. A UDT should be performed at intake to prenatal care. If positive, the mother should be referred to appropriate chronic pain management or replacement therapy specialists. The risks of Intra-Uterine Drug Exposure should be discussed, and documented, and random UDT should be performed during the prenatal course.
4. If a woman has a positive UDT on initial prenatal visit, A UDT should be performed upon admission for delivery to help identify the infant at risk for NAS.

# APPENDICES

## RISK ASSESSMENT TOOLS

There are several validated risk assessment tools available to pain clinicians. Find below some information on the most commonly used tools and links so that they can be obtained. Some tools are copyrighted and some are not, and practitioners should adhere to legal guidelines in making and obtaining copies for their use.

1. BRI (Brief Risk Interview). This is a short (5-10 minutes) clinical interview that is a validated risk assessment tool (Jones & Moore, 2013). Questions are asked about such topics as past misuse of opioid medications, presence of mental health disorders, personal history of substance abuse and family history of substance abuse. It also incorporates information from UDT's, past medical records and the CSMD. It classifies patients into risk categories of Low, Low Medium, Medium, Medium High, High and Very High. Contact Ted Jones, Ph.D. at [tedwjones@comcast.net](mailto:tedwjones@comcast.net) about copies and use.
2. DIRE (Diagnosis, Intractability, Risk, Efficacy score). This is a staff/interviewer rating scale that uses information about the patient's diagnosis, engagement in treatment and psychiatric issues (Belgrade, Schamber and Lindgren, 2007). The numerical score categorizes patients into the categories of "not a suitable candidate for long-term opioid analgesia," and "good candidate for long-term opioid analgesia". <http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Documents/D.I.R.E.%20Score.pdf>
3. ORT (Opioid Risk Tool). This is a brief ten-item patient-completed written questionnaire (Webster & Webster, 2005). It may be the most widely used risk assessment tool in the field. It asks for information such as personal and family history of substance abuse and psychiatric issues. It classifies patients into Low, Medium and High risk categories.
4. PMQ (Pain Medication Questionnaire). This is a 26-item patient-completed written risk questionnaire (Adams, Gatchel, Robinson, et. al., 2004). One study has shown that it is the best overall written risk assessment tool available.<sup>5</sup> Questions include such topics as opinions about pain medication and pain treatment, obtaining pain medication, and past medication-aberrant behavior. A few items are reverse scored, making it just slightly more difficult for staff to score. It classifies patients into Low, Medium and High categories of risk. Here is one link to a copy: <http://www.opioidrisk.com/node/507>.
5. SOAPP (Screener and Opioid Assessment for Patients with Pain). This is a 24-item patient-completed written risk assessment questionnaire (Butler, Budman, Fernandez, et. al., 2004). One study has shown that this questionnaire has the best sensitivity of any patient-completed questionnaire (best at identifying those patients which later engage in medication aberrant behavior). Items use a five-point rating scale and ask about such topics as impulsivity, cigarette smoking, overtaking medication and past substance abuse. It classifies patients into Low and High risk (no Medium category). One link to a copy is: <http://www.painedu.org/soap.asp>.
6. SOAPP-R (Screener and Opioid Assessment for Patients with Pain - Revised). This 24-item patient-completed questionnaire is a revision of the SOAPP (Butler, Fernandez, Benoit, et. al., 2008). The SOAPP-R is a widely used risk assessment tool. It uses a five-point rating scale in asking questions about such topics as impulsivity, legal problems, past substance abuse and past sexual abuse. It classifies patients in risk categories of Low and High risk (while it refers to a Medium category in the SOAPP-R manual, there has been no validation on the use of the Medium category). One link to a copy is: <http://www.opioidrisk.com/node/6100>

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## CSMD: CONTROLLED SUBSTANCE MONITORING DATABASE

### Background

The Tennessee Controlled Substance Monitoring Database (CSMD) is a prescription monitoring program designed to provide healthcare practitioners with a comprehensive view of a patient's controlled substance prescription history. The purpose of the CSMD is to assist in research, statistical analysis, criminal investigations, enforcement of state or federal laws involving controlled substances, and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse, by collecting and maintaining data regarding all controlled substances dispensed in this state.

### Access to Information

Information sent to, contained in, and reported from the database in any format is confidential, not public record and not subject to subpoena from any court and password access is made available only as provided for in Tennessee Code Annotated § 53-10-308 and to the following persons:

- personnel of the committee specifically assigned to conduct analysis or research;
- authorized committee, board, or department of health personnel or any designee appointed by the committee engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment;
- a prescriber of controlled substances to the extent the information relates specifically to a current or bona fide prospective patient of the prescriber, to whom the prescriber has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance; or a prescriber conducting medication history reviews who is actively involved in the care of the patient; a prescriber or supervising physician of the prescriber conducting a review of all medications dispensed by prescription attributed to that prescriber;
- a dispenser or pharmacist of controlled substances to the extent the information relates specifically to a current or a bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance; or a dispenser not authorized to dispense controlled substances conducting drug utilization or medication history reviews who is actively involved in the care of the patient;
- a county medical examiner appointed pursuant to T.C.A. § 38-7-104 when acting in an official capacity as established in § 38-7-109; provided, any access to information from the database shall be subject to the confidentiality provisions of this part except where information obtained from the database is appropriately included in any official report of the county medical examiners, toxicological reports or autopsy reports issued by the county medical examiner under T.C.A. § 38-7-110(c);
- personnel of the following entities actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities related directly to TennCare:
  - o the Office of Inspector General;
  - o the Medicaid Fraud Control Unit;

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- o the Bureau of TennCare's chief medical officer, associate chief medical directors, director of quality oversight, and associate director of pharmacy.
- a quality improvement committee as defined in § 68-11-272 of a hospital licensed under title 68 or title 33, as part of the committee's confidential and privileged activities under § 68-11-272(b)(4) with respect to the evaluation, supervision or discipline of a healthcare provider employed by the hospital or any of its affiliates or subsidiaries, who is known or suspected by the hospital's administrator to be prescribing controlled substances for the prescriber's personal use;
- a healthcare practitioner extender, who is acting under the direction and supervision of a prescriber or dispenser, and only to the extent the information relates specifically to a current or bona fide prospective patient to whom the prescriber or dispenser has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance;
- the following personnel of the department of mental health and substance abuse services actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities shall have access to the database for controlled substances prescription information for specific patients:
  - o The chief pharmacist;
  - o The state opioid treatment authority (SOTA) or SOTA designee; and
  - o The medical director.
  - o Aggregate controlled substances prescribing information from the database may be provided upon request by the following personnel of the department of mental health and substance abuse services, who are actively engaged in analysis of controlled substances prescription information as provided in this subsection (j), and may be shared with other personnel of the department of mental health and substance abuse services as needed to fulfill assigned duties and responsibilities:
    - The chief pharmacist;
    - The SOTA; or
    - The medical director.

Law enforcement personnel engaged in an official investigation or enforcement of state or federal laws involving controlled substances are authorized to request information from the CSMD under the guidelines outlined in T.C.A. § 53-10-306. The CSMD committee also examines database information to identify unusual patterns of prescribing and dispensing, taking into account a practitioner's specialty. The committee is authorized to refer outlying pharmacies to the chief board of pharmacy investigator and outlying prescribers to the Division of Health Related Boards' Bureau of Investigations.

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## CSMD DATA

The CSMD contains prescription information from all dispensers of controlled substances in Tennessee and also those dispensers who ship to a patient residing in Tennessee. This includes mail-order pharmacies and some Veteran's Affairs pharmacies as well. The CSMD collects and maintains dispensing data regarding all controlled substances in Schedules II, III and IV, and Schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse. Data is to be submitted at least once every seven (7) days for all the controlled substances dispensed during the preceding seven-day period. The following information is required to be submitted for each dispensing in ASAP 2009 (4.1) format:

- Prescriber DEA number;
- Dispensing date;
- Patient identifier,
- Controlled substance NDC number;
- Quantity dispensed;
- Strength of controlled substance;
- Estimated day supply;
- Dispenser DEA number;
- Date the prescription was written;
- Whether the prescription was new or a refill;
- Source of payment.

All data in the CSMD is reported as submitted to the data collection website by the dispenser. Therefore, if there are any questions about the data a practitioner should contact the dispenser identified within the report. The dispenser can, in turn, correct any errant information by coordinating with the state's data collection vendor. Neither the data collection vendor nor the Department of Health can edit prescription information found in the CSMD.

## Registration

All prescribers and dispensers of controlled substances in Tennessee must register for access to the CSMD. Healthcare practitioners wishing to register with the CSMD to access prescription information are required to navigate to [www.TNCSMD.com](http://www.TNCSMD.com) and choose the "register" link. A registration form will appear requesting information used to validate a healthcare provider's statutory authority to access CSMD data. A username and password will be sent to the approved registrant after validation and processing by CSMD administration. All passwords are case-sensitive, must be at least eight characters long and must contain an upper and lowercase letter, at least one number and one special character.

A healthcare provider may also choose to allow licensed and up to two unlicensed extenders per practice location to register with the CSMD in order to retrieve prescription information on the prescriber or dispenser's behalf. The extender should navigate to [www.TNCSMD.com](http://www.TNCSMD.com) and register for a separate account. In addition to supplying self-identifying information, the extender must provide information which identifies the supervisor permitting access to the CSMD. After validation by CSMD administrative staff, the supervisor must login to his/her account to approve the registrant as their extender. Once this process is complete, the extender may access CSMD

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information. All access by any user leaves an audit trail that can be monitored and accessed as needed. A supervisor may revoke CSMD access of their extender at any time if necessary.

Law enforcement personnel engaged in an official investigation or enforcement of state or federal laws involving controlled substances wishing to request information must follow a distinct process outlined in T.C.A. § 53-10-306 (a) (6) in order to request information from CSMD administration.

### CSMD Reports

#### Patient Report

A patient's CSMD report contains a variety of information related to the prescriber or dispenser of controlled substances. After entering the search criteria, a box of potential patient matches appears to consider incorporating into the report. Please note that many patients may have a similar name or date of birth as another patient in the CSMD and it is possible for erroneous information to be incorporated into the patient report if inappropriate patients are selected during this process.

Once the report is generated, a CSMD user will see a list of all patients incorporated into the report along with address information. The user will also see a list of all prescriptions attributed to the selected patient(s) in reverse chronologic order. On the right side of the first page is an estimated morphine equivalent dose that the patient is currently taking. For further explanation of the morphine equivalent dose, see (Morphine Equivalent Dose Appendix.) At the end of the report there is a listing of all prescribers and dispensers associated with the patient's selected prescription history, as well as additional information used to calculate the morphine equivalent dose.

#### Prescriber Self-Lookup

A prescriber can utilize the prescriber self-lookup report for multiple purposes. The report is useful for identifying potential prescription fraud, i.e. a stolen prescription pad or phoned-in prescriptions. It is also a useful snapshot of a prescriber's patient population and the prescriptions attributed to the prescriber. All data in the CSMD is reported as submitted to the data collection website by the dispenser. Therefore, if there are any questions about the data a practitioner should contact the dispenser identified within the report. The dispenser can, in turn, correct any errant information by coordinating with the state's data collection vendor. Neither the data collection vendor nor the Department of Health can edit prescription information found in the CSMD.

#### Future Enhancements

The CSMD Committee and Department of Health are committed to utilizing the CSMD to protect patient health and prevent prescription drug abuse and diversion. As resources become available, enhancements will be incorporated into the CMSD to further this mission. Enhancements such as real-time reporting by dispensers and incorporation of the CSMD into electronic health records are being investigated as well as further sharing of data between states as laws allow. Any suggested improvements can be sent to [csmd.admin@tn.gov](mailto:csmd.admin@tn.gov) for consideration.

#### Operational and Legal Resources

The statute governing the operation of the CSMD is found under T.C.A. § 53-10 Part 3 and the supporting rules are 1140-11. Current Federal Regulations (42 CFR Part II) protect the confidentiality of patients in a federally recognized substance abuse treatment facility and thus their dispensed medications are not included in the CSMD. The statute making doctor shopping illegal is found under T.C.A. § 53-11-402 and § 71-5-2601. The statute requiring reporting of a doctor shopper to law enforcement can be found at T.C.A. § 53-11-309.

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A form to report a potential doctor shopper to law enforcement is available at:  
<http://health.state.tn.us/boards/Controlledsubstance/PDFs/PH-4152.pdf>.

Please send the form to your local law enforcement or contact the Tennessee Meth and Pharmaceutical Task Force at 423-752-1479 to obtain the appropriate fax number.

Additional information about the CSMD can be obtained at:  
<http://health.state.tn.us/Boards/ControlledSubstance/index.shtml>

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### SAMPLE INFORMED CONSENT: Controlled Substance Agreement

Please read the information below carefully and ask your provider if you have any questions relating to the medication prescribed to you.

#### Using Controlled Medications to Treat Pain

- a. These medications are used to treat moderate-to-severe pain of any type, and to treat anxiety and stress associated with moderate-to-severe pain.
- b. These medications are best understood as potentially effective tools that can help reduce pain, improve function, and improve quality of life
- c. Using these medications requires that both the physician and patient work together in a responsible way to ensure the best outcome, lowest side effects, and least complications

#### How Do Opioids work?

- a. Opioid medications work at the injury site, the spinal cord, and the brain
- b. They dampen pain, but do not treat the underlying injury
- c. They may help to prevent acute pain from becoming persistent chronic pain
- d. These medications may work differently on different people because of a number of factors.
- e. Side effects and complications will also individually vary

#### How do Benzodiazepines work?

- a. The benzodiazepines are a class of drugs with varying properties, which act by slowing down the central nervous system.
- b. Benzodiazepines are useful in treating anxiety, insomnia, agitation, seizures, and muscle spasms. While Benzodiazepines do not treat acute or chronic pain, they are taken by patients with pain for other issues (such as anxiety or muscle spasms).
- c. These medications may work differently on different people because of a number of factors.
- d. Side effects and complications will also individually vary

#### What to Expect When You Take Controlled Medications for Pain and Related Conditions

- a. Pain relief
- b. Reduction of anxiety and stress caused by pain
- c. Side effects

#### What Should Not Be Expected From Treatment with Controlled Medications

- a. Cure of the underlying injury
- b. Total elimination of pain, anxiety, and stress
- c. Loss of ability to feel other physical pain

#### Negative Effects of Controlled Medications Vary in Different People

##### 1. Opioid Side effects

- a. Common effects include: Constipation, dry mouth, sweating, nausea, drowsiness, euphoria, forgetfulness, difficulty urinating, and itching

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- b. Uncommon effects include: Confusion, hallucinations, shortness of breath, depression, lack of motivation
2. Benzodiazepines Side effects
  - a. The most common side effects include: Clumsiness or unsteadiness, dizziness or lightheadedness and drowsiness; slurred speech
  - b. Less common side effects include: Anxiety; confusion (may be more common in the elderly); fast, pounding, or irregular heartbeat; mental depression; abdominal or stomach cramps or pain; blurred vision or other changes in vision; changes in sexual desire or ability; constipation; diarrhea; dryness of mouth or increased thirst; false sense of well-being; headache; increased bronchial secretions or watering of mouth; muscle spasm; nausea or vomiting; problems with urination; trembling or shaking; unusual tiredness or weakness
3. Physical dependency
  - a. Opioid medications will cause a physical dependency marked by abstinence syndrome when they are stopped abruptly. If these medications are stopped or rapidly decreased the patient will experience chills, goose bumps, profuse sweating, increased pain, irritability, anxiety, agitation, and diarrhea. The medicines will not cause these symptoms if taken as prescribed and any decision to stop these medications should be done under the supervision of your physician in a slow downward taper.
  - b. Benzodiazepines may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses. Some signs of dependence on benzodiazepines are: A strong desire or need to continue taking the medicine; a need to increase the dose to receive the effects of the medicine. Withdrawal effects occurring; for example, irritability, nervousness, trouble in sleeping, abdominal or stomach cramps, trembling or shaking.
4. Misuse of medications: Addiction

This is a psychological condition of use of a substance despite self-harm. Between six and ten percent of the population of the United States have problems with substance abuse and addiction. Controlled medications are likely to activate addictive behavior in this group of people
5. Diversion:

It is illegal to share your controlled medications with other people. It is illegal to provide false information to a prescriber in an attempt to obtain controlled medication. It is illegal to doctor shop, or visit multiple doctors in attempt to obtain controlled medications. Federal and state laws exist to address diversion problems. It is critical that you safeguard your controlled medications and use them only as prescribed by your doctor.
6. Driving

Studies of patients with chronic pain demonstrate improved driving skills when taking certain controlled medications, but individuals may have problems driving and need to realistically assess their own skills, as well as listen to others who drive with them to determine if they should be driving while taking these medications. You should consult the State Department of Transportation if you have questions about driving and taking controlled medications. This is especially important if your work involves driving, making

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important decisions that affect others, etc.

### Common Sense Rules for Using Controlled Medications

- a. Follow your doctor's recommendations
- b. Do not take more or less pills than prescribed without discussing this first with your physician and receiving permission to do so
- c. Do not share medications with family or friends
- d. Do not take medications from family or friends
- e. Do not stop these medications abruptly. Dose reductions need to be discussed and cleared by your physician. This is important no matter which controlled medication you take.
- f. Do not sell medications
- g. Do not take medications in any manner other than prescribed. For example do not chew or inject your medications
- h. Keep all medications out of reach of children
- i. Do not leave your prescriptions or controlled medications lying around unprotected for others to steal and abuse them
- j. Do not operate a motor vehicle if you feel mentally impaired using controlled medications. You are responsible for exhibiting good judgment in your daily affairs, including your use of controlled medications.
- k. Alcohol use should be curtailed when using controlled medications

Continued Use of Controlled Medication is based on your physician's judgment and a determination of whether the benefits to you of using controlled medications outweigh the risks of using them.

Your physician may discontinue treating you at his or her discretion. Your physician may require a consultation with an addiction specialist. Your physician may require more frequent visits.

We believe in treating your pain and we recognize the value of controlled medications in this process. When used properly, controlled medications can help restore comfort, function, and quality of life. However, as stated above, controlled medications may also have serious side effects and are highly controlled because of their potential for misuse and abuse. It is important to work with your physician and communicate openly and honestly with him or her about your pain control needs. By doing so, medications can be used safely and successfully.

By your signature below, you are acknowledging that you have read and reviewed these matters with your physician and that you have sufficient information to make a decision to use the controlled medications prescribed.

You should NOT sign this form if you do not believe you have enough information to make an informed decision about your use of controlled medications and how they fit in to your pain management treatment plan.

Patient Name: \_\_\_\_\_ Physician Signature: \_\_\_\_\_

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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### SAMPLE PATIENT AGREEMENT: Controlled Substance Treatment

PATIENT NAME: \_\_\_\_\_

PRIMARY CARE PHYSICIAN/SITE: \_\_\_\_\_

I understand that this agreement between myself; \_ and (insert name of medical office/group) is intended to clarify the manner in which chronic (long- term) controlled substances will be used to manage my chronic pain. Chronic controlled substance therapy for patients who do not suffer from cancer pain is a controversial issue.

I understand that there are side effects to this therapy; these include, but are not limited to, allergic reactions, depression, sedation, decreased mental ability, itching, difficulty in urinating, nausea and vomiting, loss of energy, decreased balance and falling, constipation, decreased sexual desire and function, potential for overdose and death. Care should be take when operating machinery or driving a car while taking these medications. When controlled substances are used long-term, some particular concerns include the development of physical dependence and addiction. I understand these risks and have had my questions answered by my physician.

I understand that my (insert name of medical group) physician will prescribe controlled substances only if the following rules are adhered to:

- All controlled substance prescriptions must be obtained from your (insert name of medical group) primary care physician. If a new condition develops, such as trauma or surgery, then the physician caring for that problem may prescribe narcotics for the increase in pain that may be expected. I will notify my primary care physician within 48-hours of my receiving a narcotic or any other controlled substance from any other physician or other licensed medical provider. For females only: If I become pregnant while taking this medicine, I will immediately inform my obstetrician and obtain counseling on risks to the baby.
- I will submit urine and/or blood on request for testing at any time without prior notification to detect the use of non-prescribed drugs and medications and confirm the use of prescribed ones. I will submit to pill counts without notice as per physician's request. I will pay any portion of the costs associated with urine and blood testing that is not covered by my insurance.
- All requests for refills must be made by contacting my (insert name of medical group) primary care physician during business hours at least 3-workdays in advance of the anticipated need for the refill. All prescriptions must be filled at the same pharmacy, which is authorized to release a record of my medications to this office upon request. A copy of this agreement will be sent to my pharmacy.

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- Pharmacy name/address/telephone:

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- The daily dose may not be changed without my (insert name of medical group) primary care physician's consent. This includes either increasing or decreasing the daily dose.
- Prescription refills will not be given prior to the planned refill date determined by the dose and quantity prescribed. I will accept generic medications.
- Accidental destruction, loss of medications or prescriptions will not be a reason to refill medications or rewrite prescriptions early. I will safeguard my controlled substance medications from use by family members, children or other unauthorized persons.
- You may be referred to an appropriate specialist to evaluate your physical condition.
- You may be asked to have an evaluation by either a psychiatrist or psychologist to help manage your medication needs.
- If your physician determines that you are not a good candidate to continue with the medication, you may be referred to a detoxification program or evaluation by a pain management center.
- These medications may be discontinued or adjusted at your physician's discretion.
- I understand that it is my physician's policy that all appointments must be kept or cancelled at least 2-working days in advance. I understand that the original bottle of each prescribed controlled substance medication must be brought to every visit.

I understand that I am responsible for meeting the terms of this agreement and that failure to do so will/may result in my discharge as a patient of (insert name of medical group). Grounds for dismissal from (insert name of medical group) include, but are not limited to: Evidence of recreational drug use, of drug diversion, of altering scripts (this may result in criminal prosecution), of obtaining controlled substance prescriptions from other doctors without notifying this office, abusive language toward staff, development of progressive tolerance, use of alcohol or intoxicants, engagement in criminal activities, etc.

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Patient's Signature

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Witness' Signature

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Date

---

Date

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### URINE DRUG TESTING

Urine drug testing (UDT) is a common practice accompanying chronic opiate therapy (COT). The purpose of UDT is to identify the presence or absence of prescribed medication and the presence of illicit or non-prescribed substances. UDT is an important tool to identify aberrant behavior regarding opiate use. It is one of the only objective measures for compliance monitoring. When used appropriately, it can improve the safety of COT. Unexpected UDT results are seen frequently even in patient populations identified as low risk. As detailed elsewhere in these guidelines, UDT with confirmation is required prior to the outset of COT and at least twice per year for all patients on COT.

1. There are two broad categories of UDT available: immunoassay and confirmation. Immunoassay tests are usually performed in the office (Point of Care Testing), while confirmation tests are usually completed in a laboratory. Immunoassay tests are qualitative in nature and detect the presence or absence of a drug class. They have the advantage of providing rapid results. Immunoassay tests have significant cross-reactivity with other substances. They have lower sensitivity and specificity compared to confirmation testing. Confirmation testing utilizes high performance chromatography/mass spectrometry technology.
2. Typical office based testing for COT patients usually includes opiates, benzodiazepines, cannabinoids, cocaine, amphetamines, alcohol, barbiturates, oxycodone, methadone, and fentanyl. Synthetic and semisynthetic opiates, such as oxycodone, methadone, fentanyl, and meperidine, may not appear on typical immunoassay tests. Points of care immunoassay tests are available for some of these drugs, but they have variable cut-off levels that affect sensitivity. Unexpected results on immunoassay tests should prompt confirmatory testing.
3. Frequency of UDT is left to the prescriber's discretion, but general guidelines can be discussed, based on the relative risk for addiction or death of the patient.

Lower risk patients would typically be screened 1-2 times per year. Moderate risk patients would be screened 3-4 times per year. Higher risk patients and those over 100mg MEDD should be screened 4-5 times per year. Instances of aberrant behavior such as lost or stolen medication may also prompt additional screening. Unexpected or inappropriate immunoassay results should be sent for confirmatory testing.

Higher risk patients may also need routine confirmation because there are certain aberrant behaviors that will appear normal with immunoassay testing.

4. Interpreting UDT results can be complicated. It should be noted that certain parent drugs can be metabolized into other commonly prescribed drugs. If questions exist, a provider should contact the laboratory director, toxicologist, or local Medical Review Officer. A prescriber should inform the patient of the reason for testing and the potential consequences of the results. UDT should be performed in an unannounced fashion when possible. There are many ways a sample can be adulterated to provide a "clean" sample. Validity testing using temperature, pH, or creatinine is recommended. UDT cannot be used to determine the source of drugs detected or the dose of drug taken. It may be helpful to discuss UDT in terms of "Universal Precautions" to minimize any associated stigma or detract from the physician patient relationship

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### TAPERING PROTOCOL

There are many reasons to discontinue chronic opiate therapy. Any time the risks of the continued opiate use outweigh its potential benefit, the therapy should be discontinued. Violation of the controlled substances could be another reason to discontinue opiates.

1. Opiate discontinuation does pose the potential for withdrawal syndrome. This typically consists of nausea, vomiting, myalgia, headaches, abdominal pain, and sweating. These symptoms are not usually serious, and while not fatal, opiate withdrawal can cause discomfort. It should be noted, however, that benzodiazepine withdrawal does have the potential to be life threatening.
2. Low dose opiates may not require weaning at all. If the decision is made to discontinue opiates, steps should be taken to minimize the impact of opiate withdrawal syndrome. It is the responsibility of the current prescribing provider to address this issue.
3. There are several different weaning protocols outlined by various sources. A conservative approach recommends a 10% reduction in the original dose per week. Other sources state that a 25% reduction every 4 days should avoid withdrawal syndrome. The more rapid protocols recommend for a daily reduction of 25-50% of the previous days dose. The Tennessee Department of Health does not recommend any one specific weaning protocol.
4. There are also several different medications that can help alleviate the symptoms of opiate withdrawal. Clonidine can diminish some of the symptoms of opiate withdrawal. Clonidine can be administered 0.1- 0.2mg orally every 6 hours or with a transdermal patch at 0.1mg/24hours. Hypotension and anticholinergic side effects may be encountered with clonidine. Weaning opiates is not always indicated when they are to be discontinued. If recent urine drug screening has shown that opiates are not present in the patient's system, then a weaning protocol would not be necessary.
5. If drug diversion were suspected then prescribing additional opiates would not be indicated. In any circumstance where prescribing additional opiates to a patient is thought to constitute more risk to the patient or to the community than the potential for withdrawal syndrome, no additional opiates should be prescribed.

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### MORPHINE EQUIVALENT DOSE

Morphine equivalent dose (MED) is the equipotent dose of any opioid in terms of morphine. Morphine is widely regarded as the “standard” for the treatment of moderate to severe pain and is used as the reference point. As MED increases, the likelihood of an adverse effect increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety. Various MED charts are available for use in clinical practice, for instance, the Tennessee Controlled Substance Monitoring Database (CSMD) utilizes a chart of conversion factors created by the US Centers for Disease Control and Prevention. The conversion factor is entered into the following formula:

#### **MED Conversion Formula:**

$$\text{MED} = \frac{(\text{Drug Strength}) * (\text{Drug Quantity}) * (\text{Morphine Equivalent Multiplier})}{(\text{Day Supply})}$$

CDC guidance states that fentanyl and buprenorphine patches are exceptions to using the above formula to compute MEDs. This exception only applies to the transdermal patch formulation, not the other dosage forms of either drug. A calculation of MED for these transdermal patch formulations must incorporate the frequency of patch rotation, which may vary depending upon the prescriber’s directions. Therefore, even though the duration of use of each patch may be less than the typical number of days, the quantity of drug that a patient receives each day remains constant because of the continuous release rate of active ingredient from the patch. Due to its complex pharmacokinetic properties, methadone exhibits an exponential increase in MED as dose increases above approximately 30 to 40 milligrams of methadone per day. Particular caution is warranted when methadone therapy approaches or exceeds these daily doses, or when a concomitant medication may inhibit methadone metabolism through the cytochrome CYP450 system.

No MED chart can adequately account for the patient-specific responses to a particular agent as risk of adverse events from taking any opioid can be dose-independent and may begin at low doses. Some of the variables include: age, gender, genetic variability in drug metabolism, drug-drug interactions, opioid tolerance and organ dysfunction such as renal and hepatic impairment, adrenal insufficiency, hypothyroidism, and abnormal levels of protein binding. Therefore, any conversion chart should only be used as a guide when formulating treatment plan. Dosing should be individualized and begun at conservative doses, based on assessment of risk.

## APPENDICES

TABLE OF FREQUENTLY PRESCRIBED PAIN MEDICATIONS		
Short-Acting Opioids	Controlled Substance Schedule	Available Strengths*
Acetaminophen/ Caffeine/Dihydrocodeine Capsule and Tablet	(C-III)	356.4/30/16, 712.8/60/32mg
Aspirin/Caffeine/Dihydrocodeine Capsule	(C-III)	356.4/30/16mg
Acetaminophen/Butalbital/Caffeine/Codeine Capsule	(C-III)	325/50/40/30mg
Aspirin/Butalbital/Caffeine Capsule	(C-III)	325/50/40mg
Aspirin/Butalbital/Caffeine/Codeine Capsule	(C-III)	325/50/40/30mg
Fentanyl Oral	(C-II)	100, 200, 300, 400, 600, 800, 1200, 1600 mcg
Hydrocodone/Acetaminophen	(C-II)	2.5/500, 5/325, 5/400, 5/500, 7.5/325, 7.5/400, 7.5/500, 7.5/650, 7.5/750, 10/325, 10/400, 10/500, 10/650, 10/660mg
Hydrocodone/Ibuprofen Tablet	(C-II)	7.5/200mg
Hydromorphone Tablet	(C-II)	2, 4, 8mg
Morphine Sulfate	(C-II)	
Solution		10mg/5ml, 20mg/5ml, 20mg/1ml
Tablet		15, 30 mg
Oxycodone/Acetaminophen Capsule or Tablet	(C-II)	2.5/325, 5/325, 5/500, 7.5/325, 7.5/500, 10/325, 10/650mg
Oxycodone/Oxycodone terephthalate/Aspirin Tablet	(C-II)	4.5/0.38/325 mg
Oxycodone	(C-II)	
Capsule or Tablet		5, 7.5, 10, 15, 20, 30 mg
Solution		20mg/ml
Oxymorphone Tablet	(C-II)	5, 7.5, 10mg
Meperidine	(C-II)	
Syrup		50mg/5 ml
Tablet		50, 100 mg
Tapentadol Tablet	(C-II)	50, 75, 100mg

## APPENDICES

<b>TABLE OF FREQUENTLY PRESCRIBED PAIN MEDICATIONS</b>		
<b>Long-Acting Opioids</b>	<b>Controlled Substance Schedule</b>	<b>Available Strengths*</b>
Buprenorphine Patch	(C-III)	5, 10, 15, 20mcg/hr
Fentanyl Patch	(C-II)	12, 25, 50, 75, 100mcg/hr
Hydromorphone ER Tablet	(C-II)	8, 12, 16, 32mg
Methadone Tablet	(C-II)	5, 10mg
Morphine Sulfate ER Capsule or Tablet	(C-II)	10, 15, 20, 30, 45, 50, 60, 75, 80, 90, 100, 120, 200mg
Oxycodone ER Tablet	(C-II)	10, 15, 20, 30, 40, 60, 80mg
Oxymorphone ER Tablet	(C-II)	5, 7.5, 10, 15, 20, 30, 40mg
Tapentadol ER Tablet	(C-II)	50, 100, 150, 200, 250mg
<b>Benzodiazepines</b>	<b>Controlled Substance Schedule</b>	<b>Available Strengths*</b>
Alprazolam	(C-IV)	
Tablet or Oral-Dissolving Tablet		0.25, 0.5, 1 or 2 mg
ER Tablet		0.5, 1, 2, 3mg
Clonazepam	(C-IV)	
Oral-Dissolving Tablet		0.125, 0.25, 0.5, 1, 2mg
Tablet		0.5, 1, 2mg
Diazepam Tablet	(C-IV)	2, 5, 10 mg
Lorazepam Tablet	(C-IV)	0.5, 1, 2 mg
<b>Muscle Relaxant</b>	<b>Controlled Substance Schedule</b>	<b>Available Strengths*</b>
Carisoprodol Tablet	(C-IV)	250, 350mg
Carisoprodol/Aspirin Tablet	(C-IV)	325/200mg
Carisoprodol/Aspirin/Codeine Tablet	(C-III)	325/200/16mg
<b>Other Pharmacotherapeutic Options</b>	<b>Controlled Substance Schedule</b>	<b>Available Strengths*</b>
Selective Serotonin Reuptake Inhibitors		
Tricyclic Antidepressants		
Tramadol ER Capsule or Tablet	(C-IV)	100, 150, 200, 300mg
Tramadol Tablet	(C-IV)	50mg
Tramadol/Acetaminophen Tablet	(C-IV)	37.5/325mg
Dronabinol Gelcap	(C-III)	2.5, 5, 10 mg
*Strengths are not intended to be exhaustive. Acetaminophen strength will soon be limited to 325mg in combination products.		

# APPENDICES

## TERMS/DEFINITIONS

**Acute Pain:** pain of sudden onset usually from a single, “fixable” event commonly seen with surgery, accidental injury or inflammation, however, can be from unknown cause; short duration from days to less than 3-6 months as associated with healing; considered our biological red flag that sends warning signals through the nervous system that something is either wrong within the body or that a hurtful activity should be avoided to prevent further or repeat damage.

**ABAM:** American Board of Addiction Medicine. The American Board of Addiction Medicine, Inc. (ABAM) is a not-for-profit 501 (c)(6) organization whose mission is to examine and certify diplomats. It was founded in 2007 following conferences of committees appointed by the American Society of Addiction Medicine. This action was taken as a method of identifying the qualified specialists in Addiction Medicine. ABAM offers a rigorous certifying examination that was developed by an expert panel and the National Board of Medical Examiners, as well as maintenance of certification examination to ensure that ABAM- certified physicians maintain life-long competence in Addiction Medicine. (From ABAM Web Site.)

**ABMS:** American Board of Medical Specialties. The ABMS is comprised of 24 medical specialty Member Boards...

**AOA:** American Osteopathic Association. The AOA serves as the professional family for more than 104,000 osteopathic physicians (DOs) and osteopathic medical students. The AOA promotes public health and encourages scientific research. In addition to serving as the primary certifying body for DOs, the AOA is the accrediting agency for all osteopathic medical schools and has federal authority to accredit hospitals and other health care facilities.

**ASAM:** American Society of Addiction Medicine. American Society of Addiction Medicine is a professional society representing over 3,000 physicians and associated professionals dedicated to increasing access and improving the quality of addiction treatment; educating physicians, other medical professionals and the public; supporting research and prevention; and promoting the appropriate role of physicians in the care of patients with addictions. (From ASAM Web Site.)

**Allodynia:** pain caused by a stimulus or action that does not normally cause pain, like light touch, pressure or a gentle breeze on skin.

**Chronic Pain:** pain lasting longer than expected healing time, may last for many months, years or a lifetime, may be constant or in intervals; cause may be unknown or result of recent or previous acute pain episode; may be related to another chronic disorder, such as arthritis, peripheral vascular disease, diabetes, or cancer.

**Hyperalgesia:** an increased response to a stimulus that normally would induce a mild discomfort.

**Neuropathic Pain:** chronic pain caused by the nervous system.

**Nociceptive Pain:** acute pain as a response to a noxious stimulus.

**Opioid Naïve:** patients who are not chronically receiving opioid analgesics on a daily basis.

**Opioid Tolerant:** patients who are chronically receiving opioid analgesics on a daily basis.

**Pain:** is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is personal and subjective.

## APPENDICES

**Pain Medicine Specialist:** Pain Medicine is the medical specialty dedicated to the prevention, evaluation and treatment of people with chronic pain. Additionally (See Pain Medicine Specialist Appendix)

**Somatic Pain:** pain originating from the muscles and/or bones.

**Visceral Pain:** pain originating from within internal organs.

# APPENDICES

## SAFETY NET

### Tennessee's Substance Abuse System

1. Substance abuse is a pervasive public health issue that has roots in individual, family, peer, and community conditions. Substance abuse negatively impacts families and children, increases crime, threatens public safety, and imposes tremendous social and economic costs to every community. Not surprisingly, it also prompts a wide range of responses across the public and private institutional systems.
2. The National Survey of Substance Abuse Treatment Services (N-SSATS) examines facilities providing substance abuse treatment services conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA). N-SSATS collects data on the location, characteristics, services, and number of clients in treatment at alcohol and drug abuse treatment facilities (both public and private) throughout the 50 states, the District of Columbia, and other U.S. jurisdictions. It looks at 208 facilities in Tennessee:
3. Along with these numbers, N-SSATS found that 81.7% of Tennessee's substance abuse treatment providers offer outpatient treatment services, 32.7% offer residential services, and 6.7% offer hospital inpatient services.
4. The Tennessee Department of Mental Health and Substance Abuse Services, Division of Substance Abuse Services (TDMHSAS-DSAS), serves as the single state authority for receiving and administering federal block grant funding from the U.S. Department of Health and Human Services/SAMHSA and state funding to serve indigent uninsured individuals around the state who have a substance use disorder. The mission of TDMHSAS-DSAS is to improve the quality of life of Tennesseans by providing an integrated network of comprehensive substance abuse treatment services, fostering self-sufficiency and protecting those who are at risk of substance abuse, dependence and addiction.
5. TDMHSAS licenses organizations to provide a continuum of substance abuse treatment services throughout the state. Services include outpatient, intensive outpatient, partial hospitalization, residential treatment, clinical halfway house, social detoxification, medically monitored detoxification, medically managed detoxification, and opioid treatment. All treatment providers use an assessment tool to determine the severity of a person's substance use disorder and the most appropriate service for the individual. Many of these agencies accept commercial insurance, TennCare, and self-pay.
6. To locate a substance abuse treatment facility in your community, visit [www.samhsa.gov/treatment](http://www.samhsa.gov/treatment).

## APPENDICES

### PRESCRIPTION DRUG DISPOSAL

#### Proper Disposal

Unwanted, unused or expired prescription drugs present substantial risks to communities through the potential for abusive use or by damaging the environment as a result of improper disposal. Residential supplies of pharmaceutically controlled substances, those found in home medicine cabinets, have become the supply source of choice for many young people and individuals abusing substance. According to the 2011 Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH), more than 70 percent of people abusing prescription pain relievers got them through friends or relatives, a statistic that includes raiding the medicine cabinets of family and friends. Easy access to prescription drugs is one factor leading to the prescription drug epidemic and an effective method to control access is development of mechanisms for safe, convenient, and responsible disposal. The State of Tennessee has been actively engaged in two types of disposal activities: **Take-Back Events and Permanent Prescription Collection Boxes.**

Take-back events are one-day events where the public is encouraged to discard their unused, unwanted, and expired medications including prescription drugs from their homes. In addition to removing prescription drugs from the community these events are intended to increase awareness of the prescription drug epidemic, inform the public about the need for safely disposing of prescription drugs, and raise awareness of local permanent disposal sites available year round.

Prescription drug collection boxes are established as permanent disposal sites located within law enforcement agencies where community members can safely deposit prescription drugs in a secure container. To be compliant with Drug Enforcement Administration (DEA) regulations, drug collection boxes must be located with a law enforcement entity to ensure access to prescription drugs is carefully controlled and that substances are properly destroyed once collected. Since the beginning of 2012, the number of permanent prescription drug collection boxes has more than doubled from 36 to 82 boxes. This achievement would not have been possible without the Tennessee Department of Mental Health and Substance Abuse Services, the Tennessee Department of Environment and Conservation, and the Tennessee Department of Health working together to ensure the availability of disposal boxes and working with law enforcement agencies to identify and establish safe prescription drug disposal sites. One of the goals of this multi-agency collaboration is to establish at least one permanent prescription drug collection box in all 95 counties of the state. Establishing permanent prescription drug collection boxes as the method for Tennessee citizens' to routinely dispose of medications will require continued public education concerning their use and ease of access, thereby increasing their use and reducing the amount of substances available for abuse and increase home and community safety. Locations of permanent drug collection boxes may be found at <http://www.tn.gov/mental/publications/Permanent%20Drug%20Take-Back%20Boxes.pdf>.

## APPENDICES

### USE OF OPIOIDS IN WORKERS' COMPENSATION MEDICAL CLAIMS

The use of opioids in Workers' Compensation is a significant component of the medical care of injured workers, not only in Tennessee but across the United States. Injuries to the back, knees, and shoulders are among the most frequently occurring workers' compensation injuries. These injuries frequently result in the injured worker experiencing chronic pain and the use of opioids has become a routine practice in the medical care for this type of injury.

A recent study by NCCI for the state of Tennessee found that 11% of workers' compensation medical costs nationwide were attributable to drugs. In Tennessee the percentage is even higher, 16%. Of the top ten drugs prescribed for workers' compensation patients in Tennessee, 22.5 % were opioids (Hydrocodone-Acetaminophen – 16.0 %, Tramadol – 4.3%, Oxycodone HCl-Acetaminophen – 2.2%).

The number of deaths attributable to accidental overdose is not tracked in Tennessee or most other states. It has been estimated that the number of deaths countrywide is in excess of 200, but that estimate may be low as the number of deaths in the two states that track opioid use would account for 25% of that estimate.<sup>1</sup>

These statistics are cause for concern and were a consideration in Public Chapter 289 passed by the General Assembly in 2013 that included a provision mandating the adoption of medical treatment guidelines to be effective January 1, 2016. Pain management will be the first guideline developed.

Tennessee is one of many states that are undertaking the development of guidelines for pain management with the goal of promoting the optimum use of opioids. The table below lists the states with pain management medical treatment guidelines and the basis of those guidelines.

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<sup>1</sup> Reducing Inappropriate Opioid Use in Treatment of Injured Workers: A Policy Guide. International Association of Industrial Accident Boards and Commissions. September 5, 2013. Found at: <http://www.iaabc.org/i4a/pages/index.cfm?pageID=4169>

## APPENDICES

### MEDICAL TREATMENT GUIDELINES FOR PAIN MANAGEMENT FOR WORKERS' COMPENSATION

State	Guideline type	Website, if available
California	ODG	proprietary
Colorado	state specific	<a href="http://www.colorado.gov/cs/Satellite/CDLE-WorkComp/CDLE/12480953116866">http://www.colorado.gov/cs/Satellite/CDLE-WorkComp/CDLE/12480953116866</a>
Connecticut	state specific	<a href="http://wcc.state.ct.us/download/acrobat/protocols.pdf">http://wcc.state.ct.us/download/acrobat/protocols.pdf</a>
Delaware	state specific	<a href="http://dowc.ingenix.com/info.asp?page=pracguid">http://dowc.ingenix.com/info.asp?page=pracguid</a>
Hawaii	ODG	Proprietary
Kansas	ODG	Proprietary
Louisiana	state specific modeled on Colorado, ODG	<a href="http://www.laworks.net/WorkersComp/OWC_MedicalGuidelines.asp">http://www.laworks.net/WorkersComp/OWC_MedicalGuidelines.asp</a>
Massachusetts	state specific	<a href="http://www.mass.gov/lwd/workers-compensation/hcsb/tg/">http://www.mass.gov/lwd/workers-compensation/hcsb/tg/</a>
Minnesota	state specific	<a href="http://www.dli.mn.gov/wc/TpToc.asp">http://www.dli.mn.gov/wc/TpToc.asp</a>
Montana	state specific, Colorado model, ACOEM	<a href="http://www.mtguidelines.com">www.mtguidelines.com</a>
New Mexico	ODG	proprietary
New York	state specific, adopted from Colorado model, ACOEM	<a href="http://www.wcb.ny.gov/content/main/hcpp/MedicalTreatmentGuidelines/2010TreatGuide.jsp">http://www.wcb.ny.gov/content/main/hcpp/MedicalTreatmentGuidelines/2010TreatGuide.jsp</a>
North Dakota	ODG, ACOEM et al professional organization guidelines	proprietary
Ohio	ODG	proprietary
Oklahoma	ODG	proprietary
Rhode Island	state specific	<a href="http://www.courts.ri.gov/Courts/workerscompensationcourt/Medical_AdvisoryBoard/Pages/Protocols.aspx">http://www.courts.ri.gov/Courts/workerscompensationcourt/Medical_AdvisoryBoard/Pages/Protocols.aspx</a>
Texas	ODG	proprietary
Washington	state specific	<a href="http://www.lni.wa.gov/claimsins/providers/treatingpatients/treatguide">http://www.lni.wa.gov/claimsins/providers/treatingpatients/treatguide</a>
Wisconsin	state specific	N/A
Wyoming	ODG	proprietary
ODG: Official Disability Guidelines for Treatment in Workers' Compensation, published by Work Loss Data Institute		
ACOEM: American College of Occupational and Environmental Medicine, Occupational Medicine Practice Guidelines, 3rd Ed		

## APPENDICES

### NALOXONE

Public Chapter 623 allows licensed healthcare providers to prescribe an opioid antagonist (Naloxone) when acting in good faith and exercising reasonable care via a direct or standing order for the following individuals:

1. A person at risk of experiencing an opiate related overdose, or
2. A family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose

Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist, including successful completion of the online overdose prevention education program offered by the Department of Health as evidenced by a certificate of completion.

Naloxone is a pure opioid antagonist, reversing the effects of opioids including respiratory depression, sedation, and hypotension. The onset of action is within 2 minutes when given IV, however, nasal and IM administrations have been documented in the literature. Because of variability in response, an individual may still experience withdrawal symptoms after administration.

The commissioner of health or the commissioner's designee, in consultation with other state, federal or local government personnel, including contractors, shall create and maintain an online education program with the goal of educating laypersons and the general public about the administration of opioid antagonists and appropriate techniques and follow-up procedures for dealing with opioid-related drug overdose.

The following individuals are immune from civil liability in the absence of gross negligence or willful misconduct for actions authorized by this section:

1. Any licensed healthcare practitioner who prescribes or dispenses an opioid antagonist pursuant to subsection (c); and
2. Any person who administers an opioid antagonist pursuant to subsection (e).

The duration of action of some opioids may exceed that of naloxone. Depending on a patient's age and route of administration of naloxone, the duration of action may vary from minutes to hours. The patient must be watched closely until stabilized in the appropriate healthcare facility. A repeat dose or doses may be necessary before patient reaches a healthcare facility.

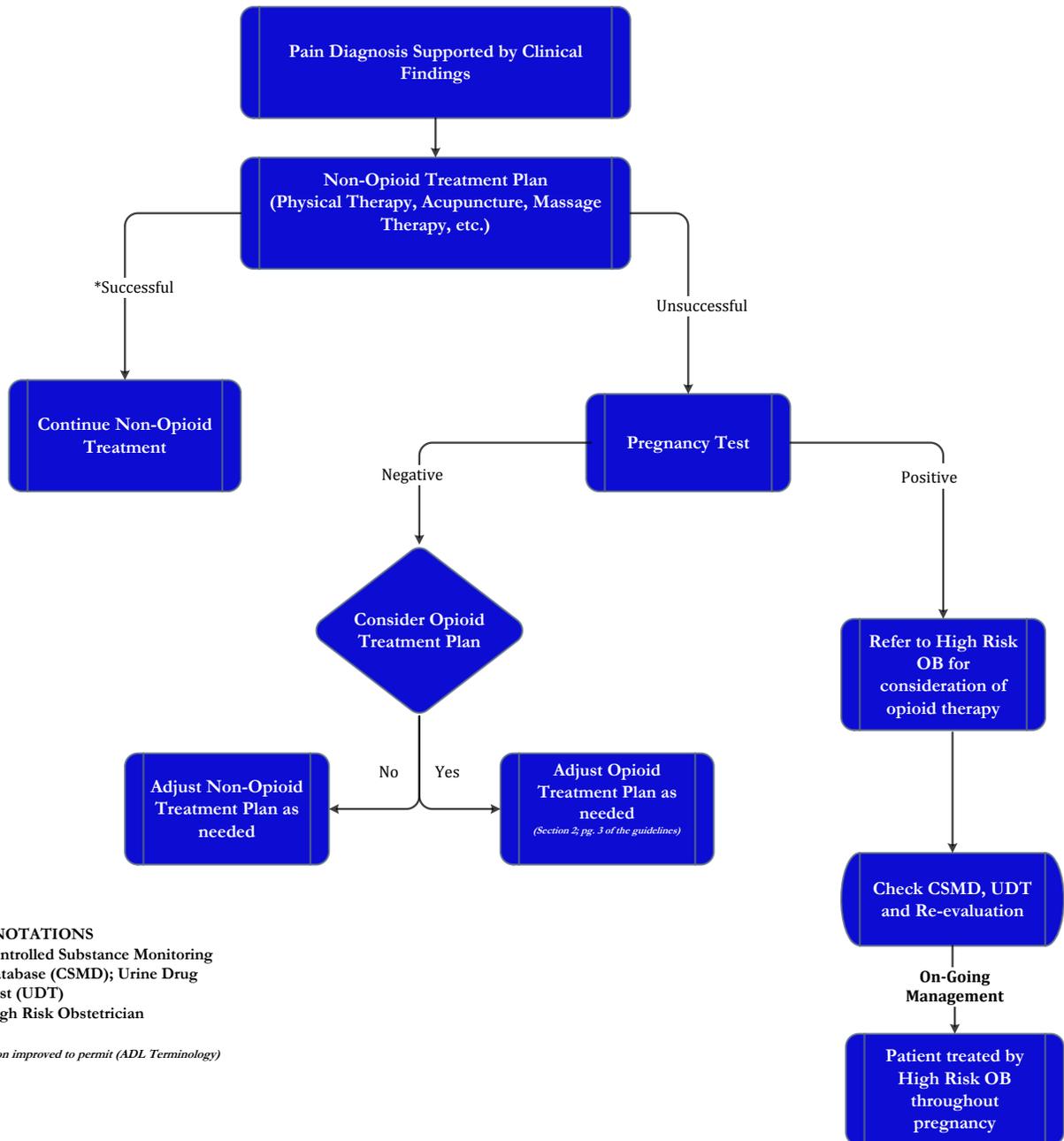
Intranasal administration via atomizer is considered a safe and effective alternative to traditional administration routes for naloxone. Advantages include elimination of the risk of needle exposure. Institution of a collaborative agreement may allow dispensing of naloxone by a pharmacist.

# APPENDICES

## CHRONIC PAIN GUIDELINE ALGORITHM WOMEN'S HEALTH

### WOMEN'S HEALTH

#### Women of Childbearing Age With Reproductive Capability



#### ANNNOTATIONS

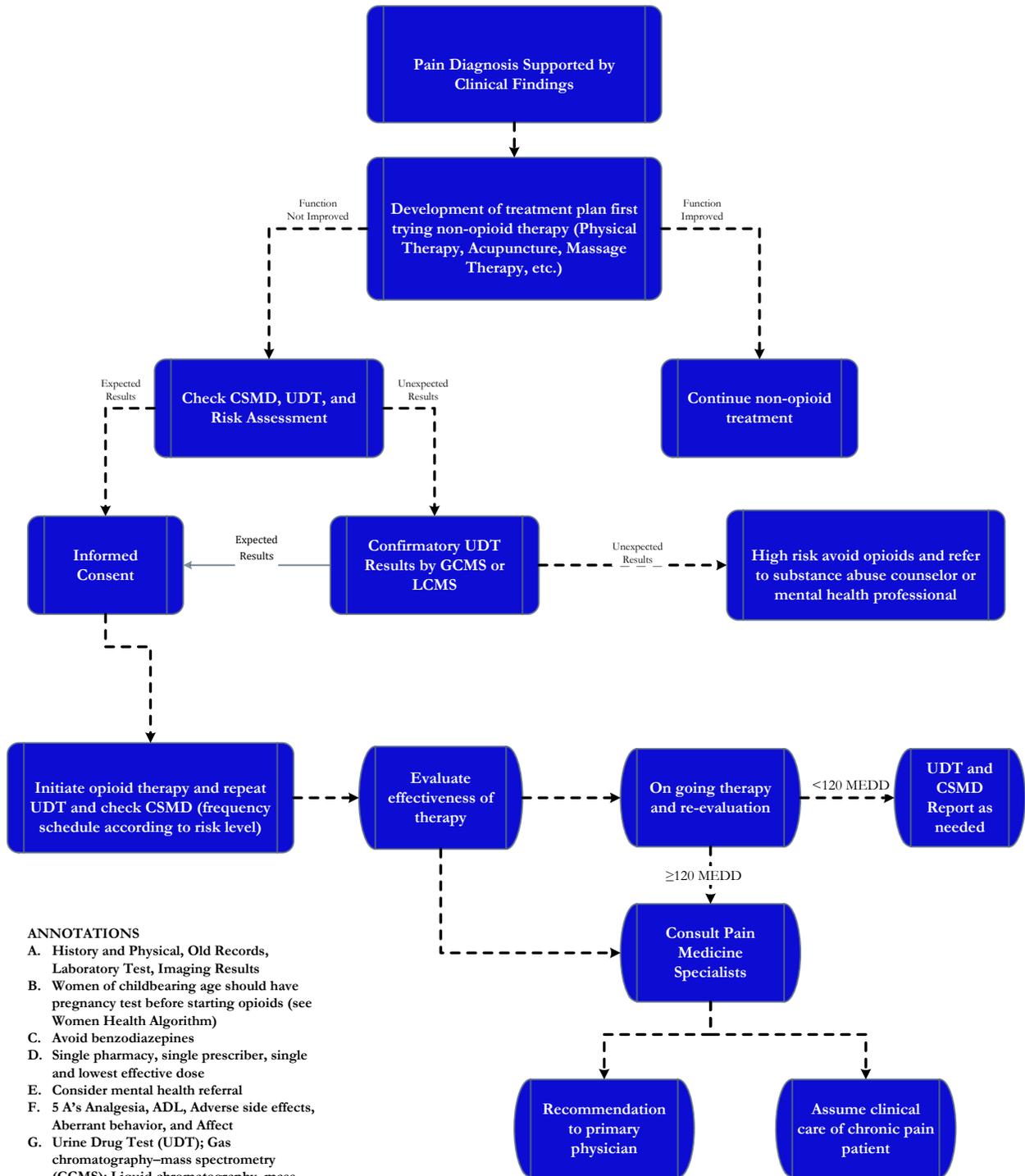
- A. Controlled Substance Monitoring Database (CSMD); Urine Drug Test (UDT)
- B. High Risk Obstetrician

*\*Function improved to permit (ADL Terminology)*

# APPENDICES

## CHRONIC PAIN GUIDELINE ALGORITHM OPIOID THERAPY

### CANDIDATE FOR OPIOID THERAPY



# APPENDICES

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This document was produced by the Tennessee Department of Health and the Chronic Pain Guidelines Steering Committee and Expert Panel.

# Texas Administrative Code

[TITLE 22](#)

## EXAMINING BOARDS

[PART 9](#)

## TEXAS MEDICAL BOARD

[CHAPTER 170](#)

## PAIN MANAGEMENT

## RULE §170.3

## Minimum Requirements for the Treatment of Chronic Pain

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A physician's treatment of a patient's pain will be evaluated by considering whether it meets the generally accepted standard of care and whether the following minimum requirements have been met:

(1) Evaluation of the patient.

(A) A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

(B) The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record must document:

(i) the nature and intensity of the pain;

(ii) current and past treatments for pain;

(iii) underlying or coexisting diseases and conditions;

(iv) the effect of the pain on physical and psychological function;

(v) any history and potential for substance abuse or diversion; and

(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

(C) Prior to prescribing dangerous drugs or controlled substances for the treatment of chronic pain, a physician must consider reviewing prescription data and history related to the patient, if any, contained in the Prescription Drug Monitoring Program described by §§481.075, 481.076, and 481.0761 of the Texas Health and Safety Code and consider obtaining at a minimum a baseline toxicology drug screen to determine the presence of drugs in a patient, if any. If a physician determines that such steps are not necessary prior to prescribing dangerous drugs or controlled substances to the patient, the physician must document in the medical record his or her rationale for not completing such steps.

(2) Treatment plan for chronic pain. The physician is responsible for a written treatment plan that is documented in the medical records. The medical record must include:

(A) How the medication relates to the chief presenting complaint of chronic pain;

(B) dosage and frequency of any drugs prescribed;

(C) further testing and diagnostic evaluations to be ordered, if medically indicated;

(D) other treatments that are planned or considered;

(E) periodic reviews planned; and

(F) objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

(3) Informed consent. It is the physician's responsibility to discuss the risks and benefits of the use of controlled substances for the treatment of chronic pain with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. This discussion must be documented by either a written signed document maintained in the records or a contemporaneous notation included in the medical records. Discussion of risks and benefits must include an explanation of the:

(A) diagnosis;

(B) treatment plan;

(C) anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning and possibilities for lack of pain relief;

(D) therapies in addition to or instead of drug therapy, including physical therapy or psychological techniques;

(E) potential side effects and how to manage them;

(F) adverse effects, including the potential for dependence, addiction, tolerance, and withdrawal; and

(G) potential for impairment of judgment and motor skills.

(4) Agreement for treatment of chronic pain. A proper patient-physician relationship for treatment of chronic pain requires the physician to establish and inform the patient of the physician's expectations that are necessary for patient compliance. If the treatment plan includes extended drug therapy, the physician must use a written pain management agreement between the physician and the patient outlining patient responsibilities, including the following provisions:

(A) the physician may require laboratory tests for drug levels upon request;

(B) the physician may limit the number and frequency of prescription refills;

(C) only one physician will prescribe dangerous and scheduled drugs;

(D) only one pharmacy designated by the patient will be used for prescriptions for the treatment of chronic pain, unless the designated pharmacy under the agreement is out of stock of the drug prescribed at the time that the prescription is communicated by the physician to the pharmacy or patient presents to have the drug dispensed; and

(E) reasons for which drug therapy may be discontinued (e.g. violation of agreement).

(5) Periodic review of the treatment of chronic pain.

(A) The physician must see the patient for periodic review at reasonable intervals in view of the

individual circumstances of the patient.

(B) Periodic review must assess progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C) Each periodic visit shall be documented in the medical records.

(D) Contemporaneous to the periodic reviews, the physician must note in the medical records any adjustment in the treatment plan based on the individual medical needs of the patient.

(E) A physician must base any continuation or modification of the use of dangerous and scheduled drugs for pain management on an evaluation of progress toward treatment objectives.

(i) Progress or the lack of progress in relieving pain must be documented in the patient's record.

(ii) Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.

(iii) Objective evidence of improved or diminished function must be monitored. Information from family members or other caregivers, if offered or provided, must be considered in determining the patient's response to treatment.

(iv) If the patient's progress is unsatisfactory, the physician must reassess the current treatment plan and consider the use of other therapeutic modalities.

(v) The physician must periodically review the patient's compliance with the prescribed treatment plan and reevaluate for any potential for substance abuse or diversion. In such a review, the physician must consider reviewing prescription data and history related to the patient, if any, contained in the Prescription Drug Monitoring Program described by §§481.075, 481.076, and 481.0761 of the Texas Health and Safety Code and consider obtaining at a minimum a toxicology drug screen to determine the presence of drugs in a patient, if any. If a physician determines that such steps are not necessary, the physician must document in the medical record his or her rationale for not completing such steps.

(6) Consultation and Referral. The physician must refer a patient with chronic pain for further evaluation and treatment as necessary. Patients who are at-risk for abuse or addiction require special attention. Patients with chronic pain and histories of substance abuse or with co-morbid psychiatric disorders require even more care. A consult with or referral to an expert in the management of such patients must be considered in their treatment.

(7) Medical records. The medical records shall document the physician's rationale for the treatment plan and the prescription of drugs for the chief complaint of chronic pain and show that the physician has followed these rules. Specifically the records must include:

(A) the medical history and the physical examination;

(B) diagnostic, therapeutic and laboratory results;

(C) evaluations and consultations;

(D) treatment objectives;

- (E) discussion of risks and benefits;
- (F) informed consent;
- (G) treatments;
- (H) medications (including date, type, dosage and quantity prescribed);
- (I) instructions and agreements; and
- (J) periodic reviews.

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**Source Note:** The provisions of this §170.3 adopted to be effective January 4, 2007, 31 TexReg 10798; amended to be effective August 4, 2015, 40 TexReg 4898

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# Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain

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Utah Department of Health  
2009

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February, 2009

I am pleased to provide a copy of "Utah Clinical Guidelines on Prescribing Opioids for Pain." This document represents the results of many months of work on the part of many people, all of whom contributed considerable time, effort, experience, and expertise. This effort is an attempt to address what I consider one of the most pressing and challenging public health problems—premature deaths, dependency and disability associated with misuse and/or abuse of prescription drugs, especially, narcotic medications.

Utah's Medical Examiner, Dr. Todd Grey, brought to my attention soon after I assumed my position as Executive Director of the Utah Department of Health in 2005, the alarming increase in deaths in our state related to misuse of prescription drugs. In recent years, prescription medications used alone, in combination, or mixed with illicit drugs, has resulted in the death of hundreds of our fellow citizens. For the past 17 years, prescription drug-related deaths have increased and now exceed deaths resulting from automobile crashes in our state. In fact, it is now the **number one cause of unintentional death.**

These guidelines are meant to be just that—suggestions on how to properly use and prescribe opioid medication. As with any effort to achieve consensus, there were members who participated in the preparation of this document who disagree at both ends of the spectrum, i.e., some believe that the guidelines are too lax, others believe they impose barriers to access of much needed narcotic medications for the control of pain. It is our hope that the guidance in this document will educate both the public and clinicians about appropriate use of these medications which will, if followed, significantly reduce deaths from misuse and abuse, but at the same time allow for the control of chronic pain with proper use of opioid medications.

I want to thank the many individuals and organizations that contributed to the preparation of this document. Thousands of hours were spent in meetings and in reviewing related literature. I particularly want to acknowledge the outstanding work of Dr. Robert Rolfs, Utah State Epidemiologist and Erin Johnson, Prescription Pain Medication Program Manager. I would also like to acknowledge that the Utah State Legislature directed the Department of Health by law to produce this report on, "Medical Treatment and Quality Care Guidelines that are Scientifically Based; and Peer Reviewed," and provided the necessary funds. Additional encouragement and strong support was provided along with matching funds from the Labor Commission Workplace Safety Fund.

I'm hopeful that these guidelines will prove to be a "living document" that will be updated over time to reflect new knowledge and science and thereby improve the public's health in our state.

Sincerely,

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The Department of Health is grateful for the leadership in addressing this issue by Representative Bradley Daw who introduced House Bill 137: Pain Medication Management and Education, which was passed by the 2007 Utah legislature providing funding and directing production of these guidelines.

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### **Disclosure of Funding**

These Guidelines are based on research conducted at the Utah Department of Health with funding from the Utah State Legislature. Additional funds were contributed to the program by the Utah Labor Commission (from the Utah Workplace Safety Account) and by the Worker's Compensation Fund of Utah.

### **Statutory Authority**

These Guidelines were authorized by the Utah Legislature which directed the Utah Department of Health to produce "medical treatment and quality care guidelines that are scientifically based; and peer reviewed" (§26-1-36 Utah Code Annotated).

### **Disclosure of Conflicts**

Alan L. Colledge, MD, is the Medical Director of the Labor Commission of Utah which oversees the care of approximately 60,000 injured individuals a year provided by over 250 different insurance and payer sources.

Edward B. Holmes, MD, MPH, is an appointed member of the Utah Labor Commission Workers Compensation Advisory Council. He is also Chief Medical Consultant for Disability Determination Services for Social Security.

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Jerry A. Shields, RPh, MBA, is a clinical pharmacy consultant for Regence Blue Cross Blue Shield of Utah which is an insurance provider.

Lynn R. Webster, MD, conducts research for the following pharmaceutical companies: Abbott Laboratories, Ameritox, Merck & Co., Inc., Arraya, AstraZeneca, Boehringer Ingelheim, Elite Pharmaceuticals, King Pharmaceuticals, Medtronic, Merck & Co., Inc., Durect Corp., Nektar, NeurogesX, Inc., PTI, Purdue Pharma, QRZ, Respiroics, Takeda Pharmaceuticals, TorreyPines Therapeutics, Wyeth, and Zars Pharma. He also conducts research for Nervo and Advanced Bionics (device companies), Ameritox (urine drug testing company), and Respiroics (manufacturer of sleep apnea machines). Dr. Webster is a consultant for Advanced Bionics, Alharma Pharmaceuticals, LLC, Cephalon, Inc., King Pharmaceuticals, Medtronic, Nektar, and Nervo. He is also an advisor to Purdue Pharma.

## Background and Introduction

Unintentional fatalities due to prescription medications are an increasing problem in the United States and Utah. In the year 2000, the Utah Medical Examiner noted an increase in the number of deaths occurring due to an overdose of prescription opioid medications that are typically used for pain management. Epidemiologic studies conducted in Utah using death certificate data, Office of the Medical Examiner data, emergency department encounter data, and data from the Utah Controlled Substances Database confirmed the increases and uncovered an alarming problem.

During the years 1999–2007 deaths attributed to poisoning by prescription pain medications increased by over 500%, from 39 to 261. Deaths of Utah residents from non-illicit drug poisoning (unintentional or intent not determined) have increased from about 50 deaths per year in 1999 to over 300 in 2007. The increase was mostly due to increased numbers of deaths from prescription opioid pain medications, including methadone, oxycodone, hydrocodone, and fentanyl (CDC, 2005).

Prescribing of opioid medications has substantially increased over the past 10-15 years, including greater use for treating acute and chronic pain. Distribution to Utah of opioids such as hydrocodone, oxycodone, and methadone increased 6-fold from 1997-2002. In addition, national data document an increase in non-medical use of prescription opioids during the past several years (Substance Abuse and Mental Health Services Administration [SAMHSA], 2004; SAMHSA, 2007). From 1990 to 2002, the number of people in the U.S. who reported using prescription pain medications non-medically for the first time that year increased from 600,000 to over 2 million people (SAMHSA, 2004).

In 2007, recognizing the need for intervention, the Utah State Legislature passed House Bill 137 appropriating funding to the Utah Department of Health (UDOH) to establish a program aimed at reducing deaths and other harm from prescription opiates. Additionally, the program's charge was to develop medical treatment and quality care guidelines for the state of Utah. The resulting

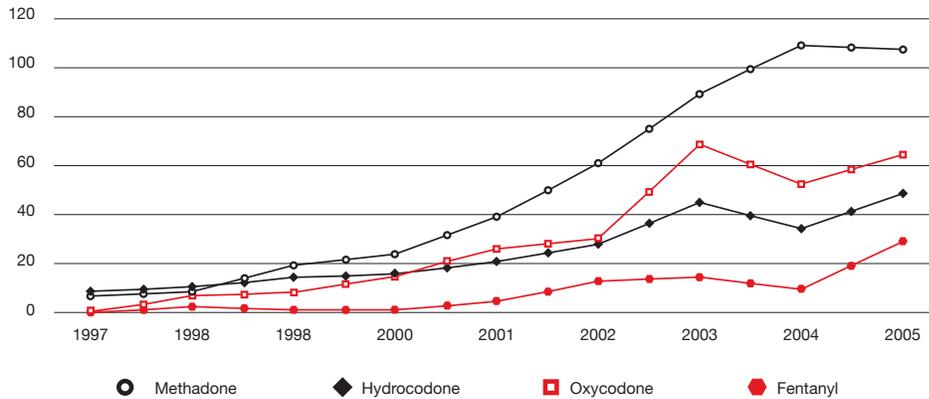
Prescription Pain Medication Program is being led by the Utah Department of Health in collaboration with the Utah Attorney General, the Labor Commission, the Division of Occupational and Professional Licensure, Department of Commerce, and Division of Substance Abuse and Mental Health, Department of Human Services.

A key goal of this Guideline is to seek a balance between appropriate treatment of pain and safety in the use of opioids for that purpose. The Model Policy for the Use of Controlled Substances for the Treatment of Pain<sup>1</sup> (Federation of State Medical Boards, 2004) acknowledged that “undertreatment of pain is...a serious public health problem,” but also sought to establish the importance of balance in treating pain as stated in the following sentence:

**“...the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.”**

As of the time these Utah Guidelines were produced, **adequate evidence was not available to determine the benefits of long-term treatment with opioids for persons with chronic pain due to musculoskeletal and other non-cancer causes on patient function and quality of life** (Von Korff & Deyo, 2004). Despite that lack of evidence, the use of these medications for treatment of these conditions has increased substantially in recent years. In the absence of adequate evidence to determine the true benefits and best practices in use of these medications,

<sup>1</sup> [The Model Policy for the Use of Controlled Substances for the Treatment of Pain](#) was developed by the Federation of State Medical Boards and endorsed by the Division of Occupational and Professional Licensing on recommendation of the Physicians Licensing Board.

**Figure 1.** Number of Utah Deaths by Year and Drug: Accidental and Undetermined Cause

these Guidelines were developed to assist physicians who choose to use opioids to treat patients with pain to manage that treatment as safely as possible.

The principal focus of these Guidelines is on the use of opioids in the long term treatment of chronic pain, especially chronic, non-cancer pain<sup>2</sup>. These guidelines were not developed to guide treatment of patients with malignant cancer or for patients in hospice or palliative care settings and should not limit treatment for patients for whom pain relief is the primary goal and improved function is not expected.

The diversion of opioid medications to non-medical uses also has contributed to the increased numbers of deaths. Therefore, these guidelines also include several recommendations on the use of opioids to treat acute pain to help address that public health problem. For purposes of these guidelines, acute pain is considered to be an episode of pain lasting six weeks or less and chronic pain to be pain lasting more than three months. Episodes of pain lasting from one to three months are sometimes referred to as subacute pain and were not explicitly addressed by these guidelines, however many of the recommendations are applicable to subacute pain.

The Utah Department of Health and its advisors recognized that clinicians have many demands on their time and have attempted to make these guidelines as practical and concise as possible. However, long-term use of opioid

medications to treat chronic pain carries substantial risks and the benefits of this treatment approach have not been adequately established by appropriate studies. The time commitment required to safely manage patients on these medications should be considered when they are prescribed. The Utah Department of Health agrees with Von Korff and Deyo (2004) that,

**“Long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up and close supervision are ensured.”**

Medicine is practiced one patient at a time and each patient is unique with individual needs and vulnerabilities. The Guidelines have attempted to guide clinicians but not to inappropriately constrain practice. The art of medicine is recognized. However, these Guidelines were based on evidence or consensus recommendations by experts. They are intended to improve outcomes of patient care and in particular to prevent deaths due to opioid use. Departures from these recommendations will be appropriate for some patients, but should be justified and documented.

<sup>2</sup> This Guideline uses the term chronic non-cancer pain to refer to chronic pain that is not associated with active cancer or occurs at the end of life (Chou et al., 2009). Some of the tools and references included in this Guideline use the term, “chronic non-malignant pain” to describe a similar or identical set of conditions.

## Summary of Recommendations

### Opioid Treatment for Acute Pain

- 1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.
- 2) When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.
- 3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, to not share with others, and to dispose of medications properly when the pain has resolved in order to prevent non-medical use of the medications.
- 4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.
- 5) The use of opioids should be reevaluated carefully, including assessing the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.
- 5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.
- 6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.
- 7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).
- 8) Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored.
- 9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult may be useful in making that decision.
- 10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.

### Opioid Treatment for Chronic Pain

- 1) A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.
- 2) Alternatives to opioid treatment should be tried (or adequate trial of such treatment by a previous provider documented), before initiating opioid treatment.
- 3) The provider should screen for risk of abuse or addiction before initiating opioid treatment.
- 4) When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.<sup>3</sup>
- 11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.
- 12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.
- 13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use, and who are prepared to conduct the necessary careful monitoring.

<sup>3</sup> "Function" as used here is defined broadly to include physical, emotional, cognitive, psychological and social function.

## Methods

### Purpose and Target Audience

These Guidelines provide recommendations for the use of opioids for management of pain that are intended to balance the benefits of use against the risks to the individual and society, and to be useful to practitioners. The target audience for these Guidelines includes all clinicians who prescribe opioids in their practice.<sup>4</sup>

### Guideline Evidence Review

The steering committee of the Utah Department of Health's Prescription Pain Medication Program developed the key questions, scope, and inclusion criteria used to guide the evidence review process. The process began with a literature review to identify existing guidelines on pain, chronic pain, opioids, pain management, and related topics. Guidelines were identified through electronic databases, reference lists from evaluated guidelines, and recommendations from experts. Electronic databases that were searched include: PubMed, Medline, CINAHL, and the National Guideline Clearinghouse. Investigators identified and evaluated 40 individual guidelines.

### Grading of the Evidence and Recommendations

As guidelines were identified they were reviewed for key information. They were evaluated based on the following categories:

- Title
- Year Published: Guidelines were included only if they were published after the year 1999. Articles published before 2000 were merely noted in the grid by their title and date with no additional information.
- Sponsorship and funding
- Medical Perspective
- Target Audience
- The Process: This describes how the guidelines were created. Most guidelines fell into two categories: "evidence-based" and/or "consensus"
- The Rating Scale: This was based on the quality of research that went into the development of the guidelines. Explicit evidence-based guidelines received higher ratings and less explicit, consensus-based guidelines received lower ratings

The complete evaluation matrix of the 40 guidelines is available from the Utah Department of Health, Bureau of Epidemiology upon request.

In total, 40 guidelines for pain management were reviewed and evaluated. As each guideline was reviewed, it received a rating from 1-10 (for a breakdown of the rating scale, see Appendix A). Guidelines that received scores of seven (7) or lower were excluded. Four (4) sets of guidelines received scores of eight (8) or above. Three (3) public health professionals reviewed the ratings to ensure that the scores were consistent with the rating scale.

### Panel Composition

The Utah Department of Health convened two multidisciplinary panels (see page 4 for complete list of panel members). The Guideline Recommendation Panel convened on four (4) occasions between May and July 2008. Their purpose was to review the evidence and formulate recommendations based on the evidence in the selected guidelines. Each member signed a Conflict of Interest disclosure. Conflicts were reported as described below (See Disclosure of Conflicts on page ii). The Guideline Implementation and Tool Panel convened twice (2) between July and August 2008 to review the recommendations to ensure that they were implementable as well as to identify tools needed in order to put the recommendations into use. The first panel consisted of twelve (12) experts and the second consisted of nine (9) experts from throughout the state of Utah.

### Recommendation Development Process

The Guideline Recommendation Panel met in person on four occasions between May and July 2008. The purpose of the first meeting was to provide panel members with copies of the selected, high-scoring guidelines and to present the purpose and plan for developing the guidelines. Prior to the second meeting, panel members were asked to review the four guidelines for commonalities. The recommendations that were supported by multiple guidelines created the basis of the first draft of the recommendations used by the Guideline Recommendation Panel. Consideration was given to adopting one of the existing evidence-based guidelines outright, but the panel

<sup>4</sup> In Utah as of January 2009 (R156-37), clinicians who can be licensed to prescribe controlled substances as part of practice (human) includes physicians and surgeons, osteopathic physicians and surgeons, podiatrists, dentists, physician assistants, advanced practice registered nurses, certified nurse midwives, certified nurse anesthetists, and optometrists.

felt that no single guideline represented sufficiently what was desired of the Utah guidelines. The panel voted to include two (2) additional sets of guidelines that had not met the inclusion criteria for consideration while drafting the recommendations. In total, content for the Utah guidelines was drawn from six (6) guidelines. The key topics to be developed into specific recommendations were posted on a website where the Guideline Recommendation Panel members posted comments and edited the text. The panelists' postings were the basis on which content was selected from the chosen guidelines. This content was then used to create a draft of actual recommendation statements and supporting paragraphs. At the third meeting, a straw poll was taken on the recommendation draft. Through discussion and rewording, consensus on content was achieved for all of the recommendations discussed over the course of the two meetings. Outside the meetings, non-content editing of the recommendations and supporting statements was performed, based on the panel's discussions, to create the final draft of the recommendations and supporting paragraphs.

### **Tool Development Process**

The Guideline Implementation and Tools Panel met in person on two occasions between July and August 2008. Prior to the first meeting, a book was compiled that included all tools that were identified in the forty (40) guidelines. Sample tools were solicited from panel members as well. In total, the workbook contained forty-seven (47) tools. At the first meeting, the panel reviewed the draft recommendations and discussed whether any specific recommendations were impossible or burdensome to implement. Panel members were each given a book containing all the tools. In between the first and second meeting, panel members reviewed and graded each tool according to usefulness and whether or not it should be included in the guidelines. Votes and rating were tallied prior to the second meeting. Tools that received an average rating of below two (2) were eliminated. At the second meeting, the remaining tools were discussed and it was determined which of the remaining tools should be included, modified, or eliminated.

Following the final panel meetings, Utah Department of Health staff formally drafted the complete guidelines document.

Drafts of the complete guidelines were then distributed to all panel members and several Utah Department of Health internal staff for feedback and revisions. External peer reviewers were solicited for additional comments. The final draft recommendations were posted for public comment during November–December 2008 and revisions were made based on consideration of those comments (copies of comments are available online at [health.utah.gov/prescription](http://health.utah.gov/prescription)). Prior to publication, the Guideline was submitted to the Utah Department of Health Executive Director for approval.

## Recommendations

Previously published evidence-based or consensus-based guidelines have been used as the foundation for many of the Utah recommendations. Each guideline has been assigned a number. After each recommendation, the numbers of the guidelines with similar or supporting recommendations are listed.

### Reference Guidelines:

1. Department of Veterans Affairs, Department of Defense. (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain*
  2. College of Physicians and Surgeons of Ontario. (2000). *Evidence-based recommendations for medical management of chronic non-malignant pain*
  3. American College of Occupational and Environmental Medicine's Occupation Medicine Practice Guidelines. (2008).
  4. *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines.* (2008).
  5. Washington State Agency Medical Directors' Group. (2007). *Interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment*
  6. Federation of State Medical Boards of the United States, Inc. (2004). *Model policy for the use of controlled substances for the treatment of pain*
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## Opioid treatment recommendations for acute pain:

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### Acute Pain Recommendation 1:

Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief. *Reference Guidelines: 3*

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Most acute pain is better treated with non-opioid medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAID), or therapies such as exercise, or specific stretching) than opioid medications which have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that use of opioid pain treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. The developing brain may be more susceptible to addiction when exposed to opioid medications and nonmedical use is more common among younger people. Those risks should be considered when prescribing to an adolescent.

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### Acute Pain Recommendation 2:

When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition.

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Prescribing more medications than the amount likely to be needed leads to unused medications being available for non-medical use or abuse. Use of opioid pain medications should be stopped when pain severity no longer requires opioid medications.

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### Acute Pain Recommendation 3:

When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved in order to prevent non-medical use of the medications.

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It is important that patients understand the need to store medications securely. Encourage patients to keep medications in a locked environment rather than in typical locations, such as the bathroom or kitchen cabinet, where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medication after they have recovered, they should dispose of their medication immediately to help protect them from being a target for theft as well as protect others from getting into the medications. The Federal Guidelines on Proper Disposal of Prescription Drugs are included in the Tool Section.

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### Acute Pain Recommendation 4:

Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

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### Acute Pain Recommendation 5:

The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

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Patients with acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course for their diagnosis should be carefully evaluated. The continuation of opioid treatment in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such at the time. The diagnosis and appropriateness of interventions should be reevaluated and the patient's medical history should be reviewed for comorbidities that could interact with opioid treatment and for risk factors for problems during opioid treatment, including substance abuse or history of substance abuse. It is recommended that the provider check the Utah Controlled Substances Database at this time as well.

## Opioid treatment recommendations for chronic pain:

### Before prescribing opioid treatment for chronic pain:

#### 1. Comprehensive initial evaluation/assessment of patient

##### 1.1 Recommendation:

A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.  
*Reference Guidelines: 1, 2, 4, 6*

There are many reasons for using caution when initiating opioid therapy, therefore the recommended comprehensive initial evaluation is very important. A major goal when prescribing opioids should be to provide greater benefit than harm to patients. Potential for serious harm exists, up to and including death, due either to overdose or to dangerous behaviors that occur while under the influence of these medications. The patient may be harmed, but others may also be harmed through diversion or because of an act performed by the patient on opioids. The most frequent harms are diversion, misuse, abuse, addiction, and overdose and predicting which patients will be affected by these harms is difficult. Initiating opioid treatment often results in short term relief, but that relief might not be maintained. Long-term use of opioid medications to treat chronic pain safely requires the commitment of adequate resources to regularly monitor and evaluate outcomes and identify occurrence of adverse consequences.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patient's function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes.

The evaluation should specifically address these issues:

##### 1) Assess pain and prior treatment of pain.

- Determine the cause of the pain and whether the pain is acute or chronic.

- Assess previous treatment approaches and trials for appropriateness, adequacy, and outcome.

##### 2) Assess presence of social factors, and medical or mental health conditions that might influence treatment especially those that might interfere with appropriate and safe use of opioid therapy (Department of Veterans Affairs & Department of Defense [VA/DOD], 2003):

- Obtain history of substance use, addiction or dependence (if present, refer to Recommendations 12.2 and 12.3).
- Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 12.4).
- Identify use of other medications that might interact with medications used to treat the pain. Particular attention should be given to benzodiazepines and other sedative medications.
- Assess social history, including employment, social network, marital history, and any history of legal problems especially illegal use or diversion of controlled substances.
- Assess for presence of medical conditions that might complicate treatment of the pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea.
- Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher dosages. Some clinicians recommend that all patients who are considered for long-term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered.

##### 3) Assess the effects of pain on the person's life and function.

- Assess the severity of pain, functional status of the patient, and the patient's quality of life using a method/instrument that can be used later to evaluate treatment effectiveness.

##### Tools to accompany Recommendation 1:

- Sheehan Disability Tool
- Pain Management Evaluation Tool

## 2. Consider alternative treatment options

### 2.1 Recommendation:

Alternatives to opioid treatment should be tried (or an adequate trial of such treatments by a previous provider documented) before initiating opioid treatment.

*Reference Guidelines: 1, 2, 3, 4, 5*

Opioid medications are not the appropriate first line of treatment for most patients with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. This approach is consistent with the World Health Organization's Pain Relief Ladder (WHO).

### 2.2 Recommendation:

Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 2:

- Non-opioid Pain Management Tool

## 3. Screening for risk of addiction or abuse

### 3.1 Recommendation:

Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long-term for chronic pain. *Reference Guidelines: 3*

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. Several of these are included in the Tool Section. The screening tool results are intended to assist the clinician in determining whether opioid therapy is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

### 3.2 Recommendation:

Consider performing drug screening before initiating long term opioid treatment for chronic pain.

Research and experience have shown that drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., diversion), undisclosed use of alcohol, or use of illicit substances, that are not identified without that testing. Several experts involved in the development of these guidelines recommended that drug screening be done on all patients before initiating opioid treatment for chronic pain. However, drug testing can damage a provider-patient relationship, the results of testing can be difficult to interpret, and that recommendation attracted a substantial number of negative comments during the public comment period. It is recommended that drug testing be strongly considered and conducted especially when other factors suggest caution.

The drug screening should be either a urine drug screen or another laboratory test that can screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use. It is recommended that this testing be considered for all patients. When screening is limited to situations when there is suspicion of substance misuse, some misuse may be missed. In one study, testing results at first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most of these discrepancies involved finding substances not reported by the patient; a small minority reported taking medications that were not found on testing (Berndt, Maier, & Schutz, 1993).

The clinician may consider testing for illegal substances (See list of Urine Drug Testing Devices in the Tool Section) in addition to screening for opioids.

A positive drug screen indicates the need for caution, but does not preclude opioid use for treatment of pain. Consideration should be given to referral to substance abuse counseling and/or to a pain management specialist. If opioid medication is subsequently prescribed, the patient should be more carefully monitored and conditions

under which opioids are being prescribed should be well documented in the treatment plan (See Recommendations 5, 6, 8, 12).

Immunoassays can be done in the office. These can determine if opioids are present but do not identify specific ones, which can subsequently be determined by confirmatory laboratory testing. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-the-counter medication, for example, can cause a positive result (Washington State Agency Medical Directors' Group [WSAMDG], 2007). The prescriber may want to consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear (WSAMDG, 2007).

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### 3.3 Recommendation:

The prescriber should check Utah's Controlled Substance Database before prescribing opioids for chronic pain.

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Most patients who request treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of controlled substance prescriptions filled by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to the potential for problems.

The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database Program, which is a searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect in 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. Access to the data is provided to authorized individuals and used

to identify potential cases of drug over-utilization, misuse, and potential abuse of controlled substances throughout the state. This database is accessible to all controlled substance prescribers online at [www.csdb.utah.gov](http://www.csdb.utah.gov). A "Getting Started" presentation is available to help orient users to the site and to appropriate uses of the database.

Tools to accompany Recommendation 3:

- SOAPP-R
- Opioid Risk Tool
- Prescription Drug Use Questionnaire
- List of Recommended Urine Drug Screens

## Establishing Treatment Goals and a Written Treatment Plan:

### 4. Establish treatment goals

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#### 4.1 Recommendation:

When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.

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The treatment plan should be tailored to the patient's circumstances and the characteristics and pathophysiology of the pain. The pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function and therefore should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan whenever possible, to maximize the likelihood of achieving treatment goals.

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#### 4.2 Recommendation:

Goals for treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.  
*Reference Guidelines: 1, 3, 5*

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For most chronic pain conditions, complete elimination of pain is an unreasonable goal (College of Physicians and

Surgeons of Ontario, 2000). Goals for treatment of chronic pain should include improvement in the tolerability of the pain and in function (College of Physicians and Surgeons of Ontario, 2000). The clinician should counsel the patient on reasonable expectations for treatment outcomes so that together they can agree on achievable treatment goals addressing pain, function, and quality of life.

The pathophysiologic basis of the pain can help establish a prognosis for future improvement (or worsening) in function and pain and should influence the goals of treatment. Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcome (VA/DOD, 2003; Hegmann, Feinberg, Genovese, Korevaar, & Mueller, 2008). These include:

- Objective physical findings obtained by the examining clinician (e.g., improved strength, range of motion, aerobic capacity);
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions); and
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living, and frequency and intensity of conditioning).

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale
- Psychosocial status (e.g., increased social engagement or decreased emotional distress)
- Familial status (e.g., improved relationships with or decreased burden on family members)
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Pain intensity should be assessed at each visit using a standard instrument such as the Numerical Rating Scale. See the Pain Management Evaluation Tool, Patient Pain and Medication Tracking Chart, Sheehan Disability Scale, and Brief Pain Inventory Form in the Tool Section or page 17 of VA/DOD guidelines.

Clinicians should consider cultural differences in assessing function, quality of life, and pain intensity (See <http://prc.coh.org/culture.asp> for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient's condition with these persons should have previously been obtained and documented (See Recommendation 5.5).

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#### 4.3 Recommendation:

Treatment goals should be developed jointly by patient and clinician. *Reference Guidelines: 2*

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Engage patients in their own healthcare. Clinicians have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the clinician should focus not just on pain control, but also on treating the patient's underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany Recommendation 4:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
- Sample Treatment Plan for Prescription Opioids
- Cultural considerations in assessing function, quality of life, and pain intensity:  
<http://prc.coh.org/culture.asp>

## 5. Informed consent and formulation of a treatment plan

### 5.1 Recommendation:

The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.

*Reference Guidelines: 4*

The patient should be counseled about appropriate use of the medication, possible adverse effects, and the risks of developing tolerance, physical or psychological dependence, and withdrawal symptoms (Trescot et al., 2008; WSAMDG, 2007). Adverse effects can include nausea, constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Hegmann et al., 2008), opioid-induced hyperalgesia (Hegmann et al., 2008; WSAMDG, 2007), allodynia (WSAMDG, 2007), abnormal pain sensitivity (WSAMDG, 2007), and depression (Daniell, 2007).

Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long term complete pain relief. Without careful guidance this may lead the patient to seek excessive dosing of opioids and to disappointment.

Sedation and cognitive impairment may occur when patients are taking opioid medication. Therefore, discuss with patients the need for caution in operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.<sup>5</sup>

Ensure the patient does not have any absolute contraindications and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent)
- Co-administration of drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed)

More detail about absolute contraindications is contained in the Tool Section.

Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

Signs of respiratory depression:

- Snoring heavily and cannot be awakened
- Periods of ataxic (irregular) or other sleep disordered breathing
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having an increased or decreased heartbeat
- Feeling faint, very dizzy, confused or has heart palpitations

### 5.2 Recommendation:

The patient and, when applicable, the family or caregiver should both be involved in the educational process.

*Reference Guidelines: 1*

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver (VA/DOD, 2003). Educating the family about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is crucial to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information about the patient can be disclosed to others, such as family members, and under what conditions discussions about the patient with others are allowed.

<sup>5</sup> Health care professionals are responsible to “counsel their patients about how their condition affects safe driving. For example, if medication is prescribed for a patient which may cause changes in alertness or coordination, the health care professional shall advise the patient about how the medication can affect safe driving, and when it would be safe to operate a vehicle.” R708-7-6(1)(b) Utah Administrative Code A health care professional or other person who becomes aware of a physical, mental, or emotional impairment that appears to present an imminent threat to driving safety and reports this information to the division in good faith has immunity from any damages claimed as a result of making the report. (§53-3-303(14)(c) Utah Code Annotated) Federal law prohibits driving a commercial motor vehicle while under the influence of a narcotic (CFR §391.15).

**5.3 Recommendation:**

The treatment plan, which defines the responsibilities of both patient and clinician, should be documented.

*Reference Guidelines: 1, 2, 3, 4, 5*

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. They could also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber (VA/DOD, 2003).

The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment “contract” or “agreement” that is signed by the patient. Patients should be encouraged to store opioid medication in a lock box to keep the medication out of the hands of others who should not have access to them.

**5.4 Recommendation:**

The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum medication level screening upon request, and reasons for possible discontinuation of drug therapy. *Reference Guidelines: 1, 2, 4, 5, 6*

The treatment plan (sometimes referred to as treatment “contracts” or “agreements”) should contain the items that were developed jointly by patient and clinician, such as follow-up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the agreement and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications (VA/DOD, 2003; Trescot et al., 2008) or obtaining them from multiple providers as documented by Utah’s Controlled Substance Database Program.

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use (VA/DOD, 2003; Trescot et al., 2008).

- Prohibition on use with alcohol or certain other medications (VA/DOD, 2003)
- Documentation of counseling regarding driving or operating heavy machinery (VA/DOD, 2003 Hegmann et al., 2008)
- Specific frequencies of urine testing

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only (VA/DOD, 2003; Trescot et al., 2008; Federation of State Medical Boards, 2004).

It is not necessary to include specific consequences for specific non-compliant behaviors, but it should be documented in the treatment agreement that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship and of opioid prescribing by that clinician.

A Sample Treatment Plan for Prescribing Opioids is included in the Tool Section.

**5.5 Recommendation:**

Discuss involvement of family members in the patient’s care and request that the patient give written permission to talk with family members about the patient’s care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the physician may want to consider a family conference to help assess the patient’s integrity (Trescot et al., 2008). Consultation with others, however, must be done within the constraints of HIPAA, as noted above (See Recommendation 5.2). Guidance about communications with family and others under HIPAA can be found at: [http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/provider\\_ffg.pdf](http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/provider_ffg.pdf)

Tools to accompany Recommendation 5:

- Absolute Contraindications to Opioid Prescribing
- Sample Treatment Plan for Prescribing Opioids

## Initiating, Monitoring, and Discontinuing Opioid Treatment:

### 6. Initiate opioid therapy as a treatment trial

#### 6.1 Recommendation:

Opioid medication should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life.

The clinician should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid medication treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to Recommendation 9 for more information on discontinuation of treatment.

#### 6.2 Recommendation:

In most instances, the trial should begin with short-acting opioid medication.

Short-acting opioid medications are in general safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the prescriber may consider switching the patient to a long-acting or sustained-release formulation (See the Dosing Guidelines in the Tool Section). The patient's individual situation should influence whether the patient is switched from short-acting medication. Treatment with long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

#### 6.3 Recommendation:

Parenteral<sup>6</sup> (intravenous, intramuscular, subcutaneous) administration of opioids for chronic pain is, in general, discouraged. *Reference Guidelines: 2*

Daily IM or SC injections should be avoided except under a highly supervised environment such as during an admission to the hospital or hospice.

Tools to accompany Recommendation 6:

- Dosing Guidelines
- COMM

### 7. Titration phase

#### 7.1 Recommendation:

Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). *Reference Guidelines: 1*

Follow-up face-to-face visits should occur at least every 2-4 weeks during the titration phase. More frequent follow-up visits may be advisable and caution should be used when prescribing opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused) (College of Physicians and Surgeons of Ontario, 2000).

#### 7.2 Recommendation:

When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered. *Reference Guidelines: 1, 2*

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than

<sup>6</sup> These guidelines did not consider intrathecal administration and this recommendation was not intended to discourage trained and qualified physicians from using intrathecal opioid medications.

necessary by going too slowly with the risk of causing harm, including fatal overdose, by going too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient (VA/DOD, 2003). Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of opioid measured in morphine equivalents. It is likely that the risk-benefit ratio is less favorable at higher doses. Clinical vigilance is needed at all dosage levels of opioids but is even more important at higher doses. Clinicians who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. No clear threshold for high dose has been established based on evidence. The Washington State guideline (WSAMDG, 2007) suggested a threshold of 120 mg of morphine equivalent per day, but has been criticized for that decision. It seems reasonable to increase clinical vigilance at daily doses that exceed 120-200 mg of morphine equivalent per day.

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to Use Only as Directed, that is, not to change doses or frequency of administration without specific instructions from the clinician.

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### 7.3 Recommendation:

During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the Controlled Substances Database at least quarterly.

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For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

## 8. Maintenance – Periodic monitoring and dose adjustments:

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### 8.1 Recommendation:

Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. *Reference Guidelines: 2, 4*

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Assess each of the following four areas of concern at each visit: Analgesia, activity, adverse effects, and aberrant behavior. These assessments can be remembered as the “four A’s” (Passik & Weinreb, 2000):

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess both the patient’s function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior

A sample checklist for signs of aberrant behavior is included in the Tool Section.

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### 8.2 Recommendation:

Providers should consider performing drug screening on randomly selected visits and any time aberrant behavior is suspected.

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As discussed in recommendation 3, drug testing has been shown to identify problems that might otherwise go undetected. It may not be appropriate or necessary for all patients, but should be strongly considered by providers and may provide an opportunity to discuss the risks and problems that can occur with opioid treatment. Base the frequency of random drug screening on the assessed degree of risk of aberrant behavior for the individual patient. Pill counts may also be useful in some circumstances.

**8.2 Recommendation:**

During maintenance phase, Controlled Substances Database should be checked at least annually.

After the titration phase is complete and the maintenance phase is underway, the frequency of checks of the Controlled Substances Database can be based on clinical judgment, but should be done no less than annually. The Controlled Substances Database should be checked more often for high risk patients and patients exhibiting aberrant behavior. For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Consider evaluating for possible drug abuse-related behavior at each visit. A sample checklist is included in the Tool Section.

Provide reinforcement for previous counseling and additional education for patients at follow-up visits (Trescot et al., 2008).

Review the pathophysiologic hypothesis (to see if the diagnosis is still valid) at each visit (Trescot et al., 2008).

**8.3 Recommendation:**

Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals. *Reference Guidelines: 4*

These include reduction in a patient's pain scores and improved physical, psychological and social function. If treatment goals, including patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications (WSAMDG, 2007; Federation of State Medical Boards, 2004).

A frequent need for dose adjustments after a reasonable time interval of titration is an indication to reevaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

**8.4 Recommendation:**

Adjustments to previously stable maintenance therapy may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.

*Reference Guidelines: 1*

Options for adjustment include reducing medication or rotating opioid medication. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., addition of supplemental short-acting medications for control of break-through pain exacerbation (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success (Quang-Cantagrel, Wallace, & Magnuson; 2000).

Only if the patient's situation has changed permanently and consideration has been given to increased risk of adverse events, is it reasonable to consider an ongoing increase in maintenance dosing (VA/DOD, 2003).

If rotating among different opioid medications, refer to a standard dosing equivalence table taking into account the current drug's half-life. (See the Dosing Guidelines in the Tool Section)

In general, if the patient's underlying medical condition is chronic and unchanging and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level (VA/DOD, 2003).

**8.5 Recommendation:**

Dosing changes should generally be made during a clinic visit. *Reference Guidelines: 1*

If the patient's underlying pain-producing chronic medical condition improves, it is expected that the clinician will begin tapering the patient off the opioid medication (See Recommendation 10 for guidelines on discontinuation.)

Tapering opioid medication with or without the goal of discontinuation may be performed as described below (Recommendation 10) or as described in Strategies for Tapering and Weaning in the Tool Section.

Tools to accompany Recommendation 8:

- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Pain Management Evaluation Tool
- Dosing Guidelines
- Strategies for Tapering and Weaning

## 9. Evaluate the treatment trial

### 9.1 Recommendation:

Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient.

### 9.2 Recommendation:

A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial.

## 10. Discontinuing opioid treatment

### 10.1 Recommendation:

An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated. *Reference Guidelines: 5*

### 10.2 Recommendation:

Discontinuation of opioid therapy is recommended if any of the following occurs:

- Dangerous or illegal behaviors are identified
- Patient claims or exhibits a lack of effectiveness
- Pain problem resolves
- Patient expresses a desire to discontinue therapy
- Opioid therapy appears to be causing harm to the patient, particularly if harm exceeds benefit

*Reference Guidelines: 1*

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver (Federation of State Medical Boards, 2004). This decision should include careful consideration of the outcomes of ongoing monitoring.

### 10.3 Recommendation:

When possible, offer to assist patients in safely discontinuing medications even if they have withdrawn from treatment or been discharged for agreement violations.

*Reference Guidelines: 1*

The goal is to taper all patients off opioid medication safely. “Strategies for Tapering and Weaning” in the Tool Section contains advice on tapering opioid medications (WSAMDG, 2007). If the patient is discharged, the clinician is obliged to offer continued monitoring for 30 days post-discharge.

Tools to accompany Recommendation 10:

- Strategies for Tapering and Weaning

## Other Issues:

### 11. Documentation and Medical Records

#### 11.1 Recommendation:

Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed. *Reference Guidelines: 1, 2, 4, 5, 6*

#### 11.2 Recommendation:

A written treatment plan should document objectives that will be used to evaluate treatment success. *Reference Guidelines: 1, 2, 4, 5, 6*

The objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned (Trescot et al., 2008). Use of validated instruments to measure pain and function is preferred. Details on establishing treatment goals and formulation of a treatment plan are covered elsewhere in these guidelines (Recommendations 4 and 5.)

#### 11.3 Recommendation:

The prescription for opioid therapy should be written on tamper-resistant prescription paper in a manner to help reduce the likelihood of prescription fraud or misuse. *Reference Guidelines: 2*

The written prescription for opioid therapy should contain the name of the drug, the strength, the number of dosage units, (written numerically and in text), how the drug is to be taken, the full name, address, and age of the patient, the name, address, and DEA registration number of the practitioner, and the signature of the physician or other authorized practitioner. It shall be dated and signed on the day when issued. After a stable maintenance therapy dosage has been established and therapy goals have been achieved, schedule II opioid medications may be prescribed for three months by providing the patient

with prescriptions for each of the three months. Each prescription for a one month supply of medication should include the date the prescription is written and the date when that prescription is to be filled.

To reduce the chance of tampering with the prescription, write legibly, and keep a copy (College of Physicians and Surgeons of Ontario, 2000). (See the Tamper Resistant Requirements in the Tool Section.)

#### 11.4 Recommendation:

Assessment of treatment effectiveness should be documented in the medical record. *Reference Guidelines: 2, 4, 5*

Document the patient's progress toward treatment goals, including functional status, at every visit, rather than merely reporting the patient's subjective report of decreased pain. Ideally, this progress would be evaluated using validated tools (Trescot et al., 2008).

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may affect the efficacy of treatment or risks of adverse events should be evaluated and documented at every visit.

#### 11.5 Recommendation:

Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record. *Reference Guidelines: 1*

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics
- Follow-up referrals, tests, and other therapies

Clinicians are encouraged to make use of resources provided by the state of Utah that are designed to assist them in managing patients with aberrant behavior (See Checklist for Adverse Effects, Function, and Opioid Dependence and Signs of Substance Misuse in Tool Section). Referral to law enforcement/legal agencies may be appropriate if actions by patients are occurring that could be criminal in nature (VA/DOD, 2003). Clinicians

should consider consulting with legal counsel before contacting law enforcement (VA/DOD, 2003). Serious non-adherence issues (illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid therapy. See Recommendation 10.

Tools to accompany Recommendation 11:

- Tamper Resistant Requirements
- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse

## 12. Consultation and management of complex patients

### 12.1 Recommendation:

Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment. *Reference Guidelines: 4, 5*

Prescribers may wish to consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis;
- The patient has significant co-morbidities (including psychiatric illness);
- The patient is high-risk for aberrant behavior or addiction; or
- The clinician suspects development of significant tolerance, particularly at higher doses.

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

### 12.2 Recommendation:

Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment.

*Reference Guidelines: 1, 4, 5*

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Utah where there is a shortage of readily available addiction specialists. The Directory of Resources in the Tool Section includes information on available resources for these patients.

### 12.3 Recommendation:

Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or substance use disorder specialist if available, for recommendations on the treatment plan and possibly for assistance in management.

The clinician may consider prescribing opioid medication for pain even if the patient has a self-reported or documented previous problem with opioids, as long as monitoring is performed during titration and maintenance phase.

### 12.4 Recommendation:

Patients with coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation (Trescot et al., 2008; Federation of State Medical Boards, 2004). Unless the clinician treating the patient is qualified to provide the appropriate care and evaluation of the coexisting psychiatric disorder, consultation should be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric conditions.

Tools to accompany Recommendation 12:

- Strategies for Tapering and Weaning
- Directory of Resources

### 13. Methadone

#### 13.1 Recommendation:

Methadone should only be prescribed by clinicians familiar with its risks and use, and who are prepared to conduct the necessary careful monitoring.

Methadone-related death rates have been increasing in Utah and the U.S. In 2006, methadone was implicated in 30% of non-illicit drug-related deaths in Utah. Methadone was the most common drug identified by the Utah Medical Examiner as causing or contributing to accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during 1998-2004. From 1997-2004, population-adjusted methadone prescriptions increased 727%. The increase in the methadone prescription rate was for treatment of pain and not addiction therapy.

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect.

Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone metabolism is complicated and varies among individuals. Methadone interacts with several other medications that can alter its metabolism changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in a patient taking other medications and before starting any medication in a patient taking methadone.

Methadone can prolong the rate-corrected QT interval (QTc) and increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias or cardiac conduction abnormalities and in patients taking another medication

associated with QTc interval prolongation (Arizona Center for Education and Research on Therapeutics 2008). A useful on-line reference of such medications is available at: <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>

Clinicians should consider obtaining an electrocardiogram (ECG) to evaluate the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline (Krantz 2009) recommended that an ECG be performed before prescribing methadone, within the first 30 days, and annually. Additional ECG examinations were recommended if the methadone dose exceeds 100 mg per day or if a patient on methadone has unexplained syncope or seizure. Guidance was provided for actions to be taken at two levels of QTc prolongation (450-500 ms and greater than 500 ms).

Methadone and other opioids have been associated with worsening obstructive sleep apnea and new onset of central sleep apnea. Clinicians should question patients about symptoms and signs of sleep apnea and consider obtaining a sleep study in patients treated with opioids if they develop any signs of sleep-disordered breathing or respiratory depression. This is particularly important for patients receiving higher doses of opioid medications. In one recent study, 92% of patients on opioid doses at or above 200 mg morphine equivalents had developed ataxic or irregular breathing (Walker, 2007).

Some clinicians recommend that all patients for whom higher doses of opioid medications are considered should be tested with a sleep study.

Tools to accompany Recommendation 13:

- Dosing Guidelines
- The Role of Methadone in the Management of Chronic Non-Malignant Pain

## GLOSSARY

Term	Definition
<b>Aberrant drug-related behavior</b>	A behavior associated with drug abuse, addiction, and diversion.
<b>Abuse</b>	Maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Often with the intent of seeking a psychotropic/euphoric effect.
<b>Acute pain</b>	An episode of pain lasting six weeks or less
<b>Addiction</b>	A primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
<b>Breakthrough pain</b>	An acute worsening of pain in a person with chronic pain.
<b>Chronic pain</b>	An episode of pain lasting more than three months
<b>Chronic non-cancer pain</b>	Chronic pain that is not associated with active cancer or occurs at the end of life
<b>Diversion</b>	The intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution.
<b>Hyperalgesia</b>	Increased or heightened sensation to pain or pain stimulation.
<b>IADL</b>	Instrumental activities of daily living are activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, and using a telephone
<b>Misuse</b>	Use of a drug in ways other than prescribed by a health professional. Misuse usually does not include use for euphoric or psychotropic effects—that would be classified as “abuse”

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<b>Term</b>	<b>Definition</b>
<b>Physical Dependence</b>	A state of adaptation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
<b>Pseudo addiction</b>	The development of abuse-like behaviors due to unrelieved pain, and that should be eliminated by measures that relieve the pain.
<b>Trial Period</b>	A period of time during which the effectiveness of using opioids is tested to see if goals of functionality and decreased pain are met. A trial should occur prior to treating someone with long-acting opioids and should include goals. If trial goals are not met, the trial should be discontinued and an alternative approach taken to treating the pain.
<b>Tolerance</b>	A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time.

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- Absolute Contraindications to Opioid Prescribing
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- Information for Patients—Opioid Analgesics for Non-Cancer Pain
- The Role of Methadone in the Management of Chronic Non-Malignant Pain
- Dosing Guidelines

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- Directory of Resources
- Utah’s Tamper Resistant Requirements

**For more tools and information visit:**

<http://prc.coh.org/culture.asp>  
<http://www.PainEdu.org>

**The tools found in this publication can be downloaded from:**

[www.health.utah.gov/prescription](http://www.health.utah.gov/prescription)

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## Pain Management and Evaluation Tool

TOOLS

Pain Management Work up and Risk Assessment							
Name		ID#		Date			
Pain Dx's:				DOB		Comments	
				Gender M/F			
Opiod Risk Tool <sup>1</sup>	Mark all that apply	Score if Female	Score if Male	Additional Risk Assessments		Comments	
				Drug Screen	Y/N		
<b>Family Hx of Substance Abuse</b>				DOPL Screen	Y/N		
Alcohol	<input type="checkbox"/>	1	3	Risk of Obstructive Sleep Disorder	Y/N		
Illeg Drugs	<input type="checkbox"/>	2	3				
Prescrp	<input type="checkbox"/>	4	4				
<b>Personal Hx of Substance Abuse</b>				Obesity Y/N	BMI =		
Alcohol	<input type="checkbox"/>	3	3	Hx of Sleep Apnea	Y/N		
Illeg Drugs	<input type="checkbox"/>	4	4				
Prescrp	<input type="checkbox"/>	5	5				
<b>Hx of Preadolescent Sexual abuse</b>		<input type="checkbox"/>	3	0	<b>Baseline Measures</b>		Comments
					Analgesia <sup>2</sup> (Pain 0-10)		
<b>Age</b>	16-45 yrs	<input type="checkbox"/>	1	1	Activity <sup>3</sup> (Function 0-10)		
<b>Depression</b>		<input type="checkbox"/>	1	1	Adverse Events Y/N		
<b>Psychiatric Disease</b>					Aberrant Behavior Identify		
	ADD	<input type="checkbox"/>	2	2			
	OCD	<input type="checkbox"/>	2	2			
	Bipolar	<input type="checkbox"/>	2	2			
	Skiz	<input type="checkbox"/>	2	2			
<b>Total</b>		<input type="checkbox"/>					Comments
<b>Consultation/Referral:</b>							
If receiving Morphine equivalent ≥ 120 mg/day or Methadone ≥ 50 mg/day				<b>then</b>	Sleep Apnea Test	Y/N	
If receiving Methadone ≥ 50 mg				<b>then</b>	EKG (Qt)	Y/N	
<b>Treatment agreement discussed and signed by patient</b>						<b>Date</b>	
<b>Patient Goals</b>			Identify aberrant behavior which indicates discontinuation				
Analgesia Pain <sup>2</sup> (0-10)	Activity - Function <sup>3</sup> (0-10)	Adverse Events - #					
<small><sup>1</sup> Opioid Risk Tool (Webster &amp; Dove, 2007 - low risk (routine care), moderate risk (increased monitoring frequency) high risk (consider referral to Substance Abuse and/or Pain Management specialists)  <sup>2</sup> Pain Intensity 0 = no pain, 5 = moderate pain, 10 = worst pain imaginable  <sup>3</sup> Activity Function 0= no limitations, 5 = limitations (difficulty working, lifting, exercising, or conducting daily living activities) 10 = severe limitations (unable to work, conduct daily living activities, lift, or exercise)</small>							

## Pain Management and Evaluation Tool

Pain Management Follow-Up							
Name			ID#		Date		
Pain Dx's:					DOB		
					Gender M/F		
Initiation of Trial			Start Date		Review Date		
Visit Frequency <sup>1</sup> Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation Change (Date)
Titration - Visit = 2 - 4 weeks							
Visit Frequency <sup>1</sup> Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation Change (Date)
Maintenance - Visit = Quarterly							
Visit Frequency <sup>1</sup> Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation Change (Date)
<sup>1</sup> Webster 2008 Monitoring Frequencies Low Risk (0-3) Routine Mod Risk 4-7 Bi-Weekly High Risk ≥ 8 Weekly							

TOOLS



## Sheehan Disability Scale

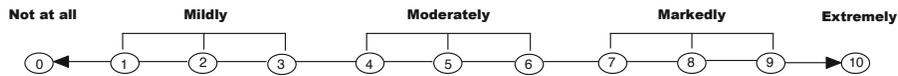
# SHEEHAN DISABILITY SCALE

## A BRIEF, PATIENT RATED, MEASURE OF DISABILITY AND IMPAIRMENT

Please mark **ONE** circle for each scale.

### WORK\* / SCHOOL

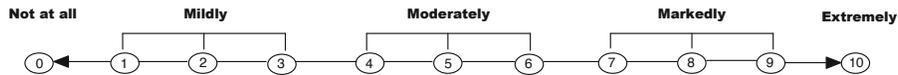
The symptoms have disrupted your work / school work:



I have not worked /studied at all during the past week for reasons unrelated to the disorder.  
\* Work includes paid, unpaid volunteer work or training

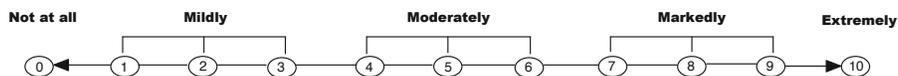
### SOCIAL LIFE

The symptoms have disrupted your social life / leisure activities:



### FAMILY LIFE / HOME RESPONSIBILITIES

The symptoms have disrupted your family life / home responsibilities:



### DAYS LOST

On how many days in the last week did your symptoms cause you to miss school or work or leave you unable to carry out your normal daily responsibilities? \_\_\_\_\_

### DAYS UNDERPRODUCTIVE

On how many days in the last week did you feel so impaired by your symptoms, that even though you went to school or work, your productivity was reduced? \_\_\_\_\_

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## Brief Pain Inventory Form

4) Please rate your pain by circling the one number that best describes your pain at its **LEAST** in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No										Pain as bad as
pain										you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the **AVERAGE**.

0	1	2	3	4	5	6	7	8	9	10
No										Pain as bad as
pain										you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have **RIGHT NOW**.

0	1	2	3	4	5	6	7	8	9	10
No										Pain as bad as
pain										you can imagine

7) What treatments or medications are you receiving for your pain?

8) In the past 24 hours, how much **RELIEF** have pain treatments or medications provided? Please circle the one percentage that most shows how much.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No										Complete
relief										relief

9) Circle the one number that describes how, during the past 24 hours, **PAIN HAS INTERFERED** with your:

A. General Activity:

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interferes

## Brief Pain Inventory Form

C. Walking ability										
0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	
D. Normal work (includes both work outside the home and housework)										
0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	
E. Relations with other people										
0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	
F. Sleep										
0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	
G. Enjoyment of life										
0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	
<p>Used with permission. May be duplicated and used in clinical practice.                  Source: Dr. Charles Cleeland, Anderson Cancer Center, Pain Research Group, 1100 Holcombe, Houston, TX 77030.</p>										

## Sample Treatment Plan for Prescribing Opioids

### Treatment Plan Using Prescription Opioids

Patient name: \_\_\_\_\_

Prescriber name: \_\_\_\_\_

**THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.**

I (patient) understand the following (initial each):

\_\_\_\_\_ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: \_\_\_\_\_

\_\_\_\_\_ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: \_\_\_\_\_

\_\_\_\_\_ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

\_\_\_\_\_ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

\_\_\_\_\_ There is a risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

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## Sample Treatment Plan for Prescribing Opioids

**I agree to the following (initial each):**

\_\_\_\_ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

\_\_\_\_ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

\_\_\_\_ I agree not to share, sell, or in any way provide my medication to any other person.

\_\_\_\_ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

\_\_\_\_ I agree not to seek or obtain **ANY** mood-modifying medication, including pain relievers or tranquilizers from **ANY** other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

\_\_\_\_ I agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

\_\_\_\_ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

\_\_\_\_ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

**I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.**

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

SF-12

TOOLS

## Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an  in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Yes, limited a lot	Yes, limited a little	No, not limited at all
▼	▼	▼

- a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....  1 .....  2 .....  3
- b. Climbing several flights of stairs .....  1 .....  2 .....  3

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**SF-12**

TOOLS

**3. During the past 4 weeks, how much of the time have you had any of the result of your physical health?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- a Accomplished less than you would like .....  1 .....  2 .....  3 .....  4 .....  5
- b Were limited in the kind of work or other activities.....  1 .....  2 .....  3 .....  4 .....  5

**4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- a Accomplished less than you would like .....  1 .....  2 .....  3 .....  4 .....  5
- b Did work or other activities less carefully than usual .....  1 .....  2 .....  3 .....  4 .....  5

**5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

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**SF-12**

**6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Did you have a lot of energy? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Have you felt downhearted and depressed? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

**7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

***Thank you for completing these questions!***

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## COMM

The Current Opioid Misuse Measure (COMM)<sup>®</sup> is a brief paper and pencil self-administered patient questionnaire to help monitor chronic pain patients who are on chronic opioid therapy. The COMM helps clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with the misuse or abuse of opioid medications. Validated in 2006 and unlike other available predictive measures, the objective was to provide clinicians with an assessment tool to periodically monitor misuse of medication for patients who have been prescribed opioids for an extended period of time over the course of treatment. Additionally, the COMM serves as an ideal way to help document risk assessment over the continuum of care with opioid treatment.

The COMM tool, instructions for administration, and scoring information guide are available for download for individual clinician use at <http://www.painedu.org/registration.asp?target=terms>.

## COMM

### Current Opioid Misuse Measure (COMM)<sup>®</sup>

The Current Opioid Misuse Measure (COMM)<sup>®</sup> is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP)<sup>®</sup> is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM is for clinician use only. The tool is not meant for commercial distribution.
- The COMM is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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## COMM

### Current Opioid Misuse Measure (COMM)<sup>®</sup>

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	<input type="radio"/>				
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	<input type="radio"/>				
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	<input type="radio"/>				
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	<input type="radio"/>				
5. In the past 30 days, how often have you seriously thought about hurting yourself?	<input type="radio"/>				
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	<input type="radio"/>				

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**COMM**

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	<input type="radio"/>				
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	<input type="radio"/>				
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	<input type="radio"/>				
10. In the past 30 days, how often have you been worried about how you're handling your medications?	<input type="radio"/>				
11. In the past 30 days, how often have others been worried about how you're handling your medications?	<input type="radio"/>				
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	<input type="radio"/>				
13. In the past 30 days, how often have you gotten angry with people?	<input type="radio"/>				
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	<input type="radio"/>				
15. In the past 30 days, how often have you borrowed pain medication from someone else?	<input type="radio"/>				
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	<input type="radio"/>				

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**COMM**

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	○	○	○	○	○

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TOOLS

**COMM****Scoring Instructions for the Current Opioid Misuse Measure (COMM)<sup>®</sup>**

To score the COMM, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
<b>&gt; or = 9</b>	<b>+</b>
<b>&lt; 9</b>	<b>-</b>

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM is at different cutoff values. These values suggest that the COMM is a sensitive test. This confirms that the COMM is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM score (at a cutoff of 9) is over 2 times (2.26 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM score suggests the patient is really at low-risk, while a high COMM score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 9 or above	.77	.66	.66	.95	2.26	.35

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## SOAPP-R

The  *Screener and Opioid Assessment for Patients with Pain- Revised Version (SOAPP®-R)*  is a brief paper and pencil self-administered patient questionnaire that was developed for clinicians to help them better assess and determine how much monitoring a patient on long-term opioid therapy might require prior to prescription. The SOAPP®-R was validated in 2008, and is an updated and revised version of SOAPP V.1 originally released in 2003. The use of opioid medications sometimes includes concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Since long-term opioid therapy may carry significant risk in certain patients, the SOAPP®-R is intended to play a role as a quick and easy-to-use tool that can help clinicians identify and mitigate that risk, document risk assessment prior to opioid prescription.

The SOAPP®-R tool, instructions for administration, and scoring information guide are available for download for individual clinician use at <http://www.painedu.org/registration.asp?target=terms>.

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## SOAPP-R

2007 Release

### Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is **NOT** intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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## SOAPP-R

### SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	<input type="radio"/>				
2. How often have you felt a need for higher doses of medication to treat your pain?	<input type="radio"/>				
3. How often have you felt impatient with your doctors?	<input type="radio"/>				
4. How often have you felt that things are just too overwhelming that you can't handle them?	<input type="radio"/>				
5. How often is there tension in the home?	<input type="radio"/>				
6. How often have you counted pain pills to see how many are remaining?	<input type="radio"/>				
7. How often have you been concerned that people will judge you for taking pain medication?	<input type="radio"/>				
8. How often do you feel bored?	<input type="radio"/>				
9. How often have you taken more pain medication than you were supposed to?	<input type="radio"/>				
10. How often have you worried about being left alone?	<input type="radio"/>				
11. How often have you felt a craving for medication?	<input type="radio"/>				
12. How often have others expressed concern over your use of medication?	<input type="radio"/>				

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**SOAPP-R**

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	<input type="radio"/>				
14. How often have others told you that you had a bad temper?	<input type="radio"/>				
15. How often have you felt consumed by the need to get pain medication?	<input type="radio"/>				
16. How often have you run out of pain medication early?	<input type="radio"/>				
17. How often have others kept you from getting what you deserve?	<input type="radio"/>				
18. How often, in your lifetime, have you had legal problems or been arrested?	<input type="radio"/>				
19. How often have you attended an AA or NA meeting?	<input type="radio"/>				
20. How often have you been in an argument that was so out of control that someone got hurt?	<input type="radio"/>				
21. How often have you been sexually abused?	<input type="radio"/>				
22. How often have others suggested that you have a drug or alcohol problem?	<input type="radio"/>				
23. How often have you had to borrow pain medications from your family or friends?	<input type="radio"/>				
24. How often have you been treated for an alcohol or drug problem?	<input type="radio"/>				

Please include any additional information you wish about the above answers.  
Thank you.

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## SOAPP-R

### Scoring Instructions for the SOAPP®-R®

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

#### What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is nearly 4 times (3.80 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	3.80	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

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## SOAPP-R

### ***How does the SOAPP-R help determine appropriate treatment?***

The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

### ***Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater\*)***

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician's care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

*\* Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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## SOAPP-R

### **Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21\*)**

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy.

*\* Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

### **Who is at a low risk for opioid misuse? (SOAPP-R score < 9\*)**

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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## SOAPP-R

Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

*\* Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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## Opioid Risk Tool

Date \_\_\_\_\_

Patient Name \_\_\_\_\_

### OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder	[ ]	2	2
	Obsessive Compulsive Disorder			
	Bipolar			
	Schizophrenia			
	Depression	[ ]	1	1
<b>TOTAL</b>		[ ]		

**Total Score Risk Category**    Low Risk 0 – 3        Moderate Risk 4 – 7        High Risk  $\geq 8$

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## Opioid Risk Tool

*Low-risk* patients should be monitored at a level that could be described as routine. This does not mean these individuals are not monitored with vigilance and care, only that no extraordinary measures are required.

- Explain the standard treatment agreement; both provider and patient should sign it.
- Schedule regular follow-up visits (monthly at first).
- Set the frequency of medication refills (monthly for the first 6 months).
- Perform initial urine (or other) drug screening.
- Communicate with pharmacies or obtain initial reports from prescription-monitoring programs (where available) and prior medical providers.
- Document every patient and clinician interaction.
- Continually review the Four A's during return visits.
- Consultations with specialists are not required.
- Medication type: adequate analgesia, no restrictions.

*Moderate risk* for drug abuse calls for another layer of vigilance in addition to the routine monitoring established for low-risk patients:

- Regular follow-up visits and prescriptions refills should occur every 2 weeks initially.
- Observe patients for signs of complicating co morbid diagnoses, such as anxiety, depression, or a sleep disorder.
- Consider referring the patient for evaluation by pain management and psychiatric specialists.
- Conduct regular checks (every 6-12 months) of your state's prescription monitoring database, if available, or consult with the patient's pharmacist.
- Visit with the patient's family members or other third parties to verify the patient's accounts and for evidence of environmental influences.
- Institute random urinalysis (or another screening method) to confirm compliance with medication levels.
- Consider checking leftover medications to verify their quantity.
- Consider limiting the use of rapid-onset analgesics.

*High-risk* patients require the following measures of intense monitoring in addition to those required by the low-risk and moderate-risk groups:

- Schedule regular follow-up visits more frequently than usual. If problems develop, shorten the treatment interval to weekly.
- Prescribe just enough medication to last until the next appointment and ensure that prescription refills are contingent upon attendance.
- Typically, psychiatric and addiction-medicine consultations are required. Consider consultation with a pain management specialist. Coordinate treatment.
- Conduct regular urine (or other) drug screenings in addition to some unexpected screenings.
- Consider using blood screenings.
- During every visit, count the patient's leftover medication.
- Consult a prescription database (if available) more frequently.
- Strongly enforce the treatment agreement.
- Avoid prescribing rapid-onset analgesics and consider limiting short-acting analgesics.

Webster & Dove, 2007

## Opioid Risk Tool

The 3 risk categories help make treatment decisions easier but should not be used to label patients. Remember that the need to monitor for aberrant behavior is ongoing, and patients can move from 1 risk group to another throughout the course of treatment. For example, a patient initially assessed as low risk may later display multiple aberrant behaviors in response to a deteriorating physical condition or life stresses.

In general, exhibiting more than 3 mildly aberrant behaviors during 1 year or exhibiting 1 egregious behavior should cause a patient to move to a higher risk category and to be monitored more closely. If patients remain in the low-risk category for 6 months, the interval between visits and refills of medication can be increased. Eventually, when patients have remained in the low-risk category for 1 year, refills that last for 3 months are common.

Webster & Dove, 2007

## Urine Drug Testing Devices

### Urine Drug Testing Devices

To the best of our knowledge, this is a comprehensive list of CLIA waived office drug testing devices that test for specific prescription drugs and are under \$10.

Test Name	Analytes that are Tested	Approx. Price
<u>Alfa Scientific Designs, Inc. Instant Verdict Multi-Drug of Abuse Urine Test</u>	Methadone, Morphine-Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	\$8.50
<u>American Bio Medica Rapid TOX</u>	Buprenorphine, Methadone, Opiates, Oxycodone, Propoxyphene- Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	\$4.15
<u>BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)</u>	Methadone, Morphine-Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	\$6.80

Search for CLIA approved tests

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm>

CLIA waived tests

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm>

CLIA waived analytes

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

## Signs of Substance Misuse

### Features of presentation that may alert practitioner to the possibility of substance misuse

- Cutaneous signs of drug abuse - skin tracks and related scars on the neck, axilla, groin, neck, forearm, wrist, foot and ankle. Such marks are usually multiple, hyper-pigmented and linear. New lesions may be inflamed. Shows signs of “pop” scars from subcutaneous injections.
- Being assertive, aggressive or emotionally labile
- Current intoxication/withdrawal
- May show unusual knowledge of controlled substances.
- Gives medical history with textbook symptoms or gives evasive or vague answers to questions regarding medical history.
- Reluctant or unwilling to provide reference information. May have no General Practitioner.
- Will often request a specific controlled drug and is reluctant to try a different drug.
- Generally has no interest in diagnosis - fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation.

## Checklist for Adverse Effects, Function, and Opioid Dependence

### Checklist for adverse effects

- Constipation, sweating, nausea
- Exacerbation of sleep apnea, COPD
- Opioid bowel syndrome
- Rebound headaches
- Fatigue and confusion (particularly in the elderly)
- Reproductive effects (impotence in men and menstrual irregularities in women)
- Sensitization to pain (higher opioid doses may be required in acute pain compared to stable chronic pain)
- Neurotoxicity, seizures and hallucinations (for example with repeated administration of Demerol)

### Checklist for function that should be assessed

- Sleep
- Mood
- Libido
- Time out of bed, ability to sit, ability to stand
- Activities within the house and outside (e.g., household chores, shopping, etc.)
- Activities at work (return to work, modified duties, trial employment, etc.)

### Checklist for signs of opioid dependence

- On high and escalating doses of opioids
- Frequently runs out of medicine early observed to be intoxicated or in withdrawal
- Alters, borrows, steals, or sells prescriptions
- Accesses multiple sources of opioids, including from ERs, other prescribers, friends, acquaintances, or on the street \*
- Injects oral medications
- Threatens or harasses staff to get immediate appointment
- Reluctant to try alternatives
- Angry, demanding, or tearful if not given drug of choice
- Deterioration of functional status while in receipt of opioid
- Concurrent abuse of alcohol or other illicit drugs
- Multiple dose escalations or other noncompliance with therapy despite warnings
- Multiple episodes of prescription loss

## Federal Guidelines on Proper Disposal of Prescriptions



### Proper Disposal of Prescription Drugs

#### Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

- Actiq** (fentanyl citrate)
- Daytrana Transdermal Patch** (methylphenidate)
- Duragesic Transdermal System** (fentanyl)
- OxyContin Tablets** (oxycodone)
- Avinza Capsules** (morphine sulfate)
- Baraclude Tablets** (entecavir)
- Reyataz Capsules** (atazanavir sulfate)
- Tequin Tablets** (gatifloxacin)
- Zerit for Oral Solution** (stavudine)
- Meperidine HCl Tablets****Percocet** (Oxycodone and Acetaminophen)
- Xyrem** (Sodium Oxybate)
- Fentora** (fentanyl buccal tablet)

Note: Patients should always refer to printed material accompanying their medication for specific instructions.

Office of National Drug Control Policy  
ONDCP, Washington, D.C. 20503p (202)  
395-6618 f (202) 395-6730



[www.WhiteHouseDrugPolicy.gov](http://www.WhiteHouseDrugPolicy.gov)

## Non-Opioid Pain Management Tool

### Non-Opioid Pain Management Tool

Area/Type of Pain	Treatment Options (Strongest Recommendations listed first)	When to Initiate	Population	Duration/Indication of Treatment	Cautions/MISC
Back Pain <4 weeks	Directed Exercise Program ( 1, 2, 3, 4, 5, 6)	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss (2)	Immediately	All ages	Life long	Consider co morbidities
	Ice/Heat (2, 4, 6, 7)	During the first 1-4 days	All ages	Most effective in first 1-3 days	Consider co morbidities
	Acetaminophen up to 4 g/day (1, 2, 4, 6, 8, 9)	Immediately	Adults	Can be long term	Consider co morbidities
	Physical therapy (4, 6, 10, 11)	After 3 weeks of conservative therapy	Adults	1-2 visits	Consider co morbidities
	NSAIDs (2, 4, 6, 9, 12)	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers (4, 9, 13)	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Back School (14, 15)	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain.
	Tramadol/acetaminophen (2)	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
Back Pain >4 weeks	Tramadol (2)	After initial acetaminophen trial	Adults	Can be long term	Consider co morbidities
	Manipulation (1, 4, 6, 16, 17, 18, 19)	Most effective when used for pain <6 weeks of duration without radiculopathy	Adults	3-4 weeks of treatment has been studied. Up to 8 treatments.	Consider co morbidities, not shown to be better than other therapies. Not to be used with herniated disks
	Directed Exercise Program (1, 2, 3, 4, 5, 8, 18, 19)	Immediately	Adults	Life Long	Consider co morbidities
	Yoga exercises (viniyoga) (20)	Immediately	Adults	Life Long, studies for 12 weekly sessions	Has been shown to be as or more beneficial than exercise in some studies.
	Controlled Weight Loss (2)	Immediately	Adults	Life Long	Consider co morbidities
	Acetaminophen up to 4 g/day (1, 2, 4, 8)	Immediately	Adults	Can be long term	Consider co morbidities

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NSAIDs (2, 4, 12)	Immediately, recommend acetaminophen trial first. Some evidence that NSAIDs are equal with acetaminophen in chronic low back pain (21) Some evidence that it is superior at pain control. (22)	Adults with no CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
Muscle Relaxers (4, 13)	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing, some studies did not show any benefit after 3-4 weeks of injury
Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and no CV risk factors	Adults with no CV risk factors	Short term	Consider co morbidities, no CV risk factors
Back School (14, 15, 18)	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain. Swedish Back School program was studied.
Tricyclic antidepressants (9, 23)	After 3-4 weeks and failing conservative therapy, acetaminophen	Adults	As long as deemed beneficial	Have significant side effects profile, consider co morbidities
Tramadol/acetaminophen (2)	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
Tramadol (2)	After failing acetaminophen trial, co administration with acetaminophen has been shown to have more favorable results	Adults	Can be long term	Consider co morbidities
Injections, epidural/facet joints (24, 25)	After failing conservative treatment	Adults	As long as beneficial, if effective often last 1-4 months in duration, can be used to help diagnosis and evaluate for additional treatment options	Choose population according to guidelines. There are conflicting opinions on efficacy
Physical Therapy (10, 11)	Recommend starting immediately	Adults	1-2 visits	Consider co morbidities
Massage Therapy (26, 27, 28)	Recommended in conjunction exercise and education	Adults	As long as beneficial has been shown to be effective for up to one year, >5 visits shows better results, most studies showed results in 6-10 treatments	Some disagreement in literature, but done by licensed therapist found to be more effective
Neuroreflexotherapy (29)	Only in Chronic LBP	Adults	Undetermined	Preliminary this has shown some effect.

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Neck Pain	Directed Exercise Program (1, 2, 3, 6, 30)	Within 7-10 days of injury	All ages	Life long	Requires lengthy training of practitioner to be considered effective Consider co morbidities, can add mechanical manipulation to an exercise program
	Acetaminophen 4g/day maximum (2, 6, 31)	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs (6, 12, 31)	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Physical Therapy (6)	After 2 weeks of conservative treatment	Adults	1-2 visits for education, counseling of home exercise	Consider co morbidities
	Manipulation (6)	Once more conservative measures fail	Adults	Best when combined with exercise	Consider co morbidities, rare instances of CVA
	IV methylprednisolone (31)	Within 8 hours of injury for acute whiplash	Adults	One time treatment	Any contraindications to IV steroids.
	IM Lidocaine (31)	Chronic neck pain with arm symptoms	Adults	Only a few treatments indicated	Consider co morbidities
	Muscle Relaxers (31)	Immediately	Adults	Short term	Consider co morbidities
	Acupuncture (32)	After failing exercise and/or acetaminophen/NSAIDs	Adults	Ideally 6 or more treatments, effects have been shown for short-term pain relief	Consider co morbidities
	Directed exercise program (33)	Immediately	Adults	When the HA is a result of a mechanical neck disorder	Consider co morbidities
	Acetaminophen 4g/day maximum (34)	Immediately	Adults	Long term, has not been shown to be effective in migraines	Consider co morbidities
	NSAIDs (12, 35, 36)	Immediately	Adults	Short term, shown to be effective in both migraine and non-migraine HAs	Consider co morbidities, not to be used with CV, renal or GI risk factors
	Triplians (36, 37)	Use if unable to control HA with NSAIDs and or acetaminophen	Adults	Beneficial for migraine headaches, IM has been shown to be more effective than oral, but both are superior to placebo. Sumatriptan most studied	Consider co morbidities
	Excedrin (36)	Immediately	Adults	Shown to be beneficial in Acute migraines	Consider co morbidities
Amitriptyline (35)	Immediately	Adults	Best for migraine headaches, can be started immediately	Monitor for side effects and complications of medication, can cause drowsiness	
Antidepressants (other TCAs, SNRIs,	After failing conservative	Adults	Migraine, tension, and mixed.	Independent of depression,	

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SSRIs (38, 39) Antiemetics (36) Anticonvulsants (40) NSAIDs combined with metoclopramide (41) DHE IM/SC/IV (36) Isometheptene (36) Normal barometric oxygen therapy (42) TENS (35) Manipulation (35) Acupuncture (43) Directed Exercise Program (1, 2, 3, 6, 44) Controlled Weight Loss (2) Acetaminophen 4g/day maximum (2, 8) NSAIDs (2, 12) Non-acetylated salicylates (2) Topical capsaicin (2) Intra-articular steroid injection (2, 45) Cox-2 inhibitors (1, 2)	therapy	Adults	Studies lasted 4-27 weeks	SSRI least effective
	With migraine associated nausea	Adults	Has been shown to help with pain and nausea with migraines	Consider co morbidities
	After failing other therapies, for prevention	Adults	For prevention of migraine headache	Sodium valproate/divalproex sodium and topiramate are the best studied
	After failing acetaminophen	Adults	Migraine	Consider co morbidities, metoclopramide can cause dystonia. NNT 3.5
	After failing more conservative therapies	Adults	Have shown to help migraines, more effective in combination with antiemetics	Consider co morbidities
	After failing more conservative therapies	Adults	Found effective for mild-moderate migraine	Consider co morbidities
	Immediately	Adults	For use in Cluster Headaches	Unknown
	Immediately	Adults	Best for cervical tension headaches, mildly affective in some migraine headaches	Do not use in patients with pacemakers, cardiac conduction abnormalities, or over the carotid body or sinus
	Immediately	Adults	Best for tension, post-traumatic headache. Can be helpful in some migraine headaches	Choose population according to literature
	As adjuvant treatment	Adults	Shown to be effective for both tension and migraine	Choose population according to literature, not effective for all
	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Immediately	All ages	Life long	Consider co morbidities
	Immediately first line	Adults	Can be long term	Consider co morbidities
	Immediately	Younger adults, without any CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Immediately	Adults	Short term	Consider co morbidities, watch for ototoxicity
	Immediately	Adults	Short term	Consider co morbidities
	Immediately	Adults	Can be long term, but if too long can consider joint replacement.	This should be considered first-line therapeutic intervention if OA is confined to a single joint.
	If unable to tolerate NSAIDs and failed Acetaminophen	Adults, not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors

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		therapy	Adults			
Acute Sports Injury	Diacerein (46, 47)	After failing other therapies	Adults		Studies lasted 2 months to 3 years	Consider co morbidities, shown to have minimal pain relief Instruct on timing to not cause tissue damage
	Ice/Heat (2)	Immediately for first 1-4 days	All ages		For first 1-4 days	
	Acetaminophen 4g/day maximum (2)	Immediately	Adults		Can be long term	Consider co morbidities
	NSAIDs (2, 12)	Immediately, recommended to try acetaminophen first	Adults		Short term	Consider co morbidities
	Acetaminophen 4g/day maximum (48)	Immediately	Adults		Can be long term	Consider co morbidities
Neuropathic Pain	Anticonvulsants (49, 50)	After failing acetaminophen	Adults		Can be long term	Have a side effect profile that must be monitored. Carbamazepine and gabapentin found to most effective, some showing carbamazepine to be more effective with lower NNT and higher NNH
	Systemic administration of local anesthetics (51)	After failing acetaminophen	Adults		Undetermined	Can be as effective as anticonvulsants. Monitor for side effects
	Antidepressants (34, 52)	After failing acetaminophen.	Adults		Can be long term, TCAs (amitriptyline) and Venlafaxine shown to be most effective. Not shown to be effective in HIV neuropathies	Monitor for side effects, follow black box warnings. Newer SSRIs have less evidence supporting their use in neuropathic pain
Post-Herpetic Pain	Anticonvulsants (49)	Immediately	Adults		While symptoms last	Can cause drowsiness
Fibromyalgia	Supervised Aerobic/Strength training exercise (53, 54, 55)	Immediately, for at least 20 minutes a day 3 times a week	All ages		Life long, most studies were conducted on average for 12 weeks, 3-24 weeks.	Consider co morbidities
	Cognitive Behavioral Therapy (54, 56)	Immediately	Adults		Data showed results from 6-30 months	Works best as a multidisciplinary approach
	Amitriptyline (54, 57, 58)	Immediately	Adults		While beneficial	Does have side effect profile, tolerance to effect can occur
	Cyclobenzaprine (54, 57)	Typically is after exercise, acetaminophen and amitriptyline	Adults		While beneficial	Significant side effects
	Acupuncture (54, 59, 60)	After exercise and	Adults		While beneficial	Mild/weak evidence

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	Deep tissue massage (64) Fluoxetine (54)	amitriptyline Immediately Typically start with exercise, acetaminophen, and amitriptyline first	Adults Adults	While beneficial While beneficial	Mild/weak evidence Secondary to amitriptyline, can be used in conjunction with tricyclics
	Dual-reuptake inhibitors (SNRIs): (54) Gabapentin (61) Pregabalin (54, 62, 63)	Immediately Immediately Immediately	Adults Adults Adults	While beneficial While beneficial, studied over a 12 week period While beneficial	Weaker evidence than previous medications Consider co morbidities Still under investigation, one study showing positive results
Dental Pain	Acetaminophen (64, 65) NSAIDs (65) Acupuncture (57, 66)	Immediately Immediately Immediately post-op	All ages Adults Adults	As needed As needed 1-4 sessions Life long	Consider co morbidities Consider co morbidities
Pelvic Pain (dysmenorrhea)	Directed exercise program (67) Acetaminophen (68)	Immediately During first 3 days of menstruation	All ages Adults	While beneficial	Consider co morbidities Consider co morbidities
	NSAIDs (68, 69) Oral contraceptives (70)	During first 3 days of menstruation Immediately	Adults Adults/Adolescents	While beneficial While beneficial	Consider co morbidities Consider co morbidities, can be traditional or extended continuous cycle
Pelvic Pain (chronic pelvic pain)	Acupuncture (71) Chinese herbal medication (72)	Immediately After other interventions	Adults Adults	10 visits over 3 months While beneficial	Consider co morbidities Not all interactions known with other medications
	Directed exercise program (73) Medroxyprogesterone acetate (73) Goserelin (73)	Immediately Immediately After failing more conservative therapies	All ages Adults Adults	Life long Not found to be effected after 9 months As long as beneficial, cannot be taken longer than six months	Consider co morbidities Consider co morbidities Consider co morbidities, extensive side effects
Pelvic Pain (Endometriosis)	Danazol (74) OCs (75) Goserelin (75)	After failing conservative therapy Immediately After failing more conservative therapies	Adults Adults Adults	For up to 6 months While beneficial While beneficial, cannot be taken for longer than six months	Consider co morbidities, extensive side effects Consider co morbidities Consider co morbidities, extensive side effects

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## Absolute Contraindications to Opioid Prescribing

### Absolute Contraindications to Opioid Prescribing: Discussion

#### 1. Allergy to opioid agents

Morphine causes the release of histamine, frequently resulting in itching, but this is not an allergic reaction. True allergy to opioid agents (e.g. anaphylaxis) is not common but does occur. Generally, allergy to one opioid agent does not mean the patient is allergic to other opioids; also switching to an agent in another opioid drug class may be effective. For example, if a patient has a hypersensitivity to a phenanthrene, then a diphenylheptane drug may be tried. (See table below.) When patients report an “allergy” to all but one agent (such as meperidine), the presence of a substance use disorder should be considered. Consultation with an allergist may be helpful to resolve these issues.

#### Classes of Opioid Medications

<u>Phenanthrenes</u>	<u>Diphenyleptanes</u>	<u>Phenylpiperidine</u>
Codeine Hydrocodone Hydromorphone Levorphanol Morphine Oxycodone	Methadone Propoxyphene	Fentanyl Meperidine
		<u>Other</u> Tramadol

<sup>a</sup> Meperidine is not recommended for chronic pain because of the potential for accumulation of the neurotoxic metabolite, normeperidine, and a potentially fatal drug interaction with monoamine oxidase inhibitors (MAOIs).

#### 2. Co-administration of a drug capable of inducing life limiting drug-drug interaction

Providers should carefully evaluate potential drug interactions prior to initiating opioid therapy, (such as MAOI with concurrent meperidine use, or propoxyphene and alcohol and other CNS depressants). (Note: meperidine is not recommended for chronic pain because of this potentially fatal drug interaction and the potential for accumulation of the neurotoxic metabolite, normeperidine, with regular dosing.)

#### 3. Active diversion of controlled substances

Diversion should be suspected when there are frequent requests for early refills, atypically large quantities are required, when purposeful misrepresentation of the pain disorder is suspected, or when a urine drug screen (UDS) is negative for the substance being prescribed, in the absence of withdrawal symptoms. Routine UDS often does not detect synthetic and semi-synthetic opioids (methadone, oxycodone, fentanyl, hydrocodone, meperidine or hydromorphone). Verified diversion is a crime and constitutes a strong contraindication to prescribing additional medications, and consultation with a pain specialist, psychiatrist, or addiction specialist may be warranted.

## Strategies for Tapering & Weaning

### Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

### Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation (“You are indifferent to my suffering”)
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

## Information for Patients—Opioid Analgesics for Non-Cancer Pain

*Photocopy for use by clinician*

### Information for Patients - Opioid (Narcotic) Analgesics for Non- Cancer Pain

FOR:

FROM: Dr.

DATE:

#### Making Pain Tolerable

The main reason for using an opioid (narcotic) analgesic for chronic non-cancer pain is to make the pain tolerable - not to eliminate it. This treatment is usually only considered after more standard treatments such as anti-inflammatory drugs have failed. If you are agreeable, your physician will prescribe an opioid analgesic for you in gradually increasing doses to minimize side effects. It is extremely important that you follow the directions exactly. Your physician will be the only one prescribing this medication to you. If you increase the dose without your physician's permission, give the medication to another person or obtain this medication from another physician without the consent of your primary physician, the physician may stop prescribing the opioid analgesic for you.

Pain medication is only part of your chronic pain treatment program. Equally important is a gradual exercise program that will increase your activity level despite ongoing pain. You and your physician should agree on specific ongoing treatment goals.

#### What is My Risk of Addiction?

There is increasing scientific evidence that strong painkillers can relieve some pain in selected patients without causing addiction. It is important to be careful, however, when defining what "addiction" is. Addiction, or psychological dependence, is a pattern of drug use in which the patient craves a drug for its ability to produce a "high" rather than for its pain-relieving properties. This can lead to the selling and injection of drugs and attempts to obtain drugs from multiple physicians - activities generally referred to as "drug abuse". Studies have shown that if a person has no past history of drug abuse and the pain is physical in origin, the risk of addiction is extremely low. If you are placed on an opioid analgesic for a period of weeks, however, and then are suddenly taken off the medication, it is possible to experience a short withdrawal reaction. Although this can be prevented by withdrawing the drug slowly, it does not mean that you have developed a craving for the drug or developed a drug addiction.

## Information for Patients—Opioid Analgesics for Non-Cancer Pain

### **What are the Side Effects?**

Although opioid analgesics can produce side effects (drowsiness, confusion, nausea, constipation), these can be minimized by slowly increasing the dose of the drug and by using anti-nausea drugs and bowel stimulants. Pain medication as prescribed will not depress your respiration or prevent you from breathing normally.

### **Remember Your Follow-up**

If you seem to benefit from the pain medications, your physician will see you about every 4 to 6 weeks for the first few months and about every two to three months thereafter. During each visit, you and your physician will assess pain relief, any side effects from the pain medication and your ability to meet your established activity goals.

### **Other Instructions:**

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TOOLS

## The Role of Methadone in the Management of Chronic Non-Malignant Pain

### The Role of Methadone in the Management of Chronic Non-Malignant Pain: Specific Considerations

#### Overview

Although the literature on methadone for non-malignant pain is scanty and based on case studies, the increasing use of methadone for this purpose requires recommendations to guide practice. There is extensive literature on the use of methadone as a potent analgesic agent for cancer pain and therefore recommendations for the use of methadone in the management of chronic non-malignant pain must be extrapolated from the cancer pain literature.

Methadone is a synthetic opioid analgesic with excellent oral bioavailability, a side effect profile similar to other opioid analgesics and a duration of action of at least eight hours with repetitive dosing. These qualities make it an attractive drug for outpatient pain management. Methadone also has an opioid receptor profile different from that of morphine and has N-methyl-D-aspartate (NMDA) antagonist activity that may confer advantages over morphine. However, experience in the use of methadone for cancer pain has revealed that methadone is far more potent as an analgesic agent than has been suggested by equianalgesic tables derived from single dose studies. With repetitive dosing, methadone is approximately ten times more potent than indicated in these standard tables. The main reason for this is probably the long elimination half-life of methadone (24-36 hours) which allows for much higher drug levels to be reached than could be predicted from single dose studies. This has obvious clinical implications since methadone takes 5-7 days to reach steady state at any particular dose. Therefore, the use of methadone as an analgesic agent requires the same pain assessment skills as for any other opioid drug, but even greater scrutiny in patient monitoring of analgesic and side effects.

#### Methadone use in the Management of Chronic Non-Malignant Pain

In Canada, methadone is available at low cost as an elixir which is usually made up at a concentration of 1 mg/ml. In opioid-naive patients or patients taking codeine preparations, methadone 2.5 mg q8h is safe and usually well-tolerated. For patients already on a major opioid analgesic like oxycodone or morphine, a reasonable starting dose of methadone is 5 mg q8h with dose increments of 5 mg q8h every 5-7 days. A general rule is to provide careful dose titration until adequate pain relief is achieved or side effects limit further dose escalation. However, one should look for a graded analgesic response to incremental dosing. The absence of a graded analgesic response may mean that the patient is not

## The Role of Methadone in the Management of Chronic Non-Malignant Pain

opioid-responsive. Patients should be seen weekly during the titration phase and every month or two during the maintenance phase.

For patients being switched from relatively large doses of an opioid analgesic (> 200 mg oral morphine or morphine equivalents daily), the table below should be used to calculate equianalgesic doses. For patients taking more than 500 mg oral morphine or morphine equivalents daily, the conversion to methadone should be staged with a third of the anticipated methadone dose being introduced every five days so that the entire conversion takes fifteen days. The dose of the previous opioid is decreased by a third every five days in inverse fashion.

### Equianalgesic Doses of Common Opioid Analgesics Relative to Oral Methadone with Repetitive Dosing

Drug	Per Os (PO)	Intramuscular/Subcutaneous
Methadone	2 mg	
Morphine	30 mg	10 mg
Hydromorphone	8 mg	2 mg
Oxycodone	15 mg	

Patients and co-habitants should be warned about potential side effects (especially drowsiness and respiratory depression) and the possibility that side effects can continue to evolve for five to seven days after each dose adjustment. The spouse or significant other should be available at least twice daily to monitor for toxicity. Since drowsiness commonly precedes respiratory depression, they should be instructed to call the prescribing physician if drowsiness develops to obtain advice about further dosing. This obviously requires physician availability 24 hours a day during the titration phase. Elderly patients (over the age of 65), patients with severe lung disease and patients who cannot be adequately monitored at home should be considered for inpatient initiation of methadone treatment.

*Note: The CPSO involvement in the opioid dependence program mentioned is unrelated to the use of Methadone for analgesic purposes. If a physician wishes to obtain a permit to prescribe Methadone for analgesic purposes, he or she needs to apply to the Office of Controlled Substances in Ottawa (613) 946-5139*

## Dosing Guidelines

### Starting Methadone Dose

Morphine Equivalent	Healthy adult <70 yrs	Adult w/ chronic illness or >70 yrs
Opioid naïve	5mg tid	2.5 mg bid
60 mg - 100 mg	5 mg tid	5 mg bid
>100mg	5 mg qid	5 mg bid

\*Webster, 2005

### MED for Selected Opioids

Opioid	Approximate Equianalgesic Dose (oral & transdermal)*
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Oxycodone	20mg
Oxymorphone	10mg

\*Adapted from Washington 2007 Guidelines

### Dosing Threshold for Selected Opioids\*

Opioid	Recommended dose threshold for pain consult (not Equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Codeine	800mg per 24 hours	30mg q 4-6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Fentanyl Transdermal	50mcg/hour (q 72 hr)		Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer
Hydrocodone	30mg per 24 hours	5-10mg q 4-6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Hydromorphone	30mg per 24 hours	2mg q 4-6 hours	

\*the Utah guidelines do not specifically recommend a pain consult

## Dosing Guidelines

Opioid	Recommended dose threshold for pain consult (not Equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Methadone**	See table above		Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids.
Morphine	120mg per 24 hours	Immediate-release: 10mg q 4 hours <hr/> Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	80mg per 24 hours	Immediate-release: 5 mg q 4-6 hours <hr/> Sustained-release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Oxymorphone	40mg per 24 hours	Immediate-release: 5-10mg q 4-6 hours	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol

\*\*the Utah guidelines do not specifically recommend a pain consult

### Acetaminophen warning with combination products

Hepatotoxicity can result from prolonged use or doses in excess of recommended maximum total daily dose of acetaminophen including over-the-counter products.

- Short-term use (<10 days) – 4000 mg/day
- Long-term use – 2500mg/day

### Key considerations in dosing long acting opioids

- Monitoring for adequate analgesia and use of “rescue” medications (at least until the long-acting opioid dose is stabilized). All new dosage calculations should include consideration for concurrent utilization of short-acting opioids.
- If the patient is more debilitated, frail and/or has significant metabolic impairments (e.g. renal or hepatic dysfunction), consider starting at the lower end of the conversion dose range.
- Always monitor for adverse effects (nausea, constipation, over-sedation, itching, etc.)

### Equianalgesic dose table for converting opioid doses

All conversions between opioids are estimates generally based on “equianalgesic dosing” or ED. Patient variability in response to these EDs can be large, due primarily to genetic factors and incomplete cross-tolerance. **It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25–50% to assure patient safety.**

## Directory of Resources

### Utah Directory of Resources

#### *Consultation and Referral*

#### ***Identifying Pain Management, Mental Health, and Substance Abuse Providers***

##### **1) The 211 Information and Referral Bank**

<http://www.informationandreferral.org>

The 211 Info Bank strives to ease the process of locating available and appropriate resources.

##### **2) Utah Cares: State Online Services**

[https://utahcares.utah.gov/erepub/en/ServiceSupplier\\_searchPage.do?\\_o3rpu=ScreenReferralHomePage.do](https://utahcares.utah.gov/erepub/en/ServiceSupplier_searchPage.do?_o3rpu=ScreenReferralHomePage.do)

This site allows you to do a search on providers by type and county.

##### **3) Utah Resources Hotline: 2-1-1**

Dial 2-1-1 and someone can direct you to providers by specialty in any county in Utah.

##### **4) Utah Medicaid Pain Management Providers**

<http://health.utah.gov/medicaid/pharmacy/documents/chronic.php>

##### **5) Utah Mental health providers**

<http://mentalhealth.samhsa.gov/databases/facility-search.aspx?state=UT&fullname=Utah>

##### **6) Substance Abuse Providers**

<http://www.dsamh.utah.gov/locationsmap.htm>

This link allows you to seek providers by location using an interactive map.

#### ***Referral Services***

##### **8) Substance Abuse Hotline: 1-866-633-HOPE (4673)**

##### **5) Utah Medicaid Restriction Program**

<http://health.utah.gov/medicaid/pharmacy/Restriction/restriction.php>

##### **9) University of Utah Assessment & Referral Services**

Assessment & Referral Services is a University of Utah Clinic within the Department of Psychiatry that provides high-quality, objective substance abuse assessments and referrals for individuals with possible substance abuse problems.

#### ***Laws Governing Use of Controlled Substances***

***Federal/DEA laws*** – [www.dea.gov](http://www.dea.gov)

##### **1) Practitioner Manual**

[http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf)

This manual has been prepared by the Drug Enforcement Administration to assist practitioners and other registrants authorized to prescribe, dispense, and

## Directory of Resources

administer controlled substances. A summary of the act can be found below in Appendix C.

### 2) Schedules of Controlled Substances

[http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr1308\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr1308_01.html)

Schedules of controlled substances can be found in Title 21, Chapter II.

### 3) Prescriptions

[http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr1306\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr1306_01.html)

Contains the rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829)

### 4) Administering and Dispensing of Controlled Substances

[http://edocket.access.gpo.gov/cfr\\_2001/aprqrtr/pdf/21cfr1306.07.pdf](http://edocket.access.gpo.gov/cfr_2001/aprqrtr/pdf/21cfr1306.07.pdf)

Persons who are entitled to fill prescriptions are described in this document found at the link above.

### *State of Utah Laws – State legislation and regulations*

#### 1) Utah Medical Practice Act Rules

<http://www.dopl.utah.gov/laws/R156-67.pdf>

#### 2) Utah Controlled Substance Act 58-37

<http://www.dopl.utah.gov/laws/58-37.pdf>

#### 3) Utah Controlled Substance Rules R156-37

<http://www.dopl.utah.gov/laws/R156-37.pdf>

#### 4) Reporting Prescription Fraud and/or Prescription Related Crime

<http://www.urxnet.org/> or <http://www.urxnet.org/tip/addtip.asp>

#### 5) Division of Occupational and Professional Licensure

<http://dopl.utah.gov/>

#### 6) Utah Controlled Substance Database

<https://csdb.utah.gov/>

#### 7) Model Policy for the Use of Controlled Substances for the Treatment of Pain—Federation of State Medical Boards

[http://www.fsmb.org/pdf/2004\\_grpol\\_Controlled\\_Substances.pdf](http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf)

The Model Policy, which was adopted by the Utah Medical Board of Examiners, is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision making.

\*If there are legal or workplace concerns, it is recommended that patients go to the industrial clinic

## Utah's Tamper Resistant Requirements

### *Tamper Resistant Prescription Pad/Paper Mandate Effective April 1, 2008*

Effective April 1, 2008, all non-electronic prescriptions must be written on tamper-resistant pads/paper in order to be eligible for reimbursement by Medicaid. The tamper resistant prescription pads/paper requirement applies to all outpatient drugs, including over-the-counter drugs. It also applies whether DOM is the primary or secondary payer of the prescription being filled. This new provision impacts all DOM prescribers: physicians, dentists, optometrists, nurse practitioners and other providers who prescribe outpatient drugs.

The Centers for Medicare & Medicaid Services (CMS) has issued guidance to the States in implementing the new federal requirement. This guidance allows for compliance with the tamper-resistant prescription pad/paper requirement to occur in two phases. For the first phase, a prescription must contain at least one of the three features outlined below by April 1, 2008, in order to be considered “tamper-resistant.” All three features are required on the prescription pads by October 1, 2008.

DOM encourages providers to implement all security features by April 1, 2008 to be in compliance with all program requirements. Note that computer generated prescriptions are not exempt from the CMS mandate.

The features listed below are recommended as best practice tamper resistant features by a national taskforce including representatives from CMS, State Medicaid agencies, and national medical and pharmacy organizations. Features listed in bold tend to be less costly and easier for prescribers to implement.

#### **Category 1 – One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.**

<b>Feature</b>	<b>Description</b>
“Void” or “Illegal” Pantograph	<b>The word “Void” appears when the prescription is photocopied. Due to the word “Void” on faxed prescriptions, this feature requires the pharmacy to document if the prescription was faxed.</b>
Reverse “RX” or White Area on prescription	“Rx” symbol or white area disappears when photocopied at light setting. This feature is normally paired with the “Void” pantograph to prohibit copying on a light setting.
Coin-reactive ink	Ink that changes color when rubbed by a coin – Can be expensive and is not recommended.
Security Back print	Printed on the back of prescription form. The most popular wording for the security back print is “Security Prescription” or the security back print can include the states name.
Watermarking (forderiner)	Special paper containing “watermarking”.
Diagonal lines (patented “Void”)	Diagonal lines with the word “void” or “copy”. Can be distracting or expensive.
Micro printing	Very small font writing, perhaps acting as a signature line. This is difficult to photocopy and difficult to implement if using computer printer. It is also difficult for a pharmacist to see.

## Utah's Tamper Resistant Requirements

<b>Category 2 - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.</b>	
<b>Feature</b>	<b>Description</b>
Uniform non-white background color	Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase or copy, the consistent background color will look altered and show the color of the underlying paper.
Quantity check off boxes	In addition to the written quantity on the prescription, Quantities are indicated in ranges. It is recommended that ranges be 25's with the highest being "151 and over". The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid. See illustration in Appendix 1.
Refill Indicator (circle or check number of refills or "NR")	Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.
Pre-print "Rx is void if more than ___ Rx's on paper" on prescription paper	Reduces the ability to add medications to the prescription. - Line must be completed for this feature to be valid. Computer printer paper can accommodate this feature by printing "This space intentionally left blank" in an empty space or quadrant.
Quantity Border and Fill (for computer generated prescriptions on paper only)	Quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional)
Refill Border and Fill (for computer generated prescriptions on paper only)	Refill quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **5** Value may also be expressed as text, e.g. (FIVE), (optional)
Chemically reactive paper	If exposed to chemical solvents, oxidants, acids, or alkalis to alter, the prescription paper will react and leave a mark visible to the pharmacist.
Paper toner fuser	Special printer toner that establishes strong bond to prescription paper and is difficult to tamper.
Safety or security paper with colored pattern	White (or some other color) mark appears when erased. This is expensive paper.

<b>Category 3 – One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.</b>	
<b>Feature</b>	<b>Description</b>
Security features and descriptions listed on prescriptions	Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code.
Logos	Sometimes used as part of the background color or pantograph.
Metal stripe security	Metal stripe on paper, difficult to counterfeit.
Heat sensing imprint	By touching the imprint or design, the imprint will disappear.
Invisible fluorescent fibers/ink	Visible only under black light.
Thermo chromic ink	Ink changes color with temperature change. This is expensive paper and problematic for storage in areas not climate controlled.
Holograms that interfere with photocopying	May interfere with photocopying or scanning.

## Utah's Tamper Resistant Requirements

Per CMS guidance, pharmacies that are presented with a prescription on a non-tamper-resistant prescription pad/paper may satisfy the federal requirement by calling the provider's office and verbally confirming the prescription with the physician or prescriber. The pharmacy shall document through placement on the original non-compliant prescription form that such communication and confirmation has taken place.

Prescriptions that the federal requirement does not apply to:

- E-prescriptions transmitted to the pharmacy;
- Prescriptions faxed to the pharmacy;
- Prescriptions communicated to the pharmacy by telephone by a prescriber;
- Transfer of a prescription between two pharmacies, provided that the receiving pharmacy is able to confirm by facsimile or phone call the authenticity of the tamper-resistant prescription with the original pharmacy;
- Written orders prepared in an institutional setting (which include Intermediate Care Facilities and Nursing Facilities), provided that the beneficiary never has the opportunity to handle the written order and the order is given by licensed staff directly to the dispensing pharmacy;
- Drugs dispensed or administered directly to the beneficiary in the physician's office or clinic;
- Written prescriptions dispensed to MS Medicaid beneficiaries who become retroactively eligible after April 1, 2008, provided the prescription was filled on or after April 1, 2008, and before the beneficiary became retroactively eligible for MS Medicaid;
- Emergency fills, provided that the prescriber provides a verbal, faxed, electronic or compliant written prescription within 72 hours;
- Refills of written prescriptions presented at a pharmacy before April 1, 2008;
- Written prescriptions paid for by Medicare, a Medicare Part D plan or Medicare Advantage Plan, unless MS Medicaid fee-for-service is a secondary payer. Part D excluded drugs paid for by Medicaid must be executed on tamper-resistant pad/paper<sup>1</sup>.

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<sup>1</sup> Prescriber may not know when Medicaid is the primary or secondary payer for MS Medicaid beneficiaries; therefore, the Division of Medicaid (DOM) recommends that prescribers use tamper-resistant prescription pads/paper for all DOM beneficiaries.

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## Appendix A: Guideline Rating Scale

<b>10/10</b>	<ul style="list-style-type: none"> <li>• Extremely explicit evidence-based guidelines The “gold standard”</li> <li>• Evidence has been analyzed thoroughly through an explicit rating system</li> <li>• Recommendations are based on the evidence with the highest rating of quality</li> <li>• Expert consensus creates the recommendations,</li> <li>• Recommendations verified through a peer review</li> </ul>
<b>9/10</b>	<ul style="list-style-type: none"> <li>• Very explicit evidence-based guidelines</li> <li>• Evidence has been analyzed thoroughly through an explicit rating system</li> <li>• Recommendations are based on the evidence with the highest rating of quality</li> <li>• Expert consensus creates the recommendations</li> </ul>
<b>8/1</b>	<ul style="list-style-type: none"> <li>• Explicit evidence-based guidelines</li> <li>• Evidence has been analyzed thoroughly through an explicit rating system</li> <li>• Expert consensus</li> </ul>
<b>7/10</b>	<ul style="list-style-type: none"> <li>• Evidence-based guidelines</li> <li>• No record of the evidence from which the guidelines have been created is present</li> <li>• No rating system of the evidence is present either</li> </ul>
<b>6/10</b>	<ul style="list-style-type: none"> <li>• Evidence-based guidelines</li> <li>• Limited details to how they were created</li> <li>• No record of the evidence from which the guidelines have been created is present</li> <li>• No rating system of the evidence is present either</li> </ul>
<b>5/10</b>	<ul style="list-style-type: none"> <li>• Expert consensus statement only</li> <li>• Very detailed explanation of how the consensus was formed</li> <li>• Reviewed thoroughly by pain experts</li> </ul>
<b>4/10</b>	<ul style="list-style-type: none"> <li>• Expert consensus statement only</li> <li>• Detailed explanation of how the consensus was formed</li> </ul>
<b>3/10</b>	<ul style="list-style-type: none"> <li>• Expert consensus statement only</li> <li>• Little explanation of how the consensus was reached</li> </ul>
<b>2/10</b>	<ul style="list-style-type: none"> <li>• Expert consensus statement only</li> <li>• No explanation of how the consensus was reached</li> </ul>
<b>1/10</b>	<ul style="list-style-type: none"> <li>• No explanation of how guidelines were created</li> </ul>



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# Interagency Guideline on Prescribing Opioids for Pain

Developed by the Washington State Agency Medical Directors' Group (AMDG) in collaboration with an Expert Advisory Panel, Actively Practicing Providers, Public Stakeholders, and Senior State Officials.

[www.agencymeddirectors.wa.gov](http://www.agencymeddirectors.wa.gov)



**AMDG** agency medical directors' group

A collaboration of state agencies, working together to improve health care quality for Washington State citizens.

*Written for Clinicians who Care for People with Pain  
3rd Edition, June 2015*

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# A Message from Washington's Secretary of Health

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STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

*PO Box 47890 • Olympia, Washington 98504-7890  
Tel: (360) 236-4030 • TTY Relay Service: 800-833-6388*

May 29, 2015

To Whom it May Concern:

Washington and many other states are in the midst of an epidemic of opioid misuse, abuse and overdose. During the past ten years, the number of hospitalizations for opioid dependence, abuse, and overdose has each more than doubled. Statewide, annual unintentional prescription opioid-related overdose deaths climbed from 24 in 1995, to 512 in 2008.

Washington was one of the first states to recognize and respond to the opioid epidemic. The Agency Medical Directors Group (AMDG) collaborated with practicing clinicians to develop and implement the groundbreaking AMDG Opioid Dosing Guideline in 2007, the first attempt in the U.S. to reduce prescribing of high doses of opioids associated with unintentional overdose.

The AMDG Guideline, along with other key statewide efforts, has resulted in a 29% decrease in the rate of prescription opioid-related deaths between 2008 and 2013. Hospitalizations for prescription opioid overdose have also declined 29% between 2011 and 2013.

Although opioids can be a useful option for pain management, their inappropriate use can result in significant harms, including addiction and death. Please help us to improve the health of Washington residents by following this updated AMDG evidence-based practice guideline.

I would like to thank the Agency Medical Directors Group and participating clinicians for their leadership and continued efforts to address this public health issue.

Sincerely,

John Wiesman, DrPH, MPH  
Secretary of Health

# Comparison of 2010-2015 Guidelines

2010 Guideline	2015 Guideline
Primary focus was on chronic non-cancer pain	Expands focus to include opioid use in acute, subacute, and perioperative pain phases and in special populations; includes sections on tapering and opioid use disorder.
<p><b>Two main sections:</b></p> <ul style="list-style-type: none"> <li>I. Initiating, transitioning, and maintaining patients on chronic opioid analgesic therapy (COAT) with principles of safe prescribing, and</li> <li>II. Optimizing treatment for patients on &gt; 120mg daily MED with brief sections on getting consultations, aberrant behaviors, tapering, and discontinuing COAT.</li> </ul>	<p><b>New and modified sections:</b></p> <ul style="list-style-type: none"> <li>I. Recommendations for All Pain Phases               <ul style="list-style-type: none"> <li>a. Clinically Meaningful Improvement in Function</li> <li>b. Expanded discussion on dosing threshold</li> <li>c. Non-opioid Options for Pain Management</li> </ul> </li> <li>II. Opioids in the Acute and Subacute Phases</li> <li>III. Opioids for Perioperative Pain</li> <li>IV. Opioids for Chronic Non-cancer Pain (similar to previous guideline)</li> <li>V. New section on Reducing or Discontinuing COAT</li> <li>VI. New section on Recognition and Treatment of Opioid Use Disorder</li> <li>VII. New sections on opioid use in special populations (during pregnancy and neonatal abstinence syndrome, in children and adolescents, in older adults, and in cancer survivors).</li> </ul>
<p><b>Appendices:</b></p> <ul style="list-style-type: none"> <li>A. Opioid Dose Calculations &amp; Calculator</li> <li>B. Screening Tools</li> <li>C. Tools to Assess Pain and Function</li> <li>D. Urine Drug Testing for COAT</li> <li>E. Consultative Assistance for WA State Payers</li> <li>F. Patient Education Resources</li> <li>G. Sample Doctor-patient Agreement for COAT</li> <li>H. Additional Resources to Streamline Clinical Care</li> <li>I. Emergency Department Opioid Guidelines</li> </ul>	<p><b>Appendices:</b></p> <ul style="list-style-type: none"> <li>A. Opioid Dose Calculations &amp; Calculator</li> <li>B. <i>Renamed:</i> Validated Risk Factor Screening Tools and combines former appendices B and C.</li> <li>C. How to use the Prescription Monitoring Program</li> <li>D. Urine Drug Testing for COAT</li> <li>E. Chronic Pain Syndromes in Cancer Survivors</li> <li>F. Diagnosis-based Pharmacotherapy for Pain</li> <li>G. Patient Education Resources (updated)</li> <li>H. <i>Renamed:</i> Clinical Tools and Resources and combines former appendices G, H, and I</li> <li>I. Guideline Development and AGREE II Criteria</li> </ul>
Recommended 120mg daily MED as a “yellow flag” dose as a strategy to prevent adverse events and overdose by advising providers to seek a consultation with a pain specialist.	Remains the same, plus adds guidance for safe prescribing <u>at any dose</u> , based on new studies showing significant risks occurring at lower doses.
Organized as narrative information and recommendations with evidence in citations.	Organized with each section having specific clinical recommendations with supporting narrative evidence sections with citations.

# Introduction

---

This is the 3<sup>rd</sup> Edition of the Washington State Agency Medical Directors' Group's (AMDG) interagency opioid guideline. First developed in 2007 and updated in 2010, all guidelines were developed in collaboration with a broad advisory group of the state's academic leaders, pain experts, and clinicians in both primary care and specialty areas in response to the growing epidemic of opioid-related unintentional overdoses.<sup>11</sup> This guideline followed a rigorous and transparent development process and is designed as an easy-to-use reference to help primary care clinicians; each section includes a set of clinical recommendations, followed by supporting evidence, and there are several resources in the appendices.

This guideline offers a **balanced approach** to pain management that includes recommendations for using opioids when appropriate, such as with acute injuries and flare ups, for postoperative pain management, and during painful procedures; and recommending multimodal therapies in general for all chronic pain patients. This guideline supplements the Washington State Department of Health's pain management rules<sup>i</sup> requiring best practices in the prescribing of opioids for chronic non-cancer pain. In keeping with these rules, use of opioids for patients receiving hospice and palliative care during active cancer or terminal conditions is outside the scope of this guideline.

**Monitoring and vigilance are critical to ensure effective and safe use of opioids for the thousands of Washington residents who are on opioids chronically, especially for those on high doses.**

## Correct Diagnosis and Realistic Expectations

Effective treatment of pain begins with an accurate diagnosis. Beyond the acute injury, the underlying cause of ongoing pain can be difficult to identify. Pain is generally described as either nociceptive (somatic) or neuropathic, but symptoms may not fit neatly into one group, often overlap and may change over time. Another common way to categorize pain is based on chronicity. Acute pain, whether related to disease, injury, or recent surgery, usually diminishes with tissue healing, whereas chronic pain typically lasts >3 months and involves neurological, emotional, and behavioral features that often impact a patient's quality of life, function, and social roles.<sup>12</sup>

Studies of interventions for chronic pain have often been of low quality, including problems associated with an increased risk of bias including difficulty with randomization and inadequate blinding.<sup>13</sup> The best recent systematic reviews have shown only modest benefits.<sup>14,15</sup> Patient expectations regarding expected outcomes may be unrealistic; expected outcomes should be balanced by potential risk of harm. Pursuing greater pain reduction via escalating opioid doses may contribute further to unrealistic expectations and even iatrogenic injury.

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<sup>i</sup> WAC Chapter 246, authorized by ESHB 2876, Chapter 209 Laws of 2010

## Uncertain Long-term Efficacy, Clear Evidence of Harm.

While the earlier guidelines focused on how prescribers could safely and effectively prescribe and manage chronic opioid analgesic therapy (COAT), more recent data suggests that the focus should also be on preventing the inappropriate transition from acute and subacute opioid use to chronic opioid use and to avoid COAT altogether when other alternatives for treating pain may be equally effective and safer in the long-term.

Three recently published systematic reviews which examine the effectiveness of opioids for chronic pain provide little support for COAT: A review of randomized controlled trials (RCTs) of opioids for chronic non-cancer pain concluded that the overall effectiveness of opioids for pain was only modest, and that the effect on function was small.<sup>16</sup> In a Cochrane review of observational studies of cases on longer duration treatment<sup>17</sup> the authors concluded, “The findings of this systematic review suggest that proper management of a type of strong painkiller (opioids) in well-selected patients with no history of substance addiction or abuse can lead to long-term pain relief for some patients...However, the evidence supporting these conclusions is weak, and longer-term studies are needed to identify the patients who are most likely to benefit from treatment”. The Agency for Healthcare Research and Quality’s (AHRQ) recent report, “The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain,” which focused on studies of effectiveness, measured at >1 year of COAT use, found *insufficient* data on long-term effectiveness to reach any conclusion.<sup>18</sup>

Adverse events most commonly reported in randomized trials include constipation, nausea and vomiting, dizziness, and drowsiness.<sup>19</sup> More serious long-term consequences have only been identified from observational and epidemiological investigations; these include abuse, inhibition of endogenous sex hormone production with resulting hypogonadism and infertility,<sup>20</sup> immunosuppression,<sup>21</sup> falls and fractures in older adults,<sup>22</sup> neonatal abstinence syndrome,<sup>23</sup> cardiac arrhythmia related to methadone,<sup>24</sup> sleep disordered breathing,<sup>25</sup> opioid-induced hyperalgesia,<sup>26</sup> nonfatal overdose hospitalizations,<sup>27</sup> emergency department visits,<sup>28</sup> and death from unintentional poisoning.<sup>29</sup>

Opioid therapy is also associated with the development of physical dependence and addiction<sup>30</sup> ([DSM 5 Opioid Use Disorder](#)). The true incidence of these serious complications is unknown but is likely to affect more patients than was previously reported.<sup>18,31,32</sup> In addition, the lack of a useful case definition for any of these dependent states makes it challenging for a primary care provider to identify and intervene appropriately.<sup>26</sup> Even with acute low dose opioids (1 – 36 mg/day morphine equivalent dose or MED), patients are at increased risk for developing opioid use disorder (OUD). The likelihood of developing OUD ranges from a 3-fold increase for acute low dose opioids, to a 122-fold increase for chronic high dose opioids ( $\geq 120\text{mg/day MED}$ ) compared to patients who are not prescribed opioids.<sup>32</sup>

**Because there is little evidence to support long term efficacy of COAT in improving function and pain, and there is ample evidence of its risk for harm, prescribers should proceed with caution when considering whether to initiate opioids or transition to COAT.**

## Opioids and Chronic Disability

Despite evidence based guidelines recommending against their use, opioids are frequently prescribed as first line agents for low back sprain and other routine musculoskeletal conditions.<sup>15,33-35</sup> In addition, there is evidence in the workers' compensation population that early opioid use increases the risk of disability<sup>6</sup> and it is difficult to discontinue COAT once initiated, as over 60% of patients taking opioids for at least 3 months are still on opioids 5 years later.<sup>1</sup> More effective early intervention strategies for acute low back pain, such as physical activity and emphasizing options for staying at or returning to work, are recommended to avoid transitioning to chronic low back pain.<sup>36</sup> Routine musculoskeletal conditions are among the top causes of disease burden in the US as measured by Years Lived with Disability (YLD), accounting for nearly 8 million YLD in 2010.<sup>37</sup> By 2011, nearly 25% of disabled Medicare beneficiaries under 65 were on opioids chronically. Preventing a transition from acute and subacute pain to chronic pain and disability could have a significant impact on saving productive lives.<sup>38</sup>

**Although opioids benefit some patients if prescribed and managed properly for appropriate conditions, from a public health perspective, preventing the next group of Washington residents from developing chronic disability due to unnecessary, ineffective, and potentially harmful COAT is a key objective of this guideline.**

# Part I. Recommendations for All Pain Phases

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## Clinically Meaningful Improvement in Function (CMIF)

Tracking function as well as pain is critical in determining the patient's ongoing response to opioids and whether any improvement is consistent with potential changes in opioid dosing. Because of the well documented evidence of risk and the limited evidence of effectiveness beyond the period of acute pain, the use of opioids should result in clinically meaningful improvement in function and pain and therefore, quality of life.

Clinically meaningful improvement is defined as an improvement in pain AND function of at least 30% as compared to the start of treatment or in response to a dose change. **A decrease in pain intensity in the absence of improved function is not considered meaningful improvement except in very limited circumstances such as catastrophic injuries (e.g. multiple trauma, spinal cord injury, etc.).**

COAT that focuses only on pain intensity can lead to rapidly escalating dosage with deterioration in function and quality of life. During the chronic phase, providers should routinely review the effects of opioid therapy on function to determine whether opioid therapy should continue. A brief but effective way to assess function is to determine the degree to which pain interferes with a patient's activities, as this is highly correlated with pain intensity when changes are tracked over time ([Figure A](#) and [Figure B](#)).

Continuing to prescribe opioids in the absence of clinically meaningful improvement in function and pain, or after the development of a severe adverse outcome (e.g. overdose event) is not considered appropriate care. In addition, the use of escalating doses to the point of developing opioid use disorder, as defined by DSM 5, is not appropriate.

**Patients who used opioids for at least 90 days were greater than 60% more likely to still be on chronic opioids in 5 years.<sup>1</sup>**

### Clinical Recommendations

1. Assess and document function and pain using validated tools ([Figure A](#) and [Figure B](#)) at each visit where opioids are prescribed.
2. Expect patients to improve in function and pain and resume their normal activities in a matter of weeks after an acute pain episode. Strongly consider re-evaluation for those who do not follow the normal course of recovery.
3. Evaluate function and pain using brief validated instruments at these critical decision-making phases:
  - a. At the end of the acute phase (6 weeks following an episode of pain or surgery), to determine whether continued opioid therapy is warranted.
  - b. At the end of the subacute or perioperative phase (12 weeks following an episode of pain or surgery), to determine whether non-opioid treatment will help or if prescribing COAT is warranted.
  - c. During chronic use with regular assessment and documentation of function and pain.

4. Use only validated instruments to measure clinically meaningful improvement in function and pain. The following tools have been validated and are easy ways to track function and pain:
  - a. PEG – A 3-item tool to assess Pain intensity, interference with Enjoyment of life, and interference with General activity.<sup>39</sup>
  - b. Graded Chronic Pain Scale – A 2-item tool to assess pain intensity and pain interference.<sup>40</sup>

Figure A. Three Item PEG Assessment Scale

<b>1. What number best describes your <u>pain on average</u> in the past week:</b>											
0	1	2	3	4	5	6	7	8	9	10	
No pain						Pain as bad as you can imagine					
<b>2. What number best describes how, during the past week, pain has interfered with your <u>enjoyment of life</u>?</b>											
0	1	2	3	4	5	6	7	8	9	10	
Does not interfere						Completely interferes					
<b>3. What number best describes how, during the past week, pain has interfered with your <u>general activity</u>?</b>											
0	1	2	3	4	5	6	7	8	9	10	
Does not interfere						Completely interferes					

Krebs 2009

Figure B. Two Item Graded Chronic Pain Scale

Graded chronic pain scale: a two-item tool to assess pain intensity and pain interference											
<p><b>In the last month</b>, on average, how would you rate your pain? Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"? <i>[That is, your usual pain at times you were in pain.]</i></p>											
<b>No pain</b>						<b>Pain as bad as could be</b>					
0	1	2	3	4	5	6	7	8	9	10	
<p><b>In the last month</b>, how much has pain interfered with your daily activities? Use a scale from 0 to 10, where 0 is "no interference" and 10 is "unable to carry on any activities."</p>											
<b>No interference</b>						<b>Unable to carry on any activities</b>					
0	1	2	3	4	5	6	7	8	9	10	

## Evidence

There is a broad consensus in published studies that a combination of outcome measures is superior to any single measure.<sup>41,42</sup> A major emphasis in earlier studies has been on the MINIMUM clinically important difference (MCID) in outcome. This measure has been tailored to clinical trials of drugs and other interventions. However, more robust definitions may be necessary to clearly define outcomes important to patients. For example, one study prospectively defined a minimally acceptable degree of improvement in patients undergoing lumbar fusion and found that these predefined outcomes established by patients themselves were not achieved.<sup>43,44</sup> For this cohort of patients, a combination of four outcomes included:

1. At least a 3/10 decrease in pain, AND
2. An improvement of at least 20 points on the Oswestry Disability Index, AND
3. Discontinuation of opioid medications, AND
4. Return to some occupational activity.

Based on the literature and expert consensus for low back pain, a 30% improvement in principal outcome measures (pain and function) is considered clinically meaningful.<sup>45</sup> This degree of improvement has also been validated in low back pain compared to actual measures of physical function.<sup>46</sup> For acute postoperative pain, a 35-45% decrease in pain was associated with reported acceptable improvement to patients.<sup>47</sup> In a short term prospective study of patients with arthritis undergoing steroid injections, patient-perceived satisfactory improvement was associated with a 55% improvement on a visual analogue scale.<sup>48</sup> Considering the potential long-term risks of opioid therapy and based on the published literature and expert consensus, two other groups have chosen a 30% improvement in pain and function to be critical for assessing changes from baseline for both acute/subacute and for chronic pain in patients placed on opioids: Washington (final) and California (draft) State Workers' Compensation Programs.<sup>ii</sup>

## Dosing Threshold

While there is evidence that opioids can provide significant pain relief in the short term, there is little evidence for sustained improvement in function and pain relief over longer periods of time. COAT is associated with the development of tolerance, a decrease in analgesic effect with the same dose over time. Providers must pay attention to the development of tolerance and avoid ongoing dose escalation to overcome this effect.

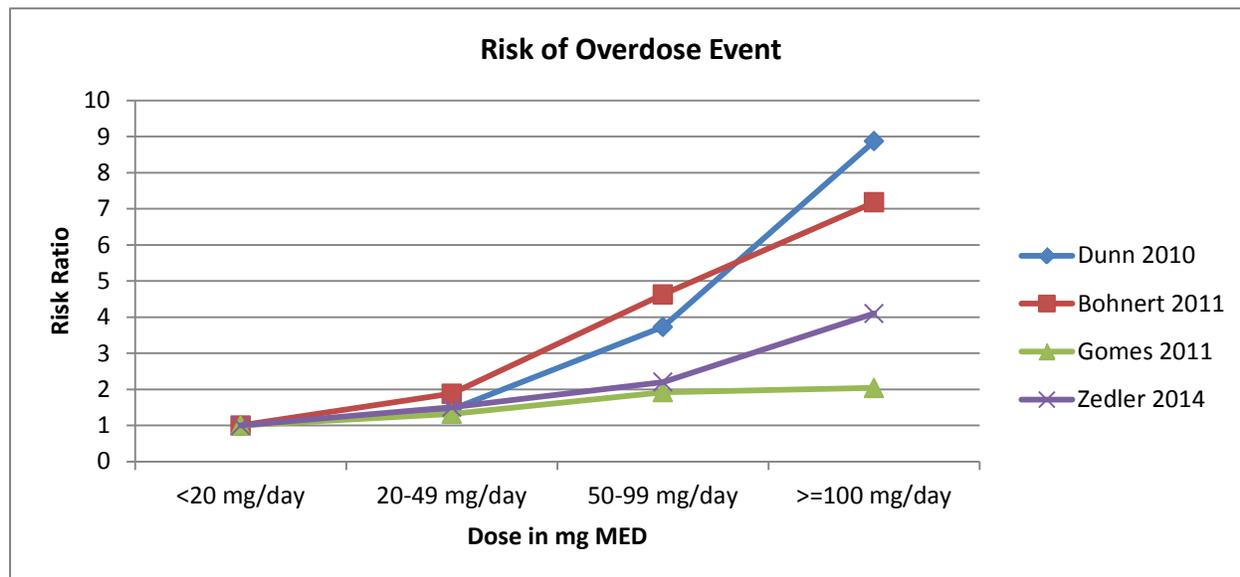
The 2010 edition recommended a 120 mg/day MED threshold to seek consultation with a pain specialist as a strategy to prevent serious adverse outcomes, including fatal overdoses. Group Health Cooperative (GHC), which implemented the best practices from the 2010 edition, has demonstrated a reduction in opioid doses for their COAT patients. For the last quarter of 2014, less than one-quarter of COAT patients seen by GHC providers received 50 mg/day MED or greater and only 7.3% exceeded 120 mg/day MED.

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<sup>ii</sup> <http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/FINALOpioidGuideline010713.pdf> and <http://www.dir.ca.gov/dwc/dwcwcabforum/Opioids.htm>

Recent studies support a dose-related risk and shed new light on significant risks occurring at doses lower than 120 mg/day MED. Overdose risk approximately doubles at doses between 20 and 49 mg/day MED, and increases nine-fold at doses of 100 mg/day MED or more (Figure C). Although the 2015 guideline maintains the 120 mg/day MED threshold for consultation and some guidelines have lower dose thresholds ranging from 50 to 90 mg/day MED, there is no completely safe opioid dose.

**Figure C. Risk of Overdose Events in Four Different Populations**



Providers should be especially cautious and assess risk for ongoing opioid therapy when a patient transitions from acute opioid use to COAT, continuing COAT at a dose to which a patient has already become accustomed, or escalating the opioid dose. Use the electronic [morphine equivalent dose \(MED\) calculator](#) for determining dose when a patient is on one or more opioids. The calculator should not be used to determine doses when converting a patient from one opioid to another.

There is a correlation between the amount of opioids prescribed for patients and their potential availability for diversion, with associated risks for individuals in the community. The recommendations below are intended to reduce the risks to both patients and the community.

**There is no completely safe opioid dose.<sup>7</sup> COAT patients should be routinely assessed for risk as medical conditions and life circumstances may change during treatment.**

### Clinical Recommendations

1. **Avoid** COAT if the patient has any of the following FDA or clinical contraindications:
  - a. Significant respiratory depression (e.g. respiratory failure), acute or severe asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected paralytic ileus or hypersensitivity (e.g. anaphylaxis)

- b. Current substance use disorder as defined by DSM 5 (except tobacco) or past opioid use disorder
  - c. History of prior opioid overdose
  - d. Pattern of aberrant behaviors ([Table 9](#))
2. Use great caution at any dose, monitor more frequently and consider prescribing take-home naloxone if the patient has one or more of the following risk factors:
    - a. Mental health disorder per DSM 5
    - b. Family or personal history of substance use disorder
    - c. Medical condition that could increase sensitivity to opioid-related side effects (e.g. impaired respiratory function, sleep apnea, high fall risk, altered drug metabolism related to advanced age or impaired renal, hepatic and/or cardiac function)
    - d. Current use of benzodiazepines
    - e. Tobacco use
  3. **Do not escalate** COAT to more than 120 mg/day MED without first obtaining a consultation from a trained pain specialist<sup>iii</sup> who agrees that a high dose is indicated and appropriate. Providers must routinely monitor and document sustained improvement in function and quality of life and an absence of the risk factors listed in recommendations 1 and 2.

## Evidence

A review of RCTs of opioids for chronic non-cancer pain concluded that the overall effectiveness of opioids for pain was only modest, and that the effect on function was small.<sup>16</sup> Recent published systematic reviews examining the effectiveness of opioids for chronic pain found insufficient data to support the wide prescribing of COAT.<sup>17,18,49</sup> However, epidemiological studies have shown that patients on COAT who are receiving > 100 mg/day MED have up to nine times the risk of overdosing compared to those on 20 mg/day MED, and for every seven overdoses, one was fatal.<sup>50-53</sup> These studies further showed that even at doses between 50 and 100 mg/day MED, the risk was 2.2 to 4.6 times higher compared to doses < 20 mg/day MED.<sup>50,51,53</sup> While the majority of overdose deaths occur in higher dose patients, recent studies in WA workers' compensation and Medicaid have shown that nearly half of all overdose hospitalizations occur in patients who are on intermittent or lower dose opioids.<sup>7,54,55</sup>

Studies have also shown dose-dependent increases in other serious adverse outcomes such as falls, fractures, and motor vehicle accidents.<sup>56</sup> At high doses, patients are at higher risk for poor functional status, increased pain sensitivity, and continuation of chronic opioids for a prolonged period.<sup>1,6,26</sup> While a cause and effect relationship is unclear, patients on high dose opioids are more likely to have high risk characteristics, such as mental health disorder, substance use disorder, and/or opioid misuse.<sup>1</sup>

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<sup>iii</sup> DOH Prescribing Rules defining [Pain Specialist](#) are listed in five separate rules according to each license type; all are in the Washington Administrative Code Chapter 246, subsections 919 (MDs); 853 (DOs); 922 (DPMs); 817 (Dentists); 840 (ARNPs); and 854 and 918 (PAs – working with DOs or MDs, respectively).

Chronic opioid analgesic therapy is also associated with the development of tolerance to its analgesic effects.<sup>26,57</sup> Evidence is accumulating that opioid therapy may also paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia.<sup>58-60</sup> In addition, higher strength opioids may be associated with poorer functional outcomes than lower strength opioids.<sup>19</sup> Thus, increasing opioid doses may not improve function and pain control, but will expose the patients to the risk of dose-dependent adverse outcomes.

The amount of opioids prescribed for patients and their potential availability for diversion has been identified as one of seventeen determinants of opioid-related mortality.<sup>61</sup> Communities with higher rates of prescribing experience higher overall overdose rates, even amongst individuals without prescriptions.

## Non-opioid Options for Pain Management

### Non-pharmacological Interventions

Pain is a multidimensional experience; so therefore, pain management is most effective when a multimodal approach is utilized ([Table 1](#)). In addition to medication, therapies should include physical activation and behavioral health interventions (such as cognitive behavioral therapy, mindfulness, coaching, patient education, and self-management).

**Table 1. Cognitive Behavioral and Non-pharmacological Therapies for Chronic Pain**

<b>Cognitive</b>	Address distressing negative cognitions and beliefs, catastrophizing (pain coping characterized by excessively negative thoughts and statements about the future)
<b>Behavioral approaches</b>	Mindfulness, meditation, yoga, relaxation, biofeedback
<b>Physical</b>	Activity coaching, graded exercise
<b>Spiritual</b>	Identify existential distress, seek meaning and purpose in life
<b>Education (patient and caregivers):</b>	Promote patient efforts aimed at increased functional capabilities

Adapted from Argoff, 2009 & Tauben, 2015

### Clinical Recommendations

1. Perform a thorough history and physical examination at initial visit for pain management.
2. Do not pursue diagnostic tests unless risk factors or “red flags” indicate the need for further evaluation ([Table 2](#)), especially getting an MRI in the first 6 weeks following low back injury <http://www.choosingwisely.org/american-society-of-anesthesiologists-asa-releases-choosing-wisely-list-for-pain-medicine/>.
3. Re-evaluate the patient for other diagnoses if pain persists beyond a few weeks, or if “red flags” develop ([Table 2](#)).
4. Identify functional goals that are important to the patient, as this increases the likelihood that treatment will improve quality of life, even if the pain intensity rating itself does not change.

5. Engage patients in behavior change counseling that promotes self-care and consider emphasizing evidence-based principles of motivational interviewing ([Appendix H: Clinical Tools and Resources](#)).
6. Use powerful interventions such as listening, providing reassurance, and involving the patient in his or her care.
7. Do not prescribe analgesics or perform interventions (e.g. injections) without also tracking pain and function over time using validated instruments.
8. Use validated instruments to assess predictors of suboptimal recovery such as depression, fear avoidance, and catastrophizing, which can lead to persistent pain and functional limitation ([Appendix B: Validated Tools for Screening and Assessment](#)).
9. Consider behavioral interventions to improve patient self-efficacy and address psychosocial barriers to recovery, such as cognitive behavioral therapy, Mindfulness-based Stress Reduction (MBSR), yoga, various forms of meditation and chronic pain self-management.
10. Recommend graded exercise unless contraindicated. Group exercise may have significant benefit and is available to most patients. Use of an activity diary may assist the patient and physician in monitoring progress.
11. Consider spinal manipulation in patients with low back pain.
12. Encourage and facilitate those who have work-related injuries to participate in programs that coordinate efforts to help them get back to work. Do this early in their recovery.
13. Address sleep disturbances by encouraging sleep hygiene ([Table 3](#)) or effective pharmacological therapy (clinical recommendation #6 under Non-opioid Analgesics). Achieving a minimum of 6 hours of restful sleep per night is a reasonable goal.
14. Refer patient to a multidisciplinary rehabilitation program if s/he has significant, persistent functional impairment due to complex chronic pain.

**Table 2. "Red Flags" Indicating Need for Further Patient Evaluation**

Presence of neurological deficit(s)
History of malignancy
New signs and symptoms of underlying disease
Sudden increase in severity or nature of previous pain complaint
Unexpected results from urine drug tests (e.g. positive for cocaine, amphetamines, alcohol, etc.)
Wounds that don't heal within normal time expectations
Evidence of adverse side effects from current treatment regimen

Adapted from Tauben 2015

**Table 3. Recommended Sleep Hygiene Habits**

Maintain a regular wake/sleep schedule: fixed bed and wake-up times, regardless of weekday or weekend
Establish a relaxing routine before bedtime
Refrain from taking naps
Make the bedroom “device-free”: no TV, computer, or handheld devices
Use the bedroom only for sleep, intimacy, and dressing routines
Set environment (light, noise, temperature) at comfortable levels
No caffeine after noon; some may need to avoid caffeine altogether
No exposure to TV or computer screens 2 hours prior to bedtime
Exercise - but not within 3 hours of bedtime
Avoid alcohol close to bedtime

Adapted from Tauben 2015

## Evidence

Overtreatment, excess attention, or labeling a patient during the acute pain phase can precipitate or increase “sickness behavior,” and avoidance of activity.<sup>62</sup> For example, in the absence of “red flags” that indicate the need for further evaluation ([Table 2](#)), obtaining an MRI in the first 6 weeks following low back injury may lead to a cascade of further unnecessary treatments and escalating costs.<sup>63</sup> Further, there is value in having patients with work-related injuries participate in programs that help them return to work, as these appear to have a small but significant impact on reducing disability among those who have missed at least four weeks of work due to acute or subacute musculoskeletal pain.<sup>64</sup>

**Importance of Activity:** Unless contraindicated, advice to remain active and engaged in usual activity seems to be the most effective intervention early in the course of a pain episode. A well-studied example is low back pain with or without sciatica. For this condition, advice to remain active has been repeatedly shown to predict better pain and functional outcomes than advice to take bed rest, and is as effective as specific exercises.<sup>65,66</sup> Aerobic and strengthening exercises have also been shown to reduce pain and disability in osteoarthritis of the knee,<sup>67</sup> but passive PT interventions have not demonstrated sustained benefit.<sup>68</sup> In subacute or chronic low back pain there is good evidence of moderate efficacy for exercise interventions.<sup>14</sup> In a recent Cochrane review of interventions for subacute or chronic LBP, exercise obtained the best outcomes when done as part of an individualized regimen with supervision during strengthening and stretching.<sup>69</sup> Resistance exercise training and aerobic exercise in women with fibromyalgia may improve pain and multidimensional function.<sup>70</sup> Patient adherence to home exercise programs may be specifically important in evaluating the success of these interventions.<sup>71</sup> This is where keeping an activity diary can be especially helpful.

**Psychosocial Factors:** Psychosocial factors, such as fear of normal activity (fear avoidance), catastrophizing, and low expectations of healing are strong predictors of the development of persistent pain in patient populations.<sup>72-74</sup> Practitioners’ beliefs and attitudes can impact clinical decision making and subsequent treatment outcomes.<sup>75</sup>

There is good evidence that cognitive behavioral therapy is effective in reducing subacute or chronic low back pain and other chronic pain conditions, including chronic orofacial pain, chronic pain in children, fibromyalgia, persistent pain in the elderly, and inflammatory bowel disease.<sup>14,76-85</sup> The treatment of depression was shown to have significant benefits in terms of pain reduction, improved functional status and quality of life in a group of older individuals with depression and arthritis.<sup>86</sup> Other psychological therapies, such as progressive relaxation and biofeedback aimed at muscle relaxation, have not been shown to be superior to active exercise therapies in large cohorts for most outcomes, in systematic reviews of low back pain treatment<sup>14</sup> although both do provide benefit.

**Group Support Activities:** While patients with acute pain may not require medically supervised rehabilitation interventions, there is evidence to support their benefits in groups of individuals with atypical recovery or with chronic musculoskeletal pathology such as arthritis. Among the benefits that group interventions provide, chronic pain self-management programs are having increasing success at reducing the physical and psychosocial burden of chronic pain while reducing healthcare costs.<sup>87</sup> These evidence based programs teach strategies for understanding chronic pain and provide a support network with both clinician and lay led (by fellow chronic pain sufferers) workshops, 2.5 hours once a week for 6 weeks. These offer a free or low-cost community based model that has demonstrated short term improvements in pain and multiple quality of life variables.<sup>88</sup> Modeled after a national study of chronic disease self-management programs, these are being heralded as an effective way to meet the “triple aim goals” of better health, better health care, and better value while reducing health care utilization.<sup>89</sup> For resources and workshop information, go to <http://livingwell.doh.wa.gov/workshops>.

**Spinal Manipulation, Acupuncture, and Yoga:** Chou et. al found good evidence of moderate efficacy for spinal manipulation for chronic or subacute low back pain. Acupuncture was associated with moderate short-term improvement in both pain and function, and yoga was associated with moderately superior outcomes in pain and decreased medication use at 26 weeks when compared to self-directed exercise and a self-care education book.<sup>14</sup> In comparative studies, exercise and spinal manipulation, but not acupuncture, appear to have a beneficial impact on improving both pain and function in chronic low back pain.<sup>90</sup> Acupuncture does not appear to be effective when compared to sham acupuncture.<sup>91</sup>

**Physical Therapies:** Although widely practiced, the application of heat and cold therapies for acute musculoskeletal pain has had a mixed evidence basis. The use of superficial heat has a stronger basis in evidence than the application of cryotherapy, or ice.<sup>14,92</sup> There is insufficient evidence to make conclusive statements about the benefits of massage therapy. There is no evidence that traction, lumbar supports, interferential therapy, diathermy or ultrasound are effective for chronic low back pain. There is good evidence that transcutaneous nerve stimulation (TENS) is ineffective.<sup>93</sup>

**Structured Intensive Multidisciplinary Pain Programs:** Evidence clearly supports the value of multimodal therapies in improving pain and function and reducing disability.<sup>94,95</sup> In chronic back pain and in other pain conditions, multidisciplinary, intensive rehabilitation involving physical, psychosocial and behavioral interventions has good evidence of moderate effectiveness for pain reduction and improvement of function.<sup>96</sup> Various tools such as the STarTBack questionnaire<sup>97</sup> for low back pain or

the Functional Recovery Questionnaire (FRQ)<sup>98</sup> can be used to stratify patients into groups that might require increased attention and rehabilitative interventions and to plan treatment.<sup>36</sup>

**Sleep Hygiene:** There is evidence to suggest that restorative sleep can help predict reduction in pain.<sup>99</sup> Although sleep treatment is not typically considered “analgesic”, poor sleep and lack of REM sleep in particular, are acutely hyperalgesic.<sup>100</sup> Further, the DSM 5 has reclassified insomnia as ‘sleep-wake’ disorders and acknowledges that, if occurring concomitantly with medical conditions and mental disorders, they are interactive and bi-directional.<sup>101</sup> Cognitive behavioral therapy has been shown to be a very effective non-drug strategy for insomnia.<sup>102</sup> Hence, having a sleep management plan is likely to help improve a patient’s pain experience. Morin and Benca have published an excellent review of chronic insomnia management in Lancet 2012.<sup>103</sup>

**Mindfulness and Stress Reduction:** Mindfulness-based therapy techniques such as meditation and Mindfulness-based Stress Reduction (MBSR) and/or yoga, may be reasonable alternative therapies for chronic pain as they have been successful in helping patients learn to self-manage their pain sensations. Recent systematic reviews have shown these approaches may be as effective as cognitive behavioral therapy, which has consistently been demonstrated in randomized trials to improve chronic pain outcomes.<sup>104-107</sup> In addition, the specific neural mechanisms activated by these treatments have been reported.<sup>107</sup>

## Non-opioid Analgesics

For most pain conditions, non-opioid analgesics (e.g. acetaminophen and NSAIDs) and adjuvant analgesics (e.g. antidepressants and anticonvulsants) are equally or more effective with less risk for harm than opioids. Providers should consider these medications during acute and subacute pain episodes and/or before initiating or transitioning patients to COAT. Selection of appropriate non-opioid or adjuvant analgesics requires a thorough history and physical exam, and will depend on the patient’s diagnosis, symptoms, pain type, comorbid conditions, and overall risk for adverse drug events ([Appendix F: Diagnosis-based Pharmacotherapy for Pain and Associated Conditions](#)). The use of medical marijuana for pain is beyond the scope of this guideline.

## Clinical Recommendations

1. Start with acetaminophen for mild to moderate pain. Acetaminophen may be dosed up to 4 grams for acute use, but <2-3 grams per day may be safer for prolonged use. Assess for all acetaminophen containing products to avoid inadvertent overdose. Use acetaminophen with caution, and at doses of <2 grams daily in those at risk for hepatotoxicity, including those with advanced age and liver disease (e.g. alcohol abuse, hepatitis B and C).
2. Use non-steroidal anti-inflammatory drugs (NSAIDs) for inflammatory, nociceptive pain. Monitor patients for potential renal, gastrointestinal (GI), and cardiac side effects. Consider concurrent H-2 blockers (e.g. famotidine, ranitidine) or proton pump inhibitors (e.g. omeprazole, pantoprazole) to help protect against GI effects. Avoid NSAIDs in patients with a calculated glomerular filtration rate (cGFR) < 60 ml/min/1.73 m<sup>2</sup>.

3. Consider tricyclic antidepressants (TCAs) or serotonin-norepinephrine reuptake inhibitors (SNRIs) and anticonvulsants (e.g. gabapentin, pregabalin) for neuropathic pain, other centralized pain syndromes, or fibromyalgia. Watch for potential cognitive impairment or sedation with anticonvulsants and TCAs.
4. Reserve baclofen or tizanidine for pain associated with spasticity from spinal cord injury or disease of the CNS (e.g. multiple sclerosis). Avoid abrupt discontinuation of baclofen because of the risk of precipitating withdrawal.
5. Do not prescribe muscle relaxants (e.g. methocarbamol, cyclobenzaprine) beyond a few weeks as they offer little long-term benefit. Avoid carisoprodol (Soma) due to the risk of misuse and abuse. Cyclobenzaprine, though not classified as a TCA, is structurally similar, so precautions are the same, and risk of adverse side effects are potentiated when used in combination with TCAs.
6. Prescribe trazodone, tricyclic antidepressants, melatonin, or other non-controlled substances if the patient requires pharmacologic treatment for insomnia.

## Evidence

**Sleep Medications:** If non-pharmacologic options to aid sleep are not effective, treatment with OTC melatonin (1-5 mg) can help, especially since endogenous levels decrease with age.<sup>101</sup> This naturally occurring hormone plays a pivotal role in the physiological regulation of sleep by reinforcing circadian and seasonal rhythms; side effects can include drowsiness, dizziness, headache, nausea, and nightmares.<sup>103</sup> Tricyclic antidepressants (TCAs) are sedating and may assist with sleep initiation and maintenance.<sup>108</sup> Trazodone, another antidepressant, is widely used for sleep but does not have any analgesic properties; and caution is advised if the patient is taking selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), triptans, or tramadol.<sup>109</sup> SNRIs are much less sedating and may disturb sleep by provoking periodic leg movement disorders; and SSRIs decrease REM sleep, increase REM latency, and fragment sleep so they are not good options for insomnia.<sup>110,111</sup>

**Benzodiazepines:** Use of benzodiazepines for sleep is not recommended in chronic pain patients because they do not improve patients' reported pain scores,<sup>111</sup> and they increase the risk of rebound insomnia, overdose (especially when combined with opioids), reduced REM sleep, and the development of tolerance, dependency, and addiction.<sup>109</sup> Although benzodiazepine receptor agonists, (e.g. the Z-drugs: zolpidem, zaleplon, zopiclone, and eszopiclone) are FDA-approved to treat insomnia, they can potentially impair cognitive and psychomotor skills that can increase the risk of falls, sleep-walking, sleep-eating, and driving unaware, or dependence and abuse.<sup>101,109</sup> For these reasons, these drugs should not be used with patients who have Alzheimer's disease and other comorbid disorders.<sup>101,112,113</sup>

**Acetaminophen (APAP):** APAP is the most widely used nonprescription pain medication. Although a recent systematic review concluded that the mean changes in pain relief by acetaminophen did not reach minimal clinically important difference as compared to placebo for acute low back and knee osteoarthritis<sup>114</sup> it is still an effective drug for mild to moderate pain.<sup>115,116</sup> When combined with ibuprofen 200 mg, the combination has been demonstrated to be more effective than opioids.<sup>117</sup> Hepatotoxicity can result from prolonged APAP use or doses in excess of recommended maximum total

daily dose including combined-acetaminophen OTC products. Although the FDA's current maximum daily dose is 4 grams, some manufacturers have voluntarily revised their label to recommend a lower maximum of 3 grams daily. The risk of hepatotoxicity increases significantly with age, concomitant alcohol use, comorbid liver disease or dose.<sup>118</sup>

**Non-steroidal anti-inflammatory drugs (NSAIDs):** NSAIDs are recommended for nociceptive pain such as traumatic musculoskeletal pain syndromes from traumatic, infectious or degenerative conditions (e.g. muscle, ligament, and or tendon injuries) with evidence to support effectiveness for spinal pain from disc, facet, or spinal ligament injuries<sup>119</sup> and neuritis related to connective tissue disorders.<sup>120</sup> In patients with non-specific low back pain, NSAIDs are equivalent to opioids in relief of pain.<sup>121</sup> The number needed to treat (NNT) for oxycodone 15 mg is approximately 4.6, (95% confidence Interval (CI), 2.9-11) while the NNT for oxycodone 10 mg + acetaminophen 650 mg is only 2.7, (95% CI, 2.4-3.1). The NNT for naproxen 500 mg or naproxen sodium 550 mg is also 2.7, and the NNT for ibuprofen 200 mg + acetaminophen 500 mg is 1.6. Hence, NSAIDs alone or in combinations can be as or more effective than opioids.<sup>122-124</sup> However, their use may be associated with serious cardiovascular (e.g. thrombotic events, myocardial infarction or stroke) and gastrointestinal (e.g. bleeding, ulceration or perforation of the stomach or small intestine) side effects. While cardiovascular risk may increase with duration of use, gastrointestinal events can occur any time during use.

**Antidepressants (TCAs/SNRIs):** TCAs have been studied in many clinical trials with positive results in the treatment of various neuropathic pain conditions and are a good first line option.<sup>125-129</sup> Among the drugs reviewed in three different neuropathic pain conditions, low-dose TCAs have the lowest NNT with an average 2.6 (range 2.0 to 5.0). In addition to pain relief, TCAs can offer added benefit to patients who also have depression or whose pain is interfering with sleep. However, caution should be used when prescribing TCAs to elderly patients or those with cardiovascular disorders due to risk of sinus tachycardia, changes in cardiac conduction time or arrhythmias. Besides TCAs, the serotonin norepinephrine reuptake inhibitor (SNRI) duloxetine has been shown to be effective in diabetic peripheral neuropathy, fibromyalgia and chronic musculoskeletal pain.<sup>130</sup> A systematic review found that there were no differences between venlafaxine and either gabapentin, pregabalin or duloxetine on average pain scores or the likelihood of achieving significant pain relief.<sup>131</sup> Serotonin syndrome has been reported with SNRIs alone and concurrently with other serotonergic agents (e.g. tramadol, fentanyl, triptans, TCAs, lithium, buspirone, St. John's Wort).

**Anticonvulsant drugs (ACDs):** Gabapentinoids (*gabapentin* and *pregabalin*) have been found to be moderately superior to other ACDs for achieving pain relief.<sup>131</sup> They have robust evidence in treating diabetic peripheral neuropathy, other neuropathies and fibromyalgia.<sup>132,133</sup> Gabapentin was found to be effective in painful polyneuropathy with an average NNT of 6.4.<sup>134</sup> In another systematic review of antiepileptic drugs used to treat neuropathic pain, gabapentin was found to be effective at doses of 1800 mg and 2400 mg, although side effects such as dizziness and drowsiness were reported at these doses.<sup>131</sup> Pregabalin has been studied in neuropathic pain conditions such as diabetic neuropathy and spinal cord injury and is FDA-approved to treat those neuropathies as well as fibromyalgia. The efficacy of pregabalin was found to be comparable to duloxetine, amitriptyline and gabapentin, however, pregabalin is classified as a controlled substance (Schedule V) with the potential for misuse or abuse, so

it argues for a more cautious approach to the use of this agent.<sup>131</sup> Other anticonvulsants such as carbamazepine, oxcarbazepine, and lamotrigine have limited or conflicting evidence of efficacy in spontaneous shooting pain of trigeminal neuropathy, diabetic peripheral neuropathy, HIV-related peripheral neuropathy, and multiple sclerosis.<sup>126,135</sup> All non-gabapentinoid ACDs are associated with risk of hepatotoxicity, hyponatremia, neutropenia, rash (including Stevens-Johnson Syndrome), sedation, and suicidality.

**Muscle relaxants and antispasticity drugs:** Muscle relaxants have limited evidence for effectiveness for chronic pain and are predominantly sedative.<sup>136</sup> Carisoprodol (Soma) should never be used due to lack of long-term efficacy, a high risk for abuse and misuse, and serious withdrawal symptoms.<sup>109</sup> When true painful spasticity is present, for instance in spinal cord injury and multiple sclerosis, antispasticity agents (e.g. baclofen and tizanidine) are good treatment options; however, serious and life threatening reactions can occur with abrupt discontinuation.

# Part II. Prescribing Opioids in the Acute and Subacute Phase

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## Opioids in the Acute Phase (0-6 weeks post episode of pain or surgery)

In general, reserve opioids for acute pain resulting from severe injuries or medical conditions, surgical procedures, or when alternatives ([Non-opioid Options](#)) are ineffective or contraindicated. If opioids are prescribed, it should be at the lowest necessary dose and for the shortest duration (usually less than 14 days). The use of opioids for non-specific low back pain, headaches, and fibromyalgia is not supported by evidence.

**Receiving a one week supply or  $\geq 2$  opioid prescriptions after an acute back sprain is associated with a doubling of the patient's risk for long-term disability.<sup>6,7</sup>**

### Clinical Recommendations

1. Explore non-opioid alternatives for treating pain and restoring function, including early activation.
2. Prescribe opioids for dental pain only after complex dental procedures and at the lowest dose and duration.
3. Help the patient set reasonable expectations about his or her recovery, and educate the patient about the potential risks and side effects. Provide patient education on safekeeping of opioids, benzodiazepines, and other controlled substances.
4. Expect patients to improve in function and pain and resume their normal activities in a matter of days to weeks after an acute pain episode. Strongly consider re-evaluation for those who do not follow the normal course of recovery.
5. Check the state's Prescription Monitoring Program (PMP) to ensure that the patient's controlled substance history is consistent with the prescribing record. Prescribers may delegate the ability to query the PMP database to any licensed health care professional ([Appendix C: How to use the Prescription Monitoring Program](#)).
6. Assess function and pain at baseline and with each follow-up visit when opioids are prescribed. Document clinically meaningful improvement in function and pain using validated tools.
7. Strongly consider tapering the patient off opioids as the acute pain episode resolves. Taper opioids by 6 weeks if clinically meaningful improvement in function and pain has not occurred.

## Opioids in the Subacute Phase (6 -12 weeks post episode of pain or surgery)

With some exceptions, resumption of normal activities should be expected during this period. Use of **activity diaries** is encouraged as a means of improving patient participation and investment in recovery. Non-pharmacological treatments such as cognitive behavioral therapy, activity coaching, and graded exercise are also encouraged ([Recommendations for All Pain Phases](#) and [Non-opioid Options](#)). With the exception of severe injuries, such as multiple trauma, opioid use beyond the acute phase (longer than 6 weeks) is rarely indicated. If opioids are to be prescribed for longer than 6 weeks, the following clinical recommendations should be followed.

**Patients with substance use and/or psychiatric disorders are more likely to have complications from opioid use, such as misuse, abuse or overdose.<sup>1</sup>**

### Clinical Recommendations

1. Do not continue to prescribe opioids if use during the acute phase does not lead to clinically meaningful improvement in function or to a pain interference with function level of  $\leq 4$  ([Figure B](#)).
2. Prescribe opioids in multiples of a 7-day supply to reduce the chance of them running out on a weekend.
3. Have a plan for how and when to discontinue opioids if treatment has not resulted in clinically meaningful improvement in function and pain or the patient has had a severe adverse outcome.
4. Check the state's [Prescription Monitoring Program](#) (PMP) to ensure that the patient's controlled substance history is consistent with the prescribing record. Prescribers may delegate the ability to query the PMP database to a licensed health care professional ([Appendix C: How to use the Prescription Monitoring Program](#)).
5. Screen for depression using PHQ-9 and for anxiety using GAD-7 or other validated tools. If comorbid mental health conditions exist in the presence of pain, they need to be treated or the patient's pain will not improve regardless of opioid therapy.
6. Administer the 4-item [PC-PTSD](#) screen or other validated tools if the patient's history suggests PTSD, or if PHQ-9 or GAD-7 remains elevated after treatment.
7. Screen for opioid misuse risk using the Opioid Risk Tool, SOAPP-R, DIRE, CAGE-AID or other validated tools. Review the patient's medical records and include the patient's support system (e.g. family, friends, etc.) to verify the risk assessment results.
8. Do not prescribe opioids if results of a baseline UDT reveal "red flags" such as the *confirmed* presence of cocaine, amphetamines, non-prescribed benzodiazepines, alcohol, or any other drugs you did not prescribe or have knowledge of ([Appendix D: Urine Drug Testing for Monitoring Opioid Therapy](#)). If cannabis is present on a UDT, the patient should be screened for cannabis use

disorder, as defined by DSM 5. In addition, it would be prudent to have a policy regarding the concomitant use of cannabis and opioids.

9. Avoid new prescriptions of benzodiazepines and sedative-hypnotics. Consider tapering or discontinuing benzodiazepines and/or sedative-hypnotics.
10. Discontinue opioids during this phase if:
  - a. There is no clinically meaningful improvement in function and pain.
  - b. Treatment resulted in a severe adverse outcome (e.g. overdose, bowel obstruction, central sleep apnea).
  - c. The patient has current or history of substance use disorder (excluding tobacco).

## Evidence

Short term use of opioids for severe acute injury (e.g. severe trauma, fracture, crush injury, postoperative) is unquestioned and is a standard of care. However, the overall data on effectiveness of opioids for longer term use, especially for improved function, and for routine conditions such as non-specific low back pain, headaches, and fibromyalgia is weak, and the evidence of potential harm is strong. Systematic reviews of efficacy of opioids for low back pain demonstrate modest improvement in pain but little improvement in function and no clear evidence that pain relief will be sustained.<sup>15,49</sup> For headaches and fibromyalgia, there is a paucity of evidence on effectiveness. Both the European Federation of Neurological Societies and the American Academy of Neurology recommend against the use of opioids for headache.<sup>137-139</sup> There is no evidence from randomized trials to support the use of opioids for fibromyalgia, despite some observational studies showing that strong opioids are used in fibromyalgia patients with significant risk factors that would normally mitigate against such use.<sup>81,140-144</sup>

In addition to these data, evidence from a population-based, prospective study of a low back pain cohort in WA workers' compensation reported that even minimal use of opioids in the first six weeks following an acute low back injury was associated with a doubling of the risk of disability one year later, after adjusting for baseline pain, function, and injury severity.<sup>6</sup>

Evidence on the use of opioids for subacute pain is limited; thus, most of the recommendations for this period represent a consensus of expert opinion of the advisory group. A systematic review of RCTs on conservative treatments for subacute low back pain (6 weeks-3 months), revealed that only advice on staying active was found to be effective.<sup>145</sup>

The use of screening tests prior to starting COAT is important in patients with certain comorbid medical conditions. Managing pain in patients with complex medical conditions such as substance use disorder or a mental health condition can be a challenge. Research has shown that patients with substance use or psychiatric disorders (e.g. depression), or both, are actually more likely than patients without these disorders to receive COAT.<sup>146,147</sup> They are also more likely to have complications such as misuse, abuse or overdose.<sup>148,149</sup> Adults with a history of depression, alcohol or other non-opioid substance use disorders are three to five times more likely to receive COAT.<sup>150</sup>

High-risk COAT prescribing practices (high opioid dose, extended COAT duration, concurrent use of sedatives/hypnotics) are associated with increased risks of opioid overdose and serious fractures.<sup>22,50</sup> Unfortunately, patients who receive high-risk COAT are also more likely to have high-risk characteristics, including younger age, history of substance use disorder, mental disorders, and presence of opioid misuse.<sup>1</sup> Because of the increased risk for adverse outcomes from the use of COAT in patients with mental health disorders, such as borderline personality disorder, depression, bipolar disorder, anxiety, post-traumatic stress disorder (PTSD) or psychotic disorders, providers should be extra cautious when prescribing COAT when one of these co-morbid conditions is present.

## Part III. Opioids for Perioperative Pain

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Opioids serve as the cornerstone for severe acute postoperative pain management with proven efficacy for this indication. Nevertheless, patients must be counseled on the limited effectiveness of any analgesic in eliminating pain entirely. A balanced, rational multimodal analgesic approach is most effective in controlling pain while at the same time, minimizing analgesic doses and their resultant side effects that interfere with rehabilitation. Patients on COAT who are undergoing elective surgeries present challenges for perioperative pain management. For this reason, it is important to assess patients' risks for both severe postoperative pain and side effects of opioids. The following recommendations are intended to help manage patients' pain and minimize risk associated with perioperative opioid use.

**The goal of opioid therapy is to prescribe the briefest, least invasive and lowest dose regimen that minimizes pain and avoids dangerous side effects.<sup>2-5</sup>**

### Preoperative Period

#### Clinical Recommendations

1. Conduct a thorough preoperative evaluation, including history and physical:
  - a. Ask about past and current use of, response to and preferences for analgesics.
  - b. Check the Prescription Monitoring Program (PMP), especially for patients with a history of COAT or benzodiazepine or sedative-hypnotic use.
  - c. Assess risk for potential postoperative opioid over-sedation and/or respiratory depression ([Table 4](#)) and difficult postoperative pain control ([Table 5](#)). Inform the entire perioperative team of the results of the risk assessment.
  - d. Consider consultation with a specialist (e.g. pain management, addiction medicine, behavioral health), particularly in patients at risk for both over-sedation ([Table 4](#)) and difficult postoperative pain control ([Table 5](#)).
2. Develop a coordinated treatment plan, including a timeline for tapering perioperative opioids. Identify which provider will be responsible for managing postoperative pain and prescribing opioids:
  - a. Generally, in opioid naïve patients, any opioids prescribed during the first 6 weeks postoperatively should be managed solely by the surgeon.
  - b. If a patient was previously using chronic opioids for the condition being addressed by surgery, the surgeon should consult with the outpatient prescriber as to whether or not the patient is likely to need continued COAT after surgery. If so, develop a plan for transition of pain care back to the outpatient prescriber.

- c. In the immediate postoperative period, during the hospital stay, the surgeon (or a specialist consultant) should manage all pain medication, including chronic methadone, buprenorphine/naloxone, or other COAT, as well as any additional opioids added for acute postoperative pain. These acute post-surgical opioids should be tapered off during the first few weeks after surgery. Continuation of previous COAT upon hospital discharge should be the responsibility of the outpatient prescriber.
3. Inform patient and family of the perioperative pain plan. Set expectations with them about realistic pain management goals, including functional recovery activities, need for multimodal treatment, limits of therapy, timely return to preoperative baseline opioid dose (if any) or lower, and the analgesic tapering timeline.
4. Avoid new prescriptions of benzodiazepines, sedative-hypnotics, anxiolytics, or other central nervous system (CNS) depressants.
5. Avoid escalating the opioid dose before surgery. The lowest effective dose should always be sought, but there is insufficient evidence to recommend routinely lowering chronic opioid doses or discontinuing opioids prior to surgery.

## Intraoperative Period

### Clinical Recommendations

1. Provide balanced multimodal analgesia, including adjuvant analgesics, when possible (e.g. acetaminophen, NSAIDs, gabapentin and local anesthetic infiltration). Under specialist direction, ketamine, lidocaine, and regional local anesthetic techniques can also help minimize perioperative opioids and their side effects.
2. Provide sufficient intraoperative opioid doses to avoid acute withdrawal in patients who are on high doses of preoperative opioids.

## Immediate Postoperative Period

### Clinical Recommendations

1. Reserve the use of opioids for moderate to severe acute pain. If used, utilize the lowest possible dose as part of a multimodal regimen, including NSAIDs, acetaminophen, and non-pharmacologic therapies, unless contraindicated.
2. Monitor sedation and respiratory status in patients receiving systemic opioids for postoperative analgesia (e.g. [Richmond Agitation Sedation Scale](#), [Ramsey Sedation Scale](#), or [Comfort Scale](#)). Due to the risk of excessive sedation and respiratory depression, patients should be monitored closely in the initial hours following surgery and with subsequent dose escalations. Monitoring should include assessments of alertness and signs or symptoms of hypoventilation or hypoxia:
  - a. The use of routine oxygen is discouraged as hypoxia is a late sign of respiratory compromise and this sign will be delayed still further by supplemental oxygen.
  - b. There is insufficient evidence to recommend the routine use of more sophisticated noninvasive methods (such as capnography) for monitoring hypoventilation postoperatively.

- c. Providers should be prepared to change or reduce opioids or administer opioid antagonists in patients who develop excess sedation or respiratory depression ([Table 4](#)).
3. Use oral opioids for managing postoperative pain in patients who can tolerate oral medications, particularly following the first or second postoperative day, as pain levels at rest and during activity become less variable.
  - a. Consider the use of patient controlled analgesia (PCA) initially in cases where repeated doses of parenteral opioids are anticipated or required. Providers should be aware of the doses being self-administered by their patients via PCA to guide adjustments. Routine use of continuous opioid infusions (basal rates with PCA) is NOT recommended:
  - b. Consider consultation with specialists for patients receiving high dose PCA, and when opioids, benzodiazepines or sedative-hypnotics are being used in combination with the PCA.
4. Use short-acting “as needed” (PRN) opioids as the foundation for acute severe postoperative pain in the opioid naïve patient. For the opioid tolerant patient, do not add or increase extended release or long-acting opioids for the immediate postoperative period.
  - a. Avoid therapeutic duplication of opioids consisting of more than one type of PRN short-acting opioid (e.g. oxycodone and morphine). Avoid co-administration of parenteral and oral PRN opioids for ongoing pain. If PRN opioids from different routes are needed, provide a clear indication for use (e.g. for a brief, severely painful, closely monitored procedure such as a dressing change).
  - b. Consider scheduling non-opioids for more steady analgesia and to avoid multiple PRNs for pain.
5. Resume chronic regimen as soon as possible if patients were previously on chronic opioids and are expected to continue these postoperatively.
6. Avoid new prescriptions of benzodiazepines, sedative-hypnotics, anxiolytics or CNS depressants. If patients were previously on chronic sedatives, restart these at lower doses in the setting of postoperative opioids to avoid synergies between CNS depressant and opioid side effects.
7. Initiate a bowel regimen as soon as possible postoperatively to minimize opioid-induced bowel dysfunction (constipation). This side effect may still require opioid dose reductions if unresponsive to stool softeners, laxatives or enemas.

**Do not discharge the patient with more than a two week supply of opioids, and many surgeries may require less. Continued opioid therapy will require appropriate re-evaluation by the surgeon.**

## At Time of Hospital Discharge

### Clinical Recommendations

1. Avoid continuing or adding new prescriptions of benzodiazepines, sedative-hypnotics, anxiolytics or CNS depressants. Counsel patients and families about risks of using alcohol and other CNS depressants with opioids.
2. Inform the patient and family which provider will be responsible for managing postoperative pain, including who will be prescribing any opioids. Instruct the patient and family on the planned taper of postoperative opioids, including a timeline for return to preoperative or lower opioid dosing for those on chronic opioids.
3. Remind the patient of the dangers of prescription opioid diversion and the importance of secure storage of their medications. Sharing medications with others is never appropriate and is illegal. Instruct the patient and family on prompt disposal of controlled substances either through a [DEA-approved take-back program](#) or FDA guideline for [safe disposal of medicine](#).
4. Follow through with the agreed upon preoperative plan to taper off opioids added for surgery as surgical healing takes place. The goal is always the shortest duration and lowest effective dose:
  - a. Most patients with major surgeries should be able to be tapered to preoperative doses or lower within 6 weeks (approximately 20% of dose per week although tapering may be slower in the 1st week or 10 days and then become much more rapid as healing progresses).
  - b. It is important to remember that for some minor surgeries, it may be appropriate to discharge patients on acetaminophen or NSAIDs only or with only a very limited supply of short-acting opioids (e.g. 2-3 days) - even if they were taking opioids preoperatively.
  - c. For patients who were not taking opioids prior to surgery, but who are still on them after 6 weeks, follow the recommendations in the [Subacute Phase](#).

**Table 4. Risks for Over-sedation and/or Respiratory Depression from Postoperative Opioids** <sup>151-160</sup>

Sleep apnea or high risk sleep disorder (morbid obesity/history of snoring/positive STOP Bang score ≥4)
Age (<1 and >65 years old)
History of over-sedation with opioids
Opioid analgesic tolerance or increased opioid dose requirement
Concurrent use of other sedating drugs (e.g. benzodiazepines, antihistamines, sedative/anxiolytics or other CNS depressants)
History of difficult to control postoperative pain
Long (>6 hours) duration of general anesthesia
Surgery location and/or type (e.g. airway, upper abdominal, thoracic, scoliosis repair in children)
Medical comorbidities (e.g. pulmonary disease/smoker, cardiac disease, other major organ failures)

**Table 5. Risks for Difficult-to-control Postoperative Pain** <sup>161-169</sup>

History of severe postoperative pain
Opioid analgesic tolerance (daily use for months)
Current mixed opioid agonist/antagonist treatment (e.g. buprenorphine, naltrexone)
Chronic pain (either related or unrelated to the surgical site)
Psychological comorbidities (e.g. depression, anxiety, catastrophizing)
History of substance use disorder
History of “all over body pain”
History of significant opioid sensitivities (e.g. nausea, sedation)
History of intrathecal pump use or nerve stimulator implanted for pain control

## Evidence

A number of reviews of the literature on perioperative pain treatment have been undertaken and published in the last few years, including those from the American Pain Society, the American Society of Anesthesiologists, the Department of Defense, the Veterans Administration, and the Washington State Department of Labor and Industries. These guidelines as well as a PubMed search for additional reviews of this topic in the last 5 years (560, excluding 32 reviews concerning a single surgical procedure) were used and combined with consensus opinions from the experts in the AMDG advisory group to formulate our final recommendations.

Although opioids are effective for short-term pain relief following surgery, side effects may limit their use.<sup>170</sup> The use of a multimodal approach including non-pharmacologic interventions to manage pain can improve treatment and limit side effects from any one class of analgesics.<sup>171-184</sup> Preparation for surgery such as training in relaxation, counseling and education can reduce anxiety, postoperative opioids use and physical therapy needs.<sup>185-189</sup> In addition, adjuvant treatments such as acetaminophen, NSAIDs and gabapentin have been demonstrated to be opioid-sparing and help minimize opioid-related side effects.<sup>184,190-192</sup> The intraoperative use of techniques such as local anesthetic blocks, ketamine and intravenous lidocaine can also reduce opioid requirements.<sup>193-195</sup>

It is important to assess patients’ risk factors for over-sedation and/or respiratory depression and for difficult-to-control postoperative pain. Predictors of postoperative opioid over-sedation and/or respiratory depression include, but are not limited to, sleep apnea, concurrent use of benzodiazepines or other CNS depressant agents, other medical conditions that affect respiratory function and prolonged anesthesia.<sup>151,156,157,159,160</sup> Risk factors for difficult to control postoperative pain include chronic pain, mental health comorbidities (e.g. anxiety, depression, catastrophizing) and history of substance use disorder.<sup>161-165,167</sup>

Patients on COAT who are undergoing surgery are at increased risk for both of these complications. These patients have higher pain rating, manifest more anxiety and have frequent and more severe respiratory depressive episodes than opioid naïve patients.<sup>162-165,196</sup>

The Prescription Monitoring Program provides an accurate picture of the patient's history of opioid, benzodiazepine, and other controlled substance use, which is especially helpful for planning perioperative pain management.<sup>197,198</sup> It is important to collaborate across the care team (surgeon, anesthesiologist, pain management specialist, bedside nurses, treating provider and the patient) to formulate a postoperative pain management plan including risk factors and a timeline for weaning analgesics. Communication of this treatment plan, as well as realistic expectations concerning postoperative pain, is important for the patient, his or her family and the entire care team to help ensure appropriate treatment and avoid dangerous side effects.<sup>199</sup>

The first 24 hours of opioid therapy is a significant period of risk for excess sedation and respiratory depression.<sup>159</sup> Assessment of sedation level and monitoring for adequate ventilation and oxygenation allow for early response and intervention.<sup>158,159,200-204</sup> When the parenteral route is needed beyond the first few hours after surgery, patient-controlled analgesia (PCA) is recommended and can add an element of safety as the sedated patient is less likely to continue to give themselves opioid doses.<sup>205-207</sup> However, routine use of PCA is not recommended, as patients can usually resume oral analgesia within hours of the surgery. Analgesic effects of oral and intravenous opioids are comparable, so patients can be transitioned to oral opioids as soon as oral intake is tolerated.<sup>208</sup> Concurrent, as needed use of intravenous and oral opioids increases the risk of side effects.<sup>209</sup> Constipation is a common adverse effect of opioids and, if left untreated, could lead to bowel impaction. Initiate a bowel regimen as soon as possible postoperatively in those taking opioids to minimize opioid-induced bowel dysfunction.<sup>210,211</sup>

# Part IV. Prescribing Opioids for Chronic Non-cancer Pain

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## Opioids in the Chronic Phase (>12 weeks after an episode of pain or surgery)

Managing chronic pain and providing appropriate opioid therapy is a challenging aspect of both primary care and specialty care practices. This is why it is critical for providers to be very conscious of the risks and intentional about the treatment plan when prescribing these drugs. The key to effective COAT is sustained improvement in physical function and pain with frequent monitoring to adjust therapy as necessary. Best practice treatment requires ongoing attention to identify adverse outcomes. Providers must balance the need for scientific evidence and skillful clinical decision making in these complex cases.

**1 in 5 patients on chronic opioid analgesic therapy will develop opioid use disorder as defined by DSM 5. If tolerance and withdrawal are considered, the prevalence rises to nearly 1 in 3.<sup>10</sup>**

### Clinical Recommendations

1. Prescribe COAT only if there is sustained clinically meaningful improvement in function and no serious adverse outcomes or contraindications.
2. Use extreme caution and consider consultation before prescribing COAT in patients with comorbid mental health disorders (especially PTSD and major depressive disorder), family or personal history of substance use disorder, concurrent use of benzodiazepines or sedative-hypnotics, or medical conditions that could increase sensitivity to opioid-related side effects (e.g. COPD, CHF, sleep apnea, advanced age, or renal or hepatic dysfunction).
3. Reassess the need for COAT in transferred patients who are already using opioids. If current treatment is not benefiting the patient, a dose reduction or discontinuation is warranted. Consider non-opioid options for pain treatment ([Recommendations for All Pain Phases](#) and [Non-opioid Options](#)).
4. Discuss the potential benefits and risks associated with COAT including addiction and overdose. Have a signed opioid treatment agreement to document this discussion and set behavioral expectations including the use of a single prescriber and pharmacy.
5. Prescribe opioids at the lowest possible effective dose. If the dose is increased but does not result in CMIF, then significant tolerance or adverse effects to opioids may be developing and opioids should be tapered back to the previous dose or possibly discontinued.
6. Prescribe opioids in multiples of a 7-day supply to reduce the incidence of the supply ending on a weekend.
7. Initiate a bowel regimen to prevent opioid-induced constipation, especially in older adults. Prescribe regularly scheduled laxatives, such as senna, polyethylene glycol, lactulose, sorbitol, milk of magnesia or magnesium citrate (caution in patients with kidney failure).

8. Use the following best practices to ensure effective treatment and minimize potential adverse outcomes:
  - a. Assess and document function and pain status using validated tools at each visit where opioids are prescribed ([Recommendations for All Pain Phases](#) and [CMIF](#)). This is critical in determining the patient’s ongoing response to opioids and to measure effects from any dose changes.
  - b. Check the state’s PMP at the frequency determined by the patient’s risk category ([Table 18](#)) to ensure controlled substance history is consistent with prescribing record. Prescribers may delegate the ability to query the PMP database to any licensed health care professional ([Appendix C: How to use the Prescription Monitoring Program](#)).
  - c. Repeat random UDTs at the frequency determined by the patient’s risk category to identify aberrant behavior, undisclosed drug use and/or abuse and verify compliance with treatment ([Appendix D: Urine Drug Testing for Monitoring Opioid Therapy](#)).
  - d. Monitor for opioid-related adverse outcomes such as central sleep apnea, endocrine dysfunction, opioid-induced hyperalgesia, opioid use disorder or signs of acute toxicity. Be especially cautious with comorbid conditions that may increase risk for adverse outcomes (including COPD, CHF, obstructive sleep apnea, history of alcohol or substance use disorder, advanced age, or renal or hepatic dysfunction). See [Table 6](#) for recommended monitoring frequency.
  - e. Monitor for medication misuse, aberrant drug-related behaviors or diversion ([Table 9](#)).
  - f. Consult with a pain management specialist before exceeding 120 mg/day MED. If the pain management specialist endorses high dose COAT, consider prescribing naloxone as a preventive rescue medication. Counsel family member or other personal contacts in a position to assist the patient at risk of opioid-related overdose.
9. Do not combine opioids with benzodiazepines, sedative-hypnotics or barbiturates.
10. Do not prescribe methadone for chronic pain unless you are knowledgeable of methadone’s non-linear pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions and additional monitoring requirements. Free mentoring services are available for prescribing methadone using the [Providers’ Clinical Support System](#).
11. Increase the frequency of monitoring for high risk patients on opioids. Monthly visits are often needed.
12. Discontinue opioids during this phase based on the criteria listed on [Table 8](#).

**Table 6. How Often to Monitor Patients on COAT**

Level of Risk	Recommended Frequency
Low risk (no risk factors)	Every 6 months
Moderate risk	Every 3 months
High risk <b>or</b> opioid doses >120 mg/day MED	Every month

**Table 7. Prescribing Methadone for Pain Management**

Prescribing methadone is complex. To prevent serious complications from methadone, prescribers should read and carefully follow the methadone (Dolophine®) prescribing information at [www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm). The American Pain Society's [clinical practice guideline](#) for safe methadone use is also a valuable resource.

Deaths, cardiac and respiratory, have been reported during initiation and conversion of pain patients to methadone treatment from treatment with other opioid agonists. It is critical to understand the pharmacokinetics of methadone when converting patients from other opioids.

Respiratory depression is the chief hazard associated with methadone or other opioid administration. Methadone's peak respiratory depressant effects typically occur later, and persist longer than its peak analgesic effects, particularly in the early dosing period. These characteristics can contribute to cases of iatrogenic overdose, particularly during treatment initiation and dose titration.

In addition, cases of QT interval prolongation and serious arrhythmia (torsades de pointes) have been observed during treatment with methadone. Most cases involve patients being treated for pain with large, multiple daily doses of methadone, although cases have been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction.

## Evidence

The efficacy of long-term opioid use for chronic non-cancer pain has not been established. However, many primary care providers have patients—in some cases inherited from other providers—who have already been placed on COAT after failing other pain management options.

While this guideline continues to identify 120 mg/day MED as the boundary beyond which specialty consultation is warranted, there is no completely safe opioid dose level. There appears to be a steady increase in overdose risk as the opioid dose rises above 20 mg/day MED.<sup>50-53</sup> The cause and effect relationship is unclear, but patients on high dose opioids are more than likely to have high risk characteristics, such as mental health disorder, a substance use disorder, and/or opioid misuse.<sup>1</sup> Recent evidence also shows that the increased risk from escalating the opioid dose is not balanced by an increased benefit in either functional status or average pain level.<sup>212</sup>

In addition to dose-associated risks, duration of opioid action (long-acting vs. short-acting) has been linked to unintentional overdose.<sup>213</sup> Patients receiving long-acting opioids had a 2.5-fold increased risk of overdose as compared to those receiving short-acting opioids after adjusting for age, sex, opioid dose and other characteristics. The risk was significantly higher during the first two weeks after initiation of long-acting opioids.

Chronic opioid analgesic therapy is also associated with the development of physical dependence and addiction (DSM 5 “opioid use disorder”). The true incidence of these serious complications is unknown but is likely to affect more patients than was previously reported.<sup>18,31,32</sup> In addition, the lack of a useful case definition for any of these dependent states makes it challenging for a primary care provider to identify and intervene appropriately.<sup>26</sup> Even with acute low dose opioids, patients are at increased risk for developing opioid use disorder. This risk ranges from an odds ratio of 3.03 for acute low dose opioids (1 – 36 mg/day MED), to 122.45 for patients on chronic high dose opioids ( $\geq$  120 mg/day

MED).<sup>32</sup> A recently published large scale study of patients on chronic opioid revealed that the lifetime prevalence of DSM 5 prescription opioid use disorder is 21% (12% mild, 9% moderate to severe).<sup>10</sup> These rates do not consider tolerance or withdrawal. If these physiologic responses are considered, the prevalence is 29%.

Other adverse events most commonly reported in randomized trials include constipation, nausea and vomiting, dizziness, and drowsiness.<sup>19</sup> Much more serious long-term consequences of opioids have only been identified from observational and epidemiological investigations; these include higher risk for poor functional status,<sup>6</sup> inhibition of endogenous sex hormone production with resulting hypogonadism and infertility,<sup>214</sup> immunosuppression,<sup>21</sup> falls and fractures in older adults,<sup>22</sup> neonatal abstinence syndrome,<sup>23</sup> cardiac arrhythmia related to methadone,<sup>24</sup> central sleep apnea,<sup>25</sup> opioid-induced hyperalgesia,<sup>60</sup> nonfatal overdose hospitalizations,<sup>27</sup> emergency department visits,<sup>28</sup> and death from unintentional poisoning.<sup>29</sup>

# Part V. Reducing or Discontinuing Chronic Opioid Analgesic Therapy (COAT)

## Reasons to Discontinue COAT and Considerations Prior to Taper

Not all patients benefit from opioids, and a prescriber frequently faces the challenge of reducing the opioid dose or discontinuing opioids altogether. Patients on COAT can be reluctant to change, and many who agree to try will have difficulty as the dose is reduced. Such reluctance and difficulty in tapering often reflect anxiety. There may be apprehension about worsening of pain and withdrawal symptoms or, if there is opioid use disorder, about reduced access to the drug. Exploring each of these possibilities in a non-judgmental manner helps the provider understand the patient’s perspective and helps the patient have realistic expectations. This, in turn, strengthens the therapeutic relationship and supports future strategies.

**Table 8. When to Reduce, Taper, or Discontinue COAT**

Patient requests opioid taper.
Patient is maintained on opioids for at least 3 months, and there is no sustained clinically meaningful improvement in function ( <a href="#">CMIF</a> ), as measured by validated instruments ( <a href="#">Appendix B: Validated Tools for Screening and Assessment</a> )
Patient’s risk from continued treatment outweighs the benefit (e.g. decreased function and increased risk for opioid-related toxicity from concurrent drug therapy or comorbid medical conditions)
Patient has experienced a severe adverse outcome or overdose event
Patient has a substance use disorder (except tobacco)
Use of opioids is not in compliance with DOH’s pain management rules or consistent with the AMDG Guideline
Patient exhibits aberrant behaviors ( <a href="#">Table 9</a> )

### Clinical Recommendations

1. Help the patient understand that chronic pain is a complex disease, and opioids alone cannot adequately address all of the patient’s pain-related needs. Exploring the patient’s resistance to discontinuing opioids will guide taper strategy. Motivational interviewing skills may be useful when having this conversation.
2. Consider tapering patients in an outpatient setting if they are not on high dose opioids or do not have comorbid substance use disorder or an active mental health disorder, as this can be done safely and they are at low risk for failing to complete the taper.
3. Seek consultation from a pain management specialist or Structured Intensive Multidisciplinary Pain Program (SIMP; described in [Non-opioid Options](#)) for patients who have failed taper in an outpatient setting or who are at greater risk for failure due to high dose opioids, concurrent benzodiazepine use, comorbid substance use disorder or any active mental health disorder. If SIMP is not available, engage patients in activities that emulate the biopsychosocial approach of such a program. Rarely, inpatient management of withdrawal may be necessary.
4. Refer patients with aberrant behaviors ([Table 9](#)) for evaluation and treatment.

## How to Discontinue Opioids

Selecting the optimal timing and approach to tapering depends on multiple factors. The rate of opioid taper should be based primarily on safety considerations, and special attention is needed for patients on high dose opioids, as too rapid a taper may precipitate withdrawal symptoms or drug-seeking behavior. In addition, behavioral issues or physical withdrawal symptoms can be a major obstacle during an opioid taper. Patients who feel overwhelmed or desperate may try to convince the provider to abandon the taper. Although there are no methods for preventing behavioral issues during taper, strategies implemented at the beginning of COAT such as setting clear expectations and development of an exit strategy are most likely to prevent later behavioral problems if a taper becomes necessary.

### Clinical Recommendations

1. Consider sequential tapers for patients who are on chronic benzodiazepines and opioids. Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.
2. Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naloxone or naltrexone with propofol, methohexital, ketamine or midazolam).
3. Establish the rate of taper based on safety considerations:
  - a. Immediate discontinuation if there is diversion or non-medical use,
  - b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or
  - c. Slow taper for patients with no acute safety concerns. Start with a taper of  $\leq 10\%$  of the original dose per week and assess the patient's functional and pain status at each visit.
4. Adjust the rate, intensity, and duration of the taper according to the patient's response (e.g. emergence of opioid withdrawal symptoms ([Table 10](#))).
5. Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions ([Appendix B: Validated Tools for Screening and Assessment](#)).
6. Consider the following factors when making a decision to continue, pause or discontinue the taper plan:
  - a. Assess the patient behaviors that may be suggestive of a substance use disorder
  - b. Address increased pain with use of non-opioid options.
  - c. Evaluate patient for mental health disorders.
  - d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is CMIF, reduced pain and no serious adverse outcomes.
7. Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.
8. Increase the taper rate when opioid doses reach a low level (e.g.  $<15$  mg/day MED), since formulations of opioids may not be available to allow smaller decreases.

9. Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms are rarely medically serious, although they may be extremely unpleasant. Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued ([Table 10](#)).
10. Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.
11. Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use.
12. Consider inpatient withdrawal management if the taper is poorly tolerated.

**Table 9. Aberrant Behaviors**

Less suggestive for addiction but are increased in depressed patients	More suggestive of addiction and are more prevalent in patients with substance use disorder
<ul style="list-style-type: none"> <li>• Frequent requests for early refills; claiming lost or stolen prescriptions</li> <li>• Opioid(s) used more frequently, or at higher doses than prescribed</li> <li>• Using opioids to treat non-pain symptoms</li> <li>• Borrowing or hoarding opioids</li> <li>• Using alcohol or tobacco to relieve pain</li> <li>• Requesting more or specific opioids</li> <li>• Recurring emergency room visits for pain</li> <li>• Concerns expressed by family member(s)</li> <li>• Unexpected drug test results</li> <li>• Inconsistencies in the patient’s history</li> </ul>	<ul style="list-style-type: none"> <li>• Buying opioids on the street; stealing or selling drugs</li> <li>• Multiple prescribers (“doctor shopping”)</li> <li>• Trading sex for opioids</li> <li>• Using illicit drugs, +UDT for illicit drugs</li> <li>• Forging prescriptions</li> <li>• Aggressive demand for opioids</li> <li>• Injecting oral/topical opioids</li> <li>• Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.)</li> </ul>

Adapted from Passik, S. 2006

**Table 10. Symptoms and Treatment of Opioid Abstinence Syndrome (withdrawal)**

<b>Restlessness, sweating or tremors</b>	Clonidine 0.1-0.2 mg orally every 6 hours or transdermal patch 0.1-0.2 mg weekly (If using the patch, oral medication may be needed for the first 72 hours) during taper. Monitor for significant hypotension and anticholinergic side effects.
<b>Nausea</b>	Anti-emetics such as ondansetron or prochlorperazine
<b>Diarrhea</b>	Loperamide or anti-spasmodics such as dicyclomine
<b>Muscle pain, neuropathic pain or myoclonus</b>	NSAIDs, gabapentin or muscle relaxants such as cyclobenzaprine, tizanidine or methocarbamol
<b>Insomnia</b>	Sedating antidepressants (e.g. nortriptyline 25 mg at bedtime or mirtazapine 15 mg at bedtime or trazodone 50 mg at bedtime). Do not use benzodiazepines or sedative-hypnotics.

## Evidence

Some patients on COAT have adverse effects or the prescriber feels that current treatment is not benefiting the patient, and the patient may do better with tapering of the dose or discontinuing opioid therapy.<sup>215-217</sup> Dose reduction, discontinuation of opioids, or transition to medication-assisted treatment for opioid use disorder frequently improves function, quality of life, and even pain control.<sup>218</sup> Because the experience of pain and the symptoms of withdrawal that accompany an opioid taper vary from one person to the next, there is not a one size fits all approach. The approach to and rate of taper in patients on COAT is based on the individual patient's needs and comorbidities. Expert opinion, rather than systematic reviews or RCTs have informed these "best practice" recommendations.

Many pharmacologic therapies have been studied for use as adjunctive agents during opioid taper to palliate opioid abstinence syndrome (withdrawal) as well as emergent insomnia and anxiety.<sup>219-224</sup>

A multidisciplinary approach to pain, including psychotherapy (behavioral activation, problem solving therapy, etc.), physical therapy, chiropractic, social work, and occupational therapy have been proven to improve function. Multidisciplinary pain programs have strong clinical efficacy and empirical data supporting their cost-efficiency.<sup>94,95,225-228</sup> These programs, while neither widely available nor well reimbursed, provide significant benefit to many patients. In addition, a multidisciplinary approach may be considered to address the psychosocial and cognitive aspects of chronic pain together with patients' physical rehabilitation.<sup>229</sup>

High quality evidence of safety and comparative efficacy is lacking for ultra-rapid detoxification, or for the use of antagonist drugs, with or without sedation.<sup>230</sup>

Extremely challenging behavioral issues may emerge during an opioid taper.<sup>231</sup> Special care must be taken by the prescriber to preserve the therapeutic relationship during opioid tapering. Otherwise, the taper can precipitate doctor-shopping, illicit drug use, or other behaviors that pose a risk to patient safety. Although there are no fool-proof methods for preventing behavioral issues during an opioid taper, strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary. Patients who exhibit aberrant behaviors during the taper may have ([Opioid Use Disorder](#)).<sup>232</sup> Also, serious suicidal ideation (with plan or intent) should prompt engagement of the crisis system or, if available, urgent psychiatric consultation.<sup>233</sup>

If the patient doesn't have substance use or any other active mental health disorder and is not on chronic high dose opioids, taper can usually be done safely in an outpatient setting.

Surprisingly, opioid tapers rarely cause significant and long term increases in pain. If these occur, they tend to be during and immediately following completion of the opioid taper. In addition to antidepressant medications, anti-inflammatories and anticonvulsants can be used to address increased pain in patients who have no contraindications.

Office-based buprenorphine treatment is an effective **evidence-based** option which should be considered for patients with both chronic pain and opioid use disorder.<sup>234</sup> Buprenorphine may be the only practical option for patients in rural areas where methadone treatment programs and structured pain programs are difficult to access.

## Part VI. Recognition and Treatment of Opioid Use Disorder

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Opioid therapy can lead to the development of opioid use disorder. Although the true incidence is unknown, this risk ranges from 3-fold for acute low dose opioids to 122-fold for chronic high dose opioids. As outlined in the DSM 5, substance use disorders including [Opioid Use Disorder](#) are now described as existing across a continuum of severity, from mild to severe. The need for or type of treatment depend on the severity of the condition. According to the broad definition in DSM 5, only two criteria must be met to make a diagnosis of a mild disorder. Two of these criteria, tolerance and withdrawal, are normal physiological consequences of COAT. However, these two criteria do not count toward the DSM 5 diagnosis of opioid use disorder *if the medication is taken appropriately under ongoing medical treatment*. Excluding tolerance and withdrawal, a recently published large scale study found a 21% lifetime prevalence of DSM 5 prescription opioid use disorder (12% mild, 9% moderate to severe) among patients on chronic opioids.<sup>10</sup>

The remaining DSM 5 criteria for opioid use disorder pertain to maladaptive behavior patterns. Examples include taking opioids in larger amounts than intended, spending a great deal of time trying to obtain opioids, strong craving for opioids, recurrent opioid use in situations where it is physically hazardous, social impairment such as withdrawal from family and friends, and conflict with medical providers over opioid use. Such behaviors are not unusual in COAT patients, and differentiating between physiologic dependence and opioid use disorder can be difficult.<sup>235</sup>

Often, patients will readily acknowledge difficulty due to some of these maladaptive behaviors. These patients may experience an improvement in their quality of life if a transition can be made to medication-assisted treatment for opioid use disorder. However, it is important to recognize the stigma attached to the word “addiction,” and it is generally best to avoid use of that term. “Opioid Use Disorder” may be a more acceptable term to patients who perceive their primary problem to be pain. The term “opioid dependence,” while often acceptable to patients, is best avoided due to possible confusion with its outdated formal definition in DSM-IV.

As efforts to address the prescription opioid overdose epidemic have decreased the supply of prescription opioids, some patients have transitioned to heroin as a cheaper alternative. The numbers of people starting to use heroin have been steadily rising since 2007 with a corresponding increase in heroin overdose.<sup>236</sup> It is important to recognize the potential for this transition and refer high risk patients for appropriate evaluation and treatment.

### Clinical Recommendations

1. Assess for opioid use disorder using DSM 5 criteria or refer for a consultation with an addiction specialist if a patient demonstrates aberrant behaviors suggestive of substance use disorder ([Table 9](#) and [Appendix H: Clinical Tools and Resources](#)).

2. Patients diagnosed with opioid use disorder should receive a combination of medication-assisted treatment and behavioral therapies.
3. Contact the Substance Abuse and Mental Health Services Administration (SAMHSA)'s [Providers' Clinical Support System for Opioids \(PCSS-O\)](#) and [Providers' Clinical Support System for Medication Assisted Treatment \(PCSS-MAT\)](#) for treatment issues. Expert physician mentors are available to assist with questions or concerns about opioid tapering and assessment and treatment of substance use disorders.
4. Consider prescribing naloxone as a preventive rescue medication for patients with opioid use disorder, especially if heroin use is suspected. Counsel family member or other personal contacts in a position to assist the patient at risk of opioid-related overdose. For more detail on opioid prevention education, visit [www.stopoverdose.org](http://www.stopoverdose.org).
5. Check the state's PMP to ensure controlled substance history is consistent with prescribing record. Prescribers may delegate the ability to query the PMP database to any licensed health care professional ([Appendix C: How to use the Prescription Monitoring Program](#)).
6. Be knowledgeable about treatment options:
  - a. Medication-assisted treatment with either sublingual buprenorphine products or methadone is common in patients who have co-occurring chronic pain and opioid use disorder.
  - b. A [DATA 2000 waiver](#) is needed to prescribe sublingual buprenorphine products for opioid use disorder in an office-based setting. Providers without a waiver should consider getting one or refer the patient to a provider with a waiver to prescribe buprenorphine. This treatment may be the only practical option for patients in rural areas where methadone and other treatment programs are difficult to access.
  - c. Patients who require methadone maintenance must be referred to a federally licensed opioid treatment program.

## Evidence

There is very little evidence that outpatient non-medication treatment for opioid use disorder is effective.<sup>237,238</sup> In these programs, patients are tapered off opioids and are expected to attend a treatment program one or more days per week to learn skills necessary to manage symptoms (e.g. pain, mood and anxiety problems, substance craving) without resorting to substance use.

Once a moderate to severe opioid use disorder has been diagnosed, there is strong evidence for efficacy of methadone or buprenorphine maintenance combined with behavioral therapies compared to non-medication treatment.<sup>237-239</sup> Maintenance treatment leads to lower rates of illicit opioid use and likely reduces health care utilization and criminal justice involvement.<sup>240-243</sup>

There is very little evidence that antagonist therapy with oral naltrexone is effective for patients with opioid use disorder, and there is no evidence in patients with chronic pain. However, it might be considered in selected, highly motivated patients (e.g. impaired professionals).<sup>244</sup>

## Part VII. Chronic Pain Management in Special Populations

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In this section, five guest authors who are recognized leaders and clinicians in their fields, provide their views and clinical recommendations for pain management during pregnancy (including neonatal abstinence syndrome (NAS)), in children and adolescents, older adults, and cancer survivors. This section serves as an overview to orient primary care providers to special needs of these populations in regards to opioid use and does not include all modalities for pain management.

### Managing Chronic Pain during Pregnancy; and Neonatal Abstinence Syndrome

Alyssa Stephenson-Famy MD, Assistant Professor, University of Washington Department of Obstetrics & Gynecology, Division of Maternal-Fetal Medicine

Opioid use during pregnancy complicates the clinical management of an already vulnerable group. Opioid use in pregnancy is increasing at an alarming rate, an estimated 3 to 4-fold increase between 2000 and 2009.<sup>245</sup> Studies of opioid exposure during pregnancy suggest increased fetal, obstetrical and neonatal risks, including NAS. Many pregnancies are unplanned, and women of reproductive age may be using opioids prior to a clinically recognized pregnancy. These factors make management of opioid use during pregnancy particularly challenging for healthcare providers.

**Women who use opioids and could become pregnant require counseling regarding maternal, fetal and neonatal risks.**

#### Clinical recommendations

1. Recommend counseling before (preconception) and during pregnancy for women on COAT to assess and educate about potential maternal, fetal, and neonatal risks.
2. Address underlying contributors to pain syndromes such as stress and anxiety and use non-pharmacologic therapies as appropriate, including stress reduction, exercise, mechanical therapies, activity modification, and complementary and alternative medicine approaches. If appropriate, refer for mental health services ([Non-opioid Options](#)).
3. Use acetaminophen during pregnancy for treatment of pain. Consider NSAIDs in consultation with an obstetrical provider for short duration of therapy (<48 hours) prior to the third trimester.
4. Use caution when initiating short-acting opioids for treatment of pain during pregnancy and limit it to women with severe pain for whom other medical treatments have failed.
5. Assess pregnant women taking opioids for opioid use disorder. If present, refer to a qualified specialist for methadone or buprenorphine treatment for pregnant women. Buprenorphine may have improved neonatal outcomes, but availability may be limited due to provider or geographic access ([Appendix H: Clinical Tools and Resources](#)).
6. Monitor fetal growth for women on opioids, using fundal height or ultrasound surveillance, given the risk of intrauterine growth restriction.

7. Consider a perinatal pediatric consultation for pregnant women on opioids to better prepare them for risks of NAS and possible increased hospital stay for the newborn.
8. Use the Finnegan score to assess neonates during the immediate postnatal period if they were exposed to opioids in utero.
9. Weigh carefully the risks/benefits of opioid detoxification during pregnancy, when making the decision to go forward with treatment; and closely monitor the treatment plan for symptoms of withdrawal and risk of relapse.
10. Assess availability of social and community support for women with opioid use disorder or escalating pain symptoms during pregnancy to help meet any needs for education and services.

## Evidence

Ideally, pharmacologic agents would not be needed during pregnancy. However, pain in pregnancy is common and may include musculoskeletal symptoms, exacerbation of previous injuries, headaches and abdominal pain. Some women will require ongoing or episodic opioid treatment for medical conditions, which may be exacerbated by pregnancy. Safety and efficacy data for non-opioid treatments for pain symptoms in pregnancy is limited. Analgesics such as acetaminophen are generally considered safe, while NSAIDs may cause oligohydramnios and premature closure of the ductus arteriosus when used for prolonged periods or during the third trimester.<sup>246,247</sup> Mechanical therapies, exercise, complementary or alternative medicine, and psychiatric treatment have been beneficial, but each may have risks to a woman's pregnancy based on her history.<sup>248</sup>

A 2015 CDC study showed that 39% of women age 15-44 on Medicaid between 2008-2012 had filled an opioid prescription each year, compared with 28% of women with private insurance.<sup>249</sup> Of pregnant women enrolled in Medicaid between 2000-2007, 21.6% filled an opioid prescription from an outpatient pharmacy during pregnancy<sup>250</sup> as compared to 14.4% of pregnant women with private insurance during 2005-2011.<sup>251</sup> These studies do not provide insight on the indications for opioid prescriptions but illustrate remarkably high rates in both the privately and publicly insured populations.

## Fetal and Obstetrical Risks

Opioids are known to cross the placenta and can be detected in fetal umbilical cord blood and meconium.<sup>252</sup> The window for teratogenicity is from 4 to 10 weeks after the last menstrual period, which is often before a clinically recognized pregnancy. Research on teratogenicity of opioids is limited and heterogeneous as there is a relatively high 2-3% incidence of major congenital malformations in the general population. Studies have shown that opioid exposed fetuses may be at increased risk for neural tube, cardiac and gastrointestinal defects.<sup>253,254</sup>

Opioid use during pregnancy is associated with adverse pregnancy outcomes such as preterm delivery, poor fetal growth, and stillbirth.<sup>255</sup> Additionally, pregnant women who use opioids have higher rates of depression, anxiety, and chronic medical conditions, with increased health care costs.<sup>255</sup> There are, however, numerous confounders that challenge the causal relationship between opioids and adverse obstetrical events, such as co-morbid medical conditions, obesity, poor nutritional status, socioeconomic background, and poly-substance abuse (alcohol, tobacco, illegal drugs).

## Risks Associated with Medically Supervised Withdrawal from Opioids

The safety of medically supervised withdrawal from opioids during pregnancy is not well studied, although there are historical reports of embryonic or fetal loss, preterm labor, and fetal distress during maternal opioid withdrawal.<sup>256-258</sup> Several recent studies have reported successful inpatient medically supervised withdrawal from opioids during pregnancy with no increased risk of adverse obstetrical outcomes.<sup>259-261</sup> Ideally, women should discontinue or minimize opioid dose *prior* to pregnancy to decrease the risk of birth defects, obstetrical complications and neonatal abstinence syndrome. The decision to proceed with opioid discontinuation or medically supervised withdrawal during pregnancy is complex and must be individualized.

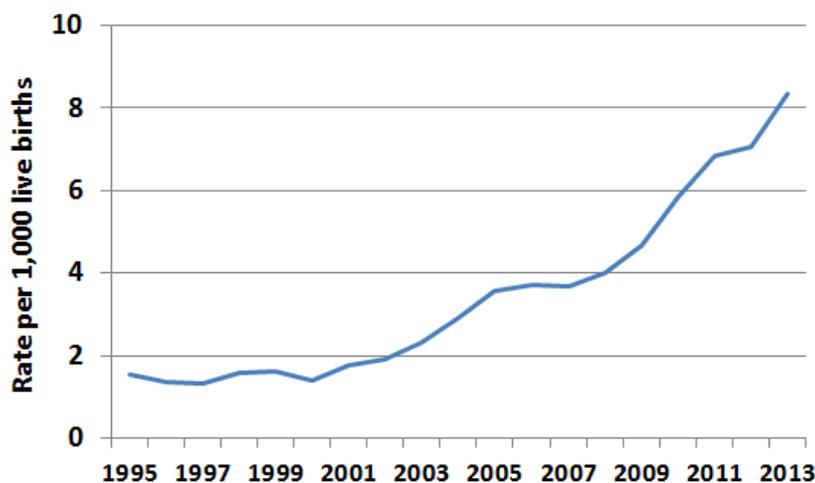
## Treatment of Opioid Use Disorder

For pregnant women with opioid use disorder (as defined by DSM 5), use of methadone or buprenorphine reduces illicit drug use, criminal activity and infectious complications (including sexually transmitted diseases, HIV, hepatitis B and C), while improving adherence to prenatal care.<sup>262</sup> The American Academy of Pediatrics supports use of methadone (without limitation) and other opioids during breastfeeding. Active use of illegal drugs, however, is a contraindication to breastfeeding.<sup>263</sup>

## Neonatal Abstinence Syndrome

Long-term opioid therapy during pregnancy can lead to NAS.<sup>245</sup> It typically occurs in the first 24 hours to 14 days of neonatal life and is characterized by the Finnegan score, which grades the degree of psychomotor irritability, vasomotor and gastrointestinal disturbances.<sup>264,265</sup> NAS may occur in up to 60-80% of opioid exposed infants<sup>245</sup> and has been increasing at an alarming rate (Figure D). Maternal methadone dose at delivery does not correlate directly with risk of NAS.<sup>266</sup> Buprenorphine is associated with a lower incidence and shorter duration of NAS, higher birth weights and longer gestation.<sup>262</sup>

Figure D. Infant Hospitalizations for Neonatal Abstinence Syndrome in WA State 1990-2013



Source: Inpatient Hospital Discharge & Birth Certificate Data,  
NAS= ICD diagnosis code of 779.5

## Managing Chronic Non-cancer Pain in Children and Adolescents

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The use of opioids to treat pain in infants and children presents challenges for a few key reasons. First, with very rare exception, opioids have not been labeled for use in individuals less than 18 years of age, indicating a dearth of quality studies on pharmacokinetics, pharmacodynamics, safety, and, in the youngest children, clinical effectiveness. Second, although acute pain problems in pediatrics have many characteristics in common with adult presentations, persistent, recurrent, and chronic pain in infants, children, and adolescents are often qualitatively different than chronic pain problems in adults. It is a corollary that treatment approaches may vary accordingly. Finally, it is often said that “children are not little adults,” meaning one cannot simply extrapolate from adult medicine to pediatrics; however, “adults are big children” and there is mounting evidence to show that poorly treated pain in childhood and adolescence is strongly associated with chronic pain and other difficulties in the adult years.

### Clinical Recommendations

1. Prescribe opioids for acute pain in infants and children only if knowledgeable in pediatric medicine, developmental elements of pain systems, and differences in pharmacokinetics and pharmacodynamics in young children.
2. Avoid opioids in the vast majority of chronic non-cancer pain problems in children and adolescents (e.g. abdominal pain, headache, pervasive musculoskeletal pain), as evidence of safety and efficacy is lacking.
3. Opioids are indicated for a small number of persistent painful conditions, including those with clear pathophysiology and when an endpoint to usage may be defined, such as pain associated with most surgical procedures, trauma (including burns), and major reconstructive surgery.
4. Opioids may be indicated for some chronic pain conditions in children and adolescents when there is clear pathophysiology and no definable endpoint. This may include treatment at the end of life or for certain ongoing nociceptive mediated painful conditions, such as osteogenesis imperfecta or epidermolysis bullosa.
5. Put safety first when prescribing opioids to younger patients: limit the total dispensed and educate parents about dosing, administration, storage and disposal to minimize risks of diversion or accidental ingestion. Adolescents should undergo similar screening for risk of substance use disorder that one would conduct with adults.
6. Consult or refer to a pediatric pain specialist when chronic pain problems in children and adolescents are complicated or persistent, given the developmental complexities and potential for ongoing pain problems in the future. These problems are best treated by those with specialty training in the area.

## Evidence

### Labeling of Opioids for Use in Pediatrics

Approximately 80 percent of drugs prescribed for children in the United States are done so “off label,” as they have not been approved by the FDA for use in the younger age groups.<sup>267,268</sup> Clinicians, therefore, are faced with a difficult dilemma: do we withhold potentially beneficial medications from young patients because they are not labeled for that age group? In the case of analgesics, this means unnecessary suffering. Or do we give the drugs based on extrapolation from adult studies (with some dosage modifications for body mass or surface area) without direct data on safety and effectiveness?

Even with innovations to improve the study of pediatric medications, such as the Best Pharmaceuticals for Children Act<sup>iv</sup> and the Pediatric Research Equity Act<sup>v</sup>, analgesic medications remain quite under-represented. No analgesic medications have been labeled for children less than 6 months of age and only ibuprofen has been labeled for those 6 to 24 months. Based on expert consensus, the effectiveness of opioids may be extrapolated from studies on adults and older children down to those 2 years of age and older. Still lacking, however, are sufficient data on drug metabolism, dose response, and toxicity.<sup>269,270</sup>

Although the benefits have been deemed to outweigh the risks for using opioids for acute pain in children, such is not the case for chronic pain and, thus, opioid treatment in this context is generally discouraged.<sup>271</sup> For example, the American Pain Society (2012) states, “Opioids are rarely indicated in the long-term treatment of chronic non-cancer pain in children, although they may be beneficial in certain painful conditions with clearly defined etiologies.” The Japanese Pediatric Society guidelines state, “The use of opiates for non-cancer chronic pain is debatable; they are generally reserved for treatment of painful syndromes related to cancer, injury, or other acute types of pain. The use of opiates is not recommended for the types of chronic pain described in the present guidelines.”<sup>272</sup> The indications are clearly for those conditions with clear underlying pathophysiology and when some endpoint is defined prior to initiation.

### Chronic Pain in Pediatrics

The most common presentations of chronic pain in children and adolescents include abdominal pain, headache, and musculoskeletal pain.<sup>273</sup> The most common pain problems in adults are rarely seen in pediatric populations, as they are frequently neuropathic in nature and often are related to degenerative aging processes.<sup>274</sup> As a consequence, treatment modalities are often quite different, i.e. biopsychosocial models are emphasized in children, and opioids rarely have a role. The possible exceptions are chronic, non-cancer conditions with known pathophysiology and a defined endpoint (e.g. a patient with avascular necrosis awaiting joint replacement), or conditions with persistent pain with an expected endpoint (e.g. post-trauma or extended post-operative pain).<sup>275</sup>

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<sup>iv</sup><http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/SignificantAmendmentstotheFDCA/ucm148011.htm> and <http://bpca.nichd.nih.gov/Pages/Index.aspx>

<sup>v</sup><http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077853.pdf>

## Developmental Trajectories: Adults are Big Children

A comprehensive review of longitudinal studies focused on the continuity or contiguity of pediatric and adolescent chronic pain problems into adulthood is beyond the scope of this guideline. Certainly, adults with chronic pain often recall having had difficulties in their earlier years. More substantial, however, are the prospective longitudinal or cross-sequential studies demonstrating these trajectories. Multiple studies have shown that children with functional abdominal pain are at risk for difficulties as adults that include anxiety or depressive disorders, functional gastrointestinal disorders, and other non-abdominal chronic pain.<sup>276-280</sup> Similar data have been generated for headaches<sup>281,282</sup> and back pain<sup>283-285</sup> Although no specific studies on prevention have been reported, it seems clear that by addressing pain complaints in the young, morbidity in the subsequent years will be reduced.

## Managing Chronic Pain in Older Adults

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Aging is associated with unique biological, psychological and social factors that all play an important role in pain management. As in all age groups, evidence of long-term effectiveness of opioid therapy is lacking. However, in carefully selected and monitored patients, opioids may provide effective pain relief if used as part of a comprehensive multimodal pain management strategy.<sup>286</sup> A combination of pharmacologic, non-pharmacologic, and rehabilitative approaches in addition to a strong therapeutic alliance between the older patient and physician is essential to achieve desired treatment outcomes.<sup>83</sup>

### Clinical Recommendations

1. Use opioids with short half-lives, as they are usually the best choices for older adults. Drugs with a long half-life can readily accumulate in older adults and result in toxicity (e.g. respiratory depression, sedation).
2. Weigh the individual patient's needs and clinical presentation with known risk factors when deciding whether short or long acting opioids are best.
3. Avoid the use of agonist-antagonist opioids in older adults as their psychomimetic side effects can be pronounced.
4. Be vigilant when treating patients over 65 to adequately relieve pain while minimizing the risk of delirium and other opioid-related adverse drug events.
5. Use the least invasive method of drug administration (e.g. oral).
6. Initiate opioid therapy at a 25% to 50% lower dose than that recommended for younger adults, and slowly and carefully titrate dosage by 25% increments on an individual basis, balancing pain relief, physical function, and side effects.
7. Have a plan for addressing constipation from the start of opioid therapy. Prophylaxis and/or treatment can include hydration, bulk fiber (only if hydration is maintained), activity, senna, and sorbitol (20 ml of 70% taken twice daily for 3 days per week).
8. Recognize and manage all potential causes of side effects, taking into consideration medications that potentiate opioid side effects:

- a. Sedatives, tranquilizers, and anti-emetics can cause sedation.
  - b. Antihypertensives and tricyclics can cause postural hypotension.
  - c. Antihistamines, phenothiazines, tricyclics, and anticholinergics can cause confusion and urinary retention.
9. Avoid using more than one opioid at the same time. This makes it is easier to identify the cause of an adverse effect or toxic reaction. The incidence of delirium and other adverse reactions increases with the number of prescription drugs taken.
10. **Avoid** the following drugs:
- a. Codeine: the doses required for effective pain relief in older adults are associated with an increased incidence of side effects (e.g. constipation, nausea and sedation).
  - b. Meperidine: the metabolite, normeperidine, is toxic to the CNS and can cause seizures, mood alterations and confusion; more so in older patients, especially if the patient has renal impairment.
  - c. Methadone: has a high drug-drug interaction potential and is associated with prolongation of the QT interval and a potential risk of accumulation due to a long elimination half-life. In addition, methadone is difficult to titrate because of its large inter-individual variability in pharmacokinetics, particularly in the frail elderly.

## Evidence

Approximately 60% of Americans over age 65 have persistent pain, most commonly from musculoskeletal disorders such as arthritis and degenerative spine conditions<sup>287</sup> but painful conditions related to neuropathies, advanced heart, kidney, or lung disease are also reported.<sup>288,289</sup> Older adults are also more likely to undergo surgeries associated with a high incidence of persistent pain.<sup>290</sup> Persistent pain or inadequate treatment in older adults is associated with reduced physical performance, falls, decreased sleep and self-rated health, mood, and cognition.<sup>286</sup>

Due to the frequency of chronic disease and potential for polypharmacy among older adults, drug-disease and drug-drug interactions should also be considered when prescribing. Nutritional alterations (e.g. protein deficiency), age-related changes (e.g. reduced hepatic and renal function, reduced body water, altered ratio of lean body mass to total body weight) and altered pharmacokinetics impact treatment options, necessitating careful evaluation and monitoring.<sup>153</sup> These age-related changes all make older adults especially vulnerable to opioid side effects and reduce the therapeutic window between beneficial doses and doses that are toxic or lethal.

Though evidence shows that older adults are less likely to misuse and abuse opioids<sup>291</sup> they are also likely to have higher levels of pain severity and depressive symptoms and more physical disability. These can increase misuse and abuse,<sup>292</sup> so an individual approach weighing risks and benefits is best.<sup>286</sup>

There is insufficient evidence to recommend short-acting versus long-acting opioids, or as-needed versus around-the-clock dosing of opioids. In general, short-acting opioids using as-needed dosing is

suggested. However, one large longitudinal nursing home study showed that extended-release opioids improved functional status and social engagement when compared to short acting opioids.<sup>293</sup> An individual's condition and need for proper pain management must be weighed against the risks of developing adverse effects of COAT.

The potential for side effects is high in older adults due to altered ability to distribute and excrete drugs, resulting in greater peak and longer duration of action. Common opioid side effects include nausea, vomiting, delirium, respiratory depression, sedation, pruritus, hypotension, and urinary retention (especially if there is coexisting benign prostatic hypertrophy). Older adults are particularly prone to constipation and even ileus, making prevention measures particularly important. Opioids have also been linked to an increased risk for falls and non-spine fractures in community living older adults.<sup>294,295</sup>

Patients over 65 who receive opioids for postoperative pain have a higher risk for opioid-related adverse drug events.<sup>296</sup> Delirium has a significant impact on the medical, functional, and cognitive outcomes of older patients, and the risk of delirium increases with inadequate pain control and the use of meperidine.<sup>297,298</sup> In fact, use of meperidine is listed in the 2012 American Geriatrics Society Beers Criteria as potentially inappropriate for older adults.<sup>299</sup>

## Managing Chronic Pain in Cancer Survivors

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Management of chronic pain in cancer survivors involves unique issues that require a careful and thoughtful approach from the clinician. Although the term cancer survivor has a variety of definitions, for this guideline, a survivor is someone who has completed cancer treatment, is cured or in full clinical remission with no current evidence of disease, and is under cancer surveillance only.<sup>8,300,301</sup> For these patients, the foremost issues to keep in mind are:

1. Cancer survivors are at risk of recurrent disease, so development of new or worsening pain in the survivor requires a thorough evaluation to explain the pain.
2. The chronic pain experienced by cancer survivors is most often due to their earlier treatment for active cancer (e.g., chemotherapy-induced peripheral neuropathy, radiation treatment effects, persistent post-surgical pain) or residual effects from the previous tumor (e.g., compression fractures) and can persist for many years after that treatment has been completed. This is termed "chronic cancer-related pain" (CCRP), and for the purpose of this guideline, should not be confused with treatment for pain in the setting of active cancer.

In the absence of "red flags" for malignancy, simple exacerbations of chronic pain in the survivor may be treated in a manner similar to chronic non-cancer pain (CNCP). Hence, the best pain management strategy combines diligent monitoring for cancer recurrence with standard chronic pain management therapies, including multimodal and interdisciplinary approaches.

Cancer survivors tend to be older, 45% are over the age of 70, and only 5% younger than age 40.<sup>8,302</sup> The most common cancer types in survivors are female breast, prostate, colorectal, melanoma, and gynecologic. With this survival benefit comes the burden of long-term and late effects of cancer and cancer therapy. The most common issues are pain, depression, and fatigue. Other chronic problems include cognitive decline, sexual dysfunction, anxiety, and sleep disorders.<sup>303-305</sup>

**Primary care providers will see more patients who are cancer survivors, as their numbers are increasing significantly due to earlier detection and improved cancer therapies.<sup>8</sup>**

### Clinical Recommendations

1. Make a medical diagnosis for the cause of pain and accurately define its location. Promptly address new and worsening complaints and determine the cause. Always consider cancer recurrence or secondary malignancy in the differential diagnosis. See [Table 13](#) for signs and symptoms of spinal cord compression.
2. Follow the recommendations for treating chronic non-cancer pain once cancer recurrence has been ruled out as the source of pain. This includes using multimodal and interdisciplinary approaches and reducing the opioid dose (if indicated) to the lowest effective levels for pain complaints that remain stable ([Reducing or Discontinuing COAT](#)).
3. Educate survivors about the cause of their pain and the role of opioids in managing chronic cancer-related pain, and discuss the risks and benefits of COAT.
4. Encourage the use of non-pharmacologic therapies with a focus on rehabilitation and pain management. This may include a graduated exercise program, physical therapy, thermal therapy, complementary and alternative measures, and counseling to help with anxiety, depression, and coping ([Non-opioid Options](#)).
5. Use an individualized approach to pain management, paying special attention to those who are hypervigilant about their body sensations and may present with frequent reports of new symptoms. Careful assessment of complaints and review of surveillance testing may help alleviate the survivors' concerns.
6. Be alert to survivors' fear of cancer recurrence, as this commonly underlies pain behaviors. Reassure and redirect them after a thorough evaluation of the pain complaint, and consultation with the oncologist as appropriate.
7. Encourage survivors to actively engage in their pain management plan and to explore options to participate in support groups. An essential component to this is for the clinician to provide a detailed explanation to the patient on the cause or causes of the pain complaint.

**During active cancer treatment, patients may have been accustomed to frequently changing and/or escalating opioid doses with any complaint of worsening pain intensity. The survivor with CCRP may be surprised when their provider not only declines to escalate an opioid dose, but instead initiates a slow taper once remission and functional goals have been achieved. Significant education is needed to assist the patient and caregiver to understand this new approach.<sup>9</sup>**

## Evidence

Chronic cancer-related pain (CCRP) is common in cancer survivors, with an overall incidence of 33% to 40%.<sup>8,306,307</sup> One study found that 16-73% of breast cancer survivors experience pain, as well as a significant symptom burden of psychological distress and insomnia.<sup>308</sup> Survivors younger than 50 years of age report more pain than older patients.<sup>309</sup> CCRP typically is more common and more severe in the first few years after completing treatment, then declines in intensity as time passes.<sup>307</sup> The Childhood Cancer Survivor Study reported 11% of adult survivors (mean interval from diagnosis 17 years) experienced medium or higher pain intensity;<sup>310</sup> and 6% of Australian adult cancer survivors at 5-6 years post treatment reported moderate to severe pain.<sup>311</sup> However, certain *late effects* of therapy may emerge or persist for years, or even decades, after completing therapy, such as radiation related plexopathies or fibrosis, producing discomfort, pain, reduced range of motion (ROM) and impacting quality of life.<sup>312</sup>

Unlike CNCP, identifiable tissue damage caused by the tumor or, more commonly, the cancer treatment, is typically the basis of the pain complaint.<sup>307</sup> Examples include painful chemotherapy-induced peripheral neuropathy (CIPN) or post radiation therapy fibrosis, scarring of somatic structures, or tumor-related vertebral compression fractures (e.g. from treated myelomatous lesions). Certain pharmacological therapies can cause lasting pain problems during use, for instance, aromatase inhibitors such as anastrozole, exemestane, and letrozole that are used to prevent recurrence of breast cancer and are taken for variable periods (2-10 years) after completing initial therapy. Nearly half of women using these agents may experience myalgias and arthralgias,<sup>313</sup> which may be of enough severity that 21-38% of patients abandon this potentially life-saving therapy<sup>314</sup> ([Table 11](#)).

**Table 11. Common Pain Syndromes Resulting from Cancer Treatment\***

Chemotherapy-induced peripheral neuropathy (CIPN)
Myalgias and arthralgias from aromatase inhibitors in breast cancer survivors
Generalized myofascial pain from deconditioning or sleep disorders
Post-operative neuropathic pain syndromes such as post-mastectomy, post-amputation, post-radical neck pain
Chronic pain from radiation therapy such as muscle fibrosis, plexopathies, lymphedema, and chronic proctitis, cystitis, enteritis, or tenesmus from pelvic radiation

\*For a more extensive description of chronic pain syndromes, the types of cancers they are associated with, along with causes and treatment options, ([Appendix E: Chronic Pain Syndromes in Cancer Survivors](#)).

Chronic cancer-related pain in the survivor can improve significantly with a variety of pharmacological and non-pharmacological therapies. Pain treatments in the survivor should be modeled after chronic non-cancer pain strategies, rather than palliative therapies. In most patients, the primary goal of therapy is functional improvement rather than exclusively a reduction in pain intensity.<sup>315</sup>

Opioids are the foundation for pain management when cancer is an active disease. Although it may often be appropriate to continue opioids in survivors, use of COAT should generally follow the guidelines for CNCP that focus on accurate diagnosis of the components of the pain complaint, and establishing patient-specific functional goals. In cancer survivors, as in CNCP, neuromodulators for neuropathic pain, such as serotonin-norepinephrine reuptake inhibitors (SNRIs), show evidence of benefit, particularly for CIPN caused by taxanes and platinum derivatives.<sup>316</sup> Tricyclic antidepressants and anticonvulsants continue to be recommended on the basis of efficacy data in other neuropathic pain conditions that are well established for various CNCP complaints.<sup>317 8</sup> However, it should be noted that efficacy of these agents has not been established in cancer survivors.

Topical agents, such as lidocaine 5% patch, capsaicin cream, or diclofenac gel may be helpful for some post-surgical pain syndromes of cutaneous or myofascial origin. Persistent severe CIPN or radiation-induced fibrosis affecting range of motion, particularly in the head, neck, and shoulder regions, may merit ongoing opioid therapy, and in such situations may be the primary agent of choice.

Non-pharmacological therapies are important strategies in the management of CCRP. Physical therapy, rehabilitation, and graded exercise programs will help reverse deconditioning and functional loss commonly experienced during cancer treatment. Specialized therapy such as manual lymphatic drainage for lymphedema will improve discomfort from swelling. Counseling for anxiety, depression, and pervasive fear of cancer recurrence is beneficial; as is mindfulness training and other cognitive behavioral strategies to reduce pain. Sleep hygiene education is essential for pain management, as sleep disruption is common in this population.<sup>313</sup> Traditional sleep-inducing agents such as zolpidem are not recommended for long-term use.

**All new or worsening pain in the cancer survivor must be promptly evaluated to eliminate the possibility of cancer recurrence as the source of pain. Consultation with the patient's oncologist is recommended to provide guidance as needed.**

### **Recurrent or Secondary Malignancy**

Most survivors struggle with a fear of cancer recurrence, and are well aware that pain may be an initial symptom.<sup>313</sup> The clinician should provide reassurance that all new or worsening pain problems will be assessed and appropriately investigated to eliminate cancer as the cause. Extensive emotional support may be needed, and formal counseling with supportive services may be required to assist with anxiety related to the potential for cancer recurrence.<sup>300,318</sup>

The oncologist will direct surveillance screening, either through his/her office, or guide the primary care provider through the Cancer Treatment Summary and Survivorship Care Plan.<sup>319-321</sup> However, it is

essential that all providers involved in the care of cancer survivors know the signs and symptoms associated with cancer, whether from recurrence or secondary malignancy ([Table 12](#)). In many situations, pain may be the only presenting symptom of recurrence, and it is essential that clinicians closely monitor and assess this complaint.

**Table 12. Signs and Symptoms Associated with Recurrence of Malignancy** <sup>313 300 322</sup>

New or worsening pain
Unexplained and unintentional weight loss of 10 pounds (4.5 kg)
Night sweats
Fever and chills
Enlarging masses
Unusual fatigue
Excessive bruising or bleeding
Change in moles or skin lesions
Altered bowel function
Persistent cough or hoarseness
Signs of breast cancer recurrence include: new lumps or skin changes in breast or axilla; new dyspnea; persistent headache; new bone, chest, or abdominal pain

Cancer may occasionally present as metastatic disease with spread to the vertebrae, and in advanced cases, cause spinal cord compression. The most common disease types where this may occur are lung, breast and prostate cancer. Symptoms include: ([Table 13](#)).

**Table 13. Signs and Symptoms of Spinal Cord Compression** <sup>300,322-324</sup>

<b>New onset of severe back pain</b>	<ul style="list-style-type: none"> <li>• Thoracic spine is most common site</li> <li>• Pain may be localized to 1-2 vertebrae or be diffuse</li> <li>• Worse at night and with recumbency</li> <li>• Worse with Valsalva maneuver such as occurs with bowel movements</li> <li>• May present as a “band” of pain or numbness around the torso</li> </ul>
<b>New weakness in the limbs</b>	May be described as “clumsiness” or “heaviness” of the limbs
<b>New sensory changes in the limbs</b>	Paresthesias, dysesthesias, lancinating pain
<b>Loss of bowel or bladder control</b>	Urinary retention causing overflow incontinence, or fecal incontinence from loss of anal sphincter tone
<b>Saddle anesthesia</b>	Numbness in perineum, lower buttocks, posterior proximal thighs

## Part VIII. Appendices

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## Appendix A: Opioid Dose Calculations

Table 14. Dosing Threshold for Selected Opioids

Opioid	Recommended dose threshold for pain consult	Recommended starting dose	Considerations
<b>Buprenorphine Transdermal</b>	Threshold is beyond maximum daily dose	5 mcg/hr q 7 days	Maximum dose: 20 mcg/hr due to risk of QTc prolongation
<b>Codeine</b>	800 mg per 24 hours	30 mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient.
<b>Fentanyl Transdermal</b>	50 mcg/hour q 72 hours	12.5 mcg/hour q 72 hours	Use only in opioid-tolerant patients who have been taking ≥60 mg MED daily for a week or longer.
<b>Hydrocodone</b>	120 mg per 24 hours	Immediate Release 5-10 mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient.
		Sustained Release 10 mg q 12 hours	<b>Use ER formulation with extreme caution due to potentially fatal interaction with alcohol or medications containing alcohol.</b>
<b>Hydromorphone</b>	30 mg per 24 hours	Immediate Release 2 mg q 4–6 hours	Because of its short half-life, hydromorphone is a good choice in older adults with renal impairment.
		Sustained Release 8 mg q 24 hours	
<b>Morphine</b>	120 mg per 24 hours	Immediate Release: 10 mg q 4 hours	Metabolites may accumulate in patients with impaired renal or hepatic function resulting in prolonged effects and toxicity.
		Sustained Release: 15 mg q 12 hours	<b>Use Avinza with extreme caution due to potentially fatal interaction with alcohol or medications containing alcohol.</b>
<b>Oxycodone</b>	80 mg per 24 hours	Immediate Release: 5 mg q 4–6 hours	See individual product labeling for maximum dosing of acetaminophen combination products. Avoid concurrent use of any OTC acetaminophen products.
		Sustained Release: 10 mg q 12 hours	

Opioid	Recommended dose threshold for pain consult	Recommended starting dose	Considerations
Oxymorphone	40 mg per 24 hours	Immediate Release: 5–10 mg q 4–6 hours	<b>Use ER formulation with extreme caution due to potentially fatal interaction with alcohol or medications containing alcohol.</b>
		Sustained Release: 10 mg q 12 hours	
Tapentadol	300 mg per 24 hours	Immediate Release 50 mg q 4-6 hours	Dual mechanism of action - binds to mu-opioid receptors and inhibits reuptake of norepinephrine. Use caution when combining with other medications that affect serotonin as it may increase risk of seizures and serotonin syndrome.  Do not exceed 600 mg/day for immediate release and 500 mg/day for sustained release formulation.
		Sustained Release 50 mg q 12 hours	
Tramadol	Threshold is beyond maximum daily dose	Immediate Release 50 mg q 4-6 hours	Dual mechanism of action - binds to mu-opioid receptors and inhibits reuptake of serotonin and norepinephrine. Use caution when combining with other medications that affect serotonin as it may increase risk of seizures and serotonin syndrome.  Do not exceed 400 mg/day for immediate release and 300 mg/day for sustained release formulation.
		Sustained Release 100 mg q 24 hours	

\*Meperidine should not be prescribed for chronic pain.

\*\*Methadone should only be prescribed for chronic pain if the provider is knowledgeable of methadone’s non-linear pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions and additional monitoring requirements.

\*\*\*Long-acting formulations should only be prescribed for opioid-tolerant patients who have been taking ≥60 mg MED daily for a week or longer

#### Morphine Equivalent Dose Table

All conversions between opioids are estimates generally based on equianalgesic dose. Patient variability in response to different opioids can be large, due primarily to genetic factors and incomplete cross-tolerance. **It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25–50% to assure patient safety.**

**Table 15. MED for Selected Opioids**

Opioid	Approximate Equianalgesic Dose (oral & transdermal) *
<b>Morphine (reference)</b>	<b>30 mg</b>
Codeine	200 mg
Fentanyl transdermal	12.5 mcg/hr
Hydrocodone	30 mg
Hydromorphone	7.5 mg
Oxycodone	20 mg
Oxymorphone	10 mg
Tapentadol	75 mg
Tramadol	300 mg

\*Adapted from Von Korff 2008 & FDA labeling

**Table 16. MED for Methadone**

Chronic Methadone Dose	Approximate Conversion Factors to Morphine Equivalent*
Up to 20 mg per day	4
21 to 40 mg per day	8
41 to 60 mg per day	10
>60 mg per day	12

\*Adapted from Ayonrinde 2000. Equianalgesic dose ratios between methadone and other opioids are complex. Methadone exhibits a non-linear relationship due to the long half-life and accumulation with chronic dosing. Because methadone pharmacokinetics are variable across patient populations, these conversion factors are approximate and doses around the cutoff can have huge differences in calculated MED.

## Calculating Morphine Equivalent Dose

This guideline provides an electronic [morphine equivalent dose \(MED\) calculator](#) for determining a patient's daily morphine equivalent dose when patients are on one or more opioids. Table 17 below shows samples of morphine equivalents that can be computed using the calculator.

**Table 17. Morphine Equivalent Dose Calculation**

For patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose ([Table 15](#)). For example, if a patient takes six hydrocodone 5 mg / acetaminophen 500 mg and two 20 mg oxycodone extended release tablets per day, the cumulative dose may be calculated as follows:

1. Hydrocodone 5 mg x 6 tablets per day = 30 mg per day.
2. Using the Equianalgesic Dose table in Appendix A, 30 mg Hydrocodone = 30 mg morphine equivalents.
3. Oxycodone 20 mg x 2 tablets per day = 40 mg per day.
4. Per Equianalgesic Dose table, 20 mg oxycodone = 30 mg morphine so 40 mg oxycodone = 60 mg morphine equivalents.
5. Cumulative dose is 30 mg + 60 mg = 90 mg morphine equivalents per day.

## Appendix B: Validated Tools for Screening and Assessment

	Tool Characteristics			
	Administration	Time to Complete	Length	Access Limitations
<b>Assessing Function and Pain</b>				
Pain, Enjoyment of life, General Activity (PEG) <a href="http://mytopcare.org/wp-content/uploads/2013/06/PEG-Pain-Screening-Tool1.pdf">http://mytopcare.org/wp-content/uploads/2013/06/PEG-Pain-Screening-Tool1.pdf</a>	Patient self-report	1 minute	3 items	
Two Item Chronic Pain Scale	Clinician or patient self-report	1 minute	2 items	
<b>Risk of Transitioning to Chronic Pain</b>				
STarTBack <a href="http://www.keele.ac.uk/sbst/startbacktool/">http://www.keele.ac.uk/sbst/startbacktool/</a>	Patient self-report	<5 minutes	9 items	
Functional Recovery Questionnaire (FRQ)	Clinician or patient self-report	<5 minutes	6 items	Requires email registration
<b>Screening for Risk of Opioid Addiction and Substance Abuse</b>				
Opioid Risk Tool (ORT) <sup>325</sup>	Clinician or patient self-report	1 minute	5 (yes/no) questions	
CAGE Adapted to Include Drugs (CAGE-AID) <sup>326-328</sup>	Clinician	<5 minutes	4 (yes/no) questions	
Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP-R) <a href="http://www.painedu.org/soapp.asp">www.painedu.org/soapp.asp</a>	Patient self-report	<10 minutes	24 items	Requires licensing agreement
Current Opioid Misuse Measure (COMM) <a href="http://www.painedu.org/soapp.asp">www.painedu.org/soapp.asp</a>	Patient self-report	<10 minutes	17 items	Requires licensing agreement
DIRE <a href="http://integratedcare-nw.org/DIRE_score.pdf">http://integratedcare-nw.org/DIRE_score.pdf</a>	Clinician interview	<2 minutes	7 items	
Alcohol Use Disorders Identification Test (AUDIT)	Clinician or patient self-report	<5 minutes	10 items	
<b>Screening for Mental Health Disorders</b>				
Patient Health Questionnaire 9 (PHQ-9)	Patient self-report	<5 minutes	10 items	
GAD-7 <a href="http://www.mpho.org/resource/d/34008/GAD708.19.08Cartwright.pdf">http://www.mpho.org/resource/d/34008/GAD708.19.08Cartwright.pdf</a>	Patient self-report	<5 minutes	7 items	
PC-PTSD	Clinician interview	<5 minutes	4 items	

\*Except for the FRQ, all of the free, publicly available tools listed in this table have demonstrated good content, face, and construct validity in screening for risk of addiction and monitoring opioid therapy. Further validation studies and prospective outcome studies are needed to determine how the use of these tools predicts and affects clinical outcomes.

## Appendix C: How to use the Prescription Monitoring Program

Chris Baumgartner, BS, Prescription Drug Monitoring Program Director  
Washington State Department of Health

Prescription Drug Monitoring Programs (PDMPs or PMPs) are now operating in 49 states, and have demonstrated their value on many levels.<sup>329-333</sup> In Washington State, the Prescription Monitoring Program (PMP) is also known as [Prescription Review](#). This database contains the history of all controlled substances dispensed by Washington licensed facilities and providers since implementation in October 2011. The PMP offers key clinical benefits, such as identifying duplicative drug therapy, dangerous drug combinations, other providers involved in the patient’s care, signs of aberrant behaviors and possible misuse, and patient’s medication compliance. Providers or their qualified delegated staff should access the PMP before prescribing and as part of ongoing monitoring of treatment with controlled substances. The PMP is an important tool for providers to improve patient care and prevent opioid misuse when prescribing controlled substances.

### How to Access the PMP

Providers can register for access online at [www.wapmp.org](http://www.wapmp.org) and the system is available 24/7. For PMP system or program assistance please refer to:

**PMP System Help Desk:**  
Health Information Designs  
P.O. Box 529 | Auburn, Alabama 36831  
**Phone:** 877-719-3121  
**Email:** [wapmp-info@hidinc.com](mailto:wapmp-info@hidinc.com)

**Washington State Department of Health**  
P.O. Box 47852 | Olympia, Washington 98504-7852  
**Phone:** 360-236-4806  
**Email:** [prescriptionmonitoring@doh.wa.gov](mailto:prescriptionmonitoring@doh.wa.gov)

Additional information, including FAQs, can be found at the [Department of Health’s PMP website](#).

### Recommendations for Integrating the PMP into Practice

- Assign someone in your organization the responsibility of ensuring all prescribing and dispensing providers register for access.
- Have all prescribers and dispensers register for master accounts. Prescribers can delegate their authority to licensed staff (e.g. nurses and medical assistants if they register for their own sub-accounts and are linked to the master accounts).
- Request PMP information as appropriate prior to patient visits and place a copy of the report in the patient’s medical chart.
- Consider training someone as a “PMP Champion,” or “Super-User,” who develops system expertise and can help train new staff or assist with questions.

## When to Check the PMP

- Prior to prescribing opioids for a new episode of pain or for transferred patients who are already using opioids.
- During the transition from subacute to COAT.
- Routinely for patients for whom you are prescribing chronic opioids and/or other controlled substances ([Table 18](#)).
- Regularly for patients who are being treated for addiction disorder.
- When conducting a preoperative history and medical exam.
- When there is evidence of aberrant behaviors ([Table 9](#)). Address aberrant behaviors in person, not by telephone.

**Table 18. Recommended Frequency of PMP Checks during COAT**

Risk Category	Recommended Frequency
Low risk	At least 1/year
Moderate risk	At least 2/year
High risk or opioid doses >120 mg/day MED	At least 3–4/year

## Interpreting a PMP Report

Providers should access and review the PMP as part of their complete assessment of the patient when prescribing controlled substances, including opioids, for an acute episode or chronic therapy:

- Keep in mind that there could be up to a 2-week lag time for dispensing information, so recently dispensed controlled substances may not be reflected in the PMP report. Also, the PMP database does not contain information from the Department of Defense and Opioid Treatment Programs.
- Compare the PMP report against your medical records. Any discrepancies should be reconciled with the dispensing pharmacy.
- Estimate the patient’s controlled substance consumption with “as needed” or PRN use by reviewing the prescription dispensed dates.
- Coordinate care, which may include requesting medical records, when multiple prescribers are identified on the PMP report.
- Discuss in person with the patient when aberrant behaviors (e.g. early refills) or dangerous combinations of opioids with benzodiazepines, sedative-hypnotics and/or carisoprodol are identified on the PMP report. Provide patient education on the [safe use of controlled substances](#).
- Confirm the patient is taking medication as prescribed.

If the PMP report reveals concerns such as aberrant behaviors, dangerous drug combinations or multiple prescribers, the provider should follow the clinical recommendations in the sections: [Reducing or Discontinuing Opioids](#) or [Opioid Use Disorder](#) and take appropriate actions.

# Appendix D: Urine Drug Testing for Monitoring Opioid Therapy

- [i. Using Urine Drug Testing \(UDT\) to Monitor Opioid Therapy for Chronic Non-cancer Pain](#) ..... 63
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## i. Using Urine Drug Testing (UDT) to Monitor Opioid Therapy for Chronic Non-cancer Pain <sup>334-336</sup>

The purpose of drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse and verify compliance with treatment. If a decision has been made to prescribe opioids for chronic non-cancer pain, the prescriber should get a baseline UDT and screen all patients for risk level to develop an appropriate monitoring plan as well as a basis for consultation or referral. Although UDT and other screening tools are helpful in identifying aberrant behavior, it is also important for prescribers to use their clinical judgment in the development of a monitoring plan. The Prescriber should repeat random UDT based on the patient’s risk category. There are several validated screening tools available to assess risk of aberrant behavior. The Opioid Risk Tool (ORT) provides a brief questionnaire that can easily be used in the primary care setting ([Appendix B](#)).

Prior to drug testing, the prescriber should inform the patient of the reason for testing, frequency of testing and consequences of unexpected results. This gives the patient an opportunity to disclose drug use and allows the prescriber to modify the drug screen for the individual circumstances and more accurately interpret the results.

Risk Category	UDT Frequency	Drugs or Drug Classes to Test	Consideration
Low Risk	1/year	<ul style="list-style-type: none"> <li>• Drug you are prescribing if not listed</li> <li>• Amphetamines</li> <li>• Opioids</li> <li>• Cocaine</li> <li>• Benzodiazepines</li> <li>• Alcohol</li> </ul>	Typically, the initial (screening) drug test uses an immunoassay method to identify the presence of a drug (presumptive positive). Because of cross-reactivity and different sensitivity and specificity between immunoassays, <b>a second confirmatory test is required</b> unless result is expected or the patient has disclosed drug use. Confirmatory drug tests use gas chromatography/mass spectrometry or liquid chromatography/tandem mass spectrometry (GC/MS or LC/MS/MS) to verify a presumptive positive result.
Moderate Risk	2/year	<ul style="list-style-type: none"> <li>• Barbiturates</li> <li>• Oxycodone</li> <li>• Methadone</li> <li>• Fentanyl</li> <li>• Marijuana</li> </ul>	
High Risk <b>or</b> opioid doses >120 mg MED/d	3-4/year		
Aberrant Behavior (lost prescriptions, multiple requests for early refills, opioids from multiple providers, unauthorized dose escalation, apparent intoxication, etc.)	At time of visit  (Address aberrant behaviors in person, not by telephone)	Testing for all drug classes may not be necessary, depending on clinical situation.	<p><b>Contact the laboratory director, toxicologist or a certified Medical Review Officer (MRO) in your area for questions about drug testing or result.</b></p> <p>If a point-of-care (POC) device is used, contact technical support from the manufacturer for questions.</p>

## UDT Results

Interpreting UDT results can be challenging, especially when the parent drug can be metabolized to other commonly prescribed drugs. The table on the next page may aid prescribers when interpreting UDT results. The following UDT results should be viewed as a “red flag”, requiring confirmation and intervention:

- Negative for opioid(s) you prescribed
- Positive for drug (benzodiazepines, opioids, etc.) you did NOT prescribe or have knowledge of
- Positive for amphetamine or methamphetamine
- Positive for alcohol
- Positive for cocaine or metabolites

If a **confirmatory drug test** substantiates a “red flag” result AND is:

- **Positive for prescribed opioid(s)**, prescriber should consider a controlled taper and a referral to an addiction specialist or drug treatment program depending on the circumstances.
  - **Negative for prescribed opioid(s)**, prescriber should stop prescribing opioid(s) and consider a referral to an addiction specialist or drug treatment program depending on the circumstances.
-

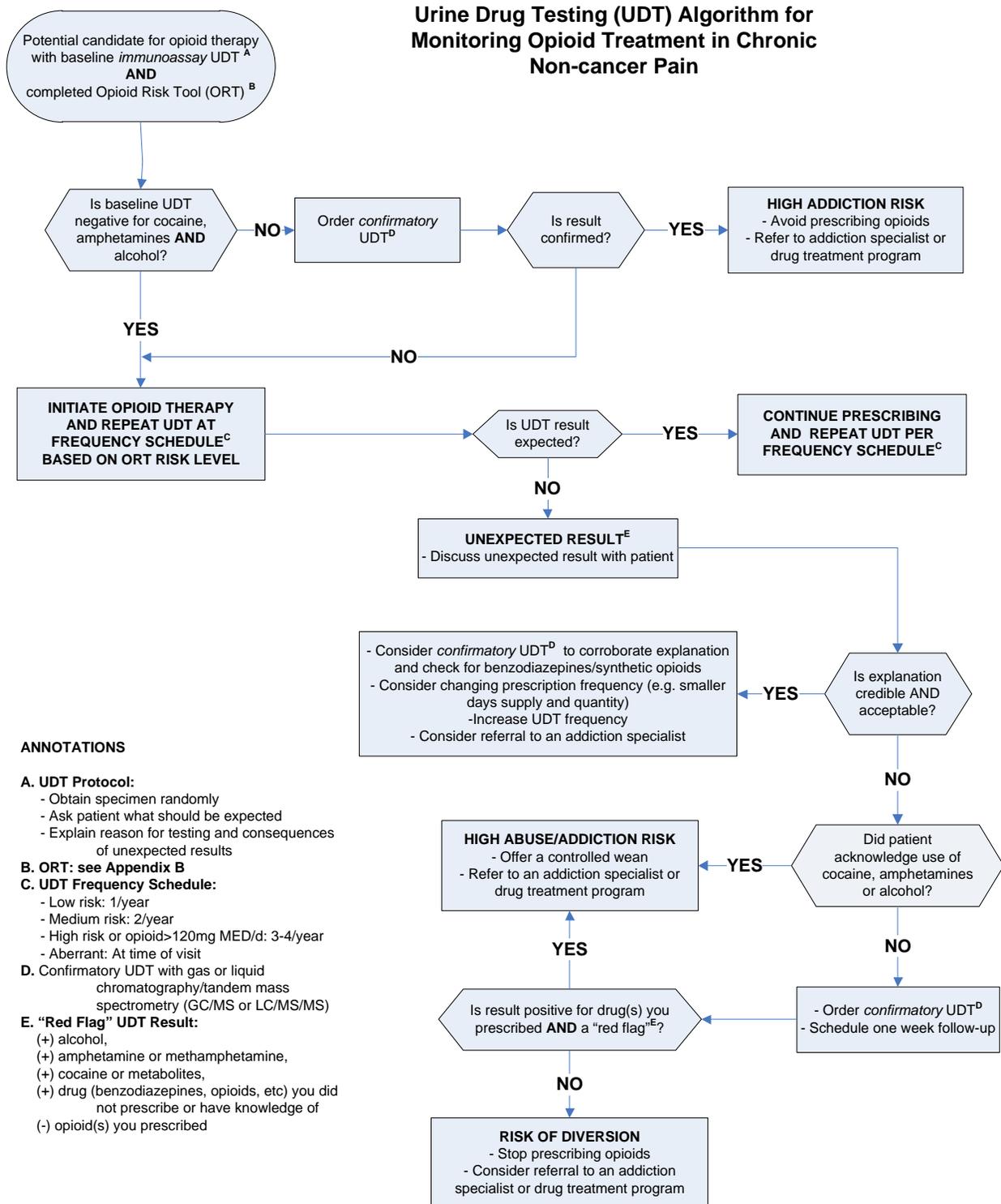
Drugs or Drug Classes	Detection Time in Urine*	Test to Order	Expected Results	Consideration
<b>Opioids or “opiates” – Natural (from opium)</b>				
Codeine (Tylenol #2/3/4)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay – positive GC/MS or LC/MS/MS – codeine, possibly morphine & hydrocodone	Immunoassays for “opiates” are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.
Morphine (Avinza, Embeda, MS Contin, Kadian)	1-3 days		Opiates Immunoassay – positive GC/MS or LC/MS/MS – morphine, possibly hydromorphone	
<b>Opioids – Semisynthetic (derived from opium)</b>				
Hydrocodone (Lorcet, Lortab, Norco, Vicodin, Zohydro, Hysingla)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay – positive GC/MS or LC/MS/MS – hydrocodone, possibly hydromorphone	“Opiates” immunoassays may also detect semisynthetic opioids depending on their cross-reactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS or LC/MS/MS) is required to verify compliance with the prescribed semisynthetic opioid(s).
Hydromorphone (Dilaudid, Exalgo)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay – positive GC/MS or LC/MS/MS –hydromorphone	
Oxycodone (Roxicet, OxyContin, Percocet, Targiniq)	1-3 days	Oxycodone Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates Immunoassay – positive GC/MS or LC/MS/MS – oxycodone possibly oxymorphone	Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.
Oxymorphone (Opana)	1-3 days	Opiates or Oxycodone Immunoassay + GC/MS or LC/MS/MS Opiates	Opiates or Oxycodone Immunoassay – positive GC/MS or LC/MS/MS – oxymorphone	
<b>Opioids – Synthetic (man-made)</b>				
Fentanyl (Duragesic)	1-3 days	GC/MS or LC/MS/MS Fentanyl	GC/MS or LC/MS/MS – fentanyl & norfentanyl	<b>Current “opiates” immunoassays do not detect synthetic opioids.</b> Thus confirmatory testing (GC/MS or LC/MS/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.
Meperidine (Demerol)	1-3 days	GC/MS or LC/MS/MS Meperidine	GC/MS or LC/MS/MS – normeperidine, possibly meperidine	
Methadone (Methadose)	3-7 days	Methadone Immunoassay + GC/MS or LC/MS/MS Methadone	Methadone Immunoassay – positive GC/MS or LC/MS/MS – methadone & EDDP	

Drugs or Drug Classes	Detection Time in Urine*	Test to Order	Expected Results	Consideration
<b>Others</b>				
Alcohol	Up to 8 hours	Alcohol	Alcohol – see Consideration	Additional testing for alcohol metabolites, ethyl glucuronide (EtG) or ethyl sulfate (EtS), can identify alcohol up to 80 hours after consumption.
Amphetamines	2-3 days	Amphetamines, Methamphetamines or MDMA Immunoassay + GC/MS or LC/MS/MS Amphetamines	Amphetamines, methamphetamines or MDMA Immunoassay – see Consideration  GC/MS or LC/MS/MS – amphetamine, methamphetamine or MDMA	Amphetamines immunoassays are highly cross-reactive so results should be interpreted cautiously, and may require consultation with the lab. They may detect other sympathomimetic amines, such as ephedrine, pseudoephedrine or selegiline. Confirmatory testing can identify which amphetamine is present.
Barbiturates	1-3 days w/short-acting; up to 30 days w/long acting	Barbiturates Immunoassay	Barbiturates Immunoassay – see Consideration	The clearance half-life of intermediate-acting barbiturates averages 24 hours. It takes about 5 to 7 half-lives to clear 98% of a drug dose. Thus, the presence of an intermediated-acting barbiturate indicates exposure within 5-7 days.
Benzodiazepines	1-3 days w/short-acting; up to 30 days w/long-acting	Benzodiazepines Immunoassay	Benzodiazepines Immunoassay – see Consideration  GC/MS or LC/MS/MS – alprazolam, diazepam, clonazepam, lorazepam, etc.	Immunoassays for benzodiazepines have a 28% overall false negative rate and vary in cross-reactivity. Certain benzodiazepines (clonazepam and alprazolam) have limited detectability by most available immunoassays. Confirmatory testing is needed when use is expected or suspected.
Cocaine or benzoylecgonine	2-4 days	Cocaine Metabolites Immunoassay	Cocaine Metabolites Immunoassay – see Consideration	Cocaine immunoassays do not cross-react with other topical anesthetics that end in “caine” (e.g. lidocaine) and are highly specific for cocaine use.
Marijuana	2-4 days; up to 30 days w/chronic heavy use	Cannabinoids (THC) Immunoassay	Cannabinoids Immunoassay – see Consideration  GC/MS or LC/MS/MS – THC	THC may be an indicator of the patient’s risk category. Prescribers should have an office policy, discuss with the patients reason for use and adjust monitoring plan accordingly.

\*detection time for most drugs depends on the drug, dose, frequency of use and individual metabolism

## ii. UDT Algorithm for Monitoring Opioid Therapy

Figure E: UDT Algorithm for Monitoring COAT for CNCP



### iii. UDT Clinical Vignettes in Chronic Non-cancer Pain

Case Studies	Discussion
<p><b>New Patient:</b> A 31-year-old female with low back pain from an injury 2 months ago. She wants to establish care. According to the patient, she was initially prescribed naproxen and hydrocodone in the emergency room. She is currently taking naproxen OTC, but no reported opioids. Her other medical conditions include depression for which she takes citalopram. You are considering prescribing opioid(s) and your suspicion for drug abuse is low. What should you do?</p>	<p>IF you have decided to initiate chronic opioid therapy AND prior to prescribing, you should:</p> <ol style="list-style-type: none"> <li>1. Obtain a baseline UDT;</li> <li>2. Assess risk of aberrant behavior with ORT;</li> <li>3. Assess psychiatric status (e.g. PHQ-9);</li> <li>4. Obtain a signed opioid agreement;</li> <li>5. Establish treatment goals including improvements in both function and pain;</li> <li>6. Describe expectations for behavior related to use of opioids (take as prescribed, use one pharmacy, one prescriber, no early refills, no self-escalation, no sharing of drugs, etc.)</li> <li>7. Develop a follow-up plan to monitor treatment, including the frequency of UDT's based on ORT</li> </ol>
<p><b>New Patient on Opioids:</b> A 45-year-old male presents with severe neck pain from a motor vehicle accident 2 years ago. He has been treated with OxyContin 30 mg BID and oxycodone 5 mg 1 tab Q3h PRN (MED = 150 mg/day). He reports no history of substance abuse. Due to "personality differences" with previous provider, he would like you to assume care and continue prescribing OxyContin and oxycodone for his neck pain. You have no medical records to confirm previous treatment. What should you do?</p>	<p><b>Do not prescribe opioids at initial visit since records are unavailable:</b></p> <ul style="list-style-type: none"> <li>• Comprehensively evaluate the patient,</li> <li>• Order a baseline UDT,</li> <li>• <b>Inform patient that a signed release of information form is required prior to prescribing opioids.</b> Also request medical records from previous provider(s) or consider contacting the previous prescriber for information on treating this patient and</li> <li>• Schedule a follow-up visit for when UDT results and medical records are available.</li> </ul> <p>On follow-up visit, if UDT is consistent and prior medical records show improved pain and function with no history of aberrant behaviors, follow steps 2–7 above before prescribing.</p>
<p><b>Compliance Testing in a patient on &lt; 120 mg MED/day:</b> A 55-year-old male with chronic knee pain comes in for a routine visit. His opioid regimen consists of methadone 5 mg QID and hydrocodone/acetaminophen 5/500 mg 1 tab Q6h PRN (MED = 100 mg/day). He has moderate risk on ORT and last random UDT was a year ago. What should you do?</p>	<p>Assess the risks and benefits of current opioids. Discuss with the patient reason for testing, frequency of testing and consequences of unexpected results, order an immunoassay test for the drug classes below, and follow the UDT algorithm.</p> <ul style="list-style-type: none"> <li>• Amphetamines</li> <li>• Opiates</li> <li>• Cocaine metabolites</li> <li>• Methadone</li> <li>• Benzodiazepines</li> <li>• Alcohol metabolites</li> <li>• Oxycodone</li> </ul>
<p><b>Unexpected Results:</b> The immunoassays from the above vignette were positive for methadone, opiates and cocaine metabolites but negative for the remainder of the drug classes tested. Confirmatory testing with GC/MS was done per laboratory protocol. The confirmatory results show methadone, hydrocodone and benzoylecgonine (cocaine metabolite). What should you do?</p>	<p>Discuss the unexpected results with the patient and offer a controlled taper and referral to an addiction specialist.</p>

Case Studies	Discussion
<p><b>Point of Care Testing:</b> A 47-year-old male with rotator cuff tendonitis has chronic shoulder pain managed with morphine SR 30 mg TID and oxycodone/acetaminophen 5/325 mg 1 tab Q4h PRN (MED = 135 mg/day). He reports no other drug therapy. A treatment agreement has been signed by you and the patient recently. You perform a random UDT using a point-of-care testing kit. The immunoassays are positive for opiates but also positive for benzodiazepines. What should you do?</p>	<p>Discuss the unexpected results with the patient:</p> <ul style="list-style-type: none"> <li>• If explanation is credible (e.g. receiving treatment for anxiety from another provider), you may want to send the urine sample to laboratory to confirm his story. You may also want to discuss future expectations with the patient and request records from other treating providers for possible specialty consultation.</li> <li>• If explanation is not accepted (e.g. patient admits benzodiazepine use that is not prescribed for the patient), confirmatory testing is not necessary but offer a controlled taper and/or referral to an addiction specialist depending on the circumstances.</li> <li>• If result cannot be explained, send original urine sample to laboratory for confirmatory testing.</li> </ul>

## iv. UDT Frequently Asked Questions (FAQ)

### Q **Drug screening implies that I don't trust my patients. How do I get around this?**

A Self-report of drug use has limited validity, and monitoring behavior alone can fail to detect problems revealed by UDTs. Creating a UDT policy in advance and applying it consistently to all patients on opioids may help de-stigmatize the testing. Inform patients that drug testing is a routine procedure for all patients starting or maintained on opioid therapy and it is an important tool for monitoring the safety of opioid therapy. Possible language for explaining to patient includes:

- “Ensures my capacity to provide treatment for your pain while balancing the need for safety.”
- “Provides critical information needed to assess the success of your therapy.”
- “Prescription medications are a common form of treatment for chronic pain. However, each person reacts differently to them. UDT enables us to identify individual risks related to your medications and avoid problems.”
- “Our clinic uses ‘universal precautions’ in opioid prescribing, which includes UDT. This is the same as wearing gloves on all patients when drawing blood.”

### Q **Can I tell whether my patient has taken the dose of opioid(s) I prescribed?**

A No. It is very difficult to correlate urine drug concentration with a patient's dose. UDT can detect the parent drug and/or its metabolite(s) and demonstrate recent use of prescribed drugs and illegal substances. However, it CANNOT determine the amount of drug used and when the last dose was taken, nor can it identify the source of the drug.

### Q **My patient says he is a “high metabolizer” and that is why the expected drug is not found in the urine. Is this possible?**

A A small percentage of persons are ultrarapid metabolizers. They metabolize specific drugs more rapidly than typical patients. It would be rare to take an opioid as prescribed and have a totally negative UDT. It is important that you use testing that is specific to the medication of interest and with cutoff thresholds that are extremely low.

### Q **How do I deal with marijuana?**

A This is a complex issue. Marijuana is currently classified as a Schedule I drug by the DEA. For that reason, many providers will not prescribe opioids to patients using cannabis. Other providers reference State “Medical Marijuana” laws (<http://apps.leg.wa.gov/RCW/default.aspx?cite=69.51A&full=true>) and feel comfortable prescribing opioids to cannabis users. Some providers adopt a “don't ask, don't tell” policy, and request the lab to remove marijuana from the UDT so that positive results are not seen. Do your homework and create an office policy. Then disclose this policy to your patients.

### Q **Would short-acting opioids show up in UDT?**

A Urine testing typically has a 1 to 3-day window of detection for most drugs depending on dose and individual differences in drug metabolism. Short-acting opioids can be detected if the lab removes the cutoff concentration so that the presence of lower concentrations is detected. If the laboratory uses LC/MS/MS, then it will have a lower limit of detection (LOD) with less interference.

**Q Why confirm results?**

**A** Immunoassays used in drug screening can cross-react with other drugs and vary in sensitivity and specificity. Thus, confirmation with a more accurate method may be required for clinical decision making. Confirmatory drug testing (GC/MS or LC/MS/MS) of the original specimen is recommended for unexpected results, or in cases where patients are known to be high risk. However, on occasion, even confirmatory testing requires expert assistance for interpretation. Consider consultation with the lab before discussing/confronting the patient with unexpected test results and discontinuing opioid therapy.

**Q Should I use temperature and adulteration strips?**

**A** It depends. Drug testing for clinical compliance, unlike employment testing, does not require a strict “chain-of-custody”. However, if tampering is a concern, the specimen should be monitored for temperature and/or adulterants. Normal human urine should have a temperature between 90°F – 100°F, pH between 4.5 – 8.5 and creatinine >20mg/dL. Be aware that there are multiple websites and devices devoted to getting a “clean” urine drug screen.

**Q Should I perform a drug screen on every visit for patients using opioids for chronic pain?**

**A** No. Random screening based on the frequency recommended in the guideline should suffice for most patients. Those patients who you feel require drug screening on every visit, are perhaps not candidates for chronic opioid therapy.

## Appendix E: Chronic Pain Syndromes in Cancer Survivors

Sources: <sup>322 337 307 313 338 339 340 8</sup>

Pain Syndrome	System	Type of Cancer	Cause of Pain	Treatment Options & Notes
Chemotherapy-induced peripheral neuropathy (CIPN)	Neurological	Breast Ovarian Colorectal Lymphoma Multiple myeloma	Vinca alkaloids (vincristine), platinum compounds (cisplatin), taxanes (paclitaxel), bortezomib	Antidepressant: SNRI: duloxetine TCAs: nortriptyline, desipramine Anticonvulsants: gabapentin, pregabalin Opioids PT/OT/ Rehabilitation CBT
Chronic post-operative neuropathic pain syndromes	Neurological	Breast Neck Lung Sarcoma	Post-mastectomy, post-radical neck, post-thoracotomy, post-amputation pain syndromes Neuroma	Antidepressant: SNRI: duloxetine TCAs: nortriptyline, desipramine Anticonvulsants: gabapentin, pregabalin Opioids Topical: lidocaine 5% patch, capsaicin cream PT/OT for ROM CBT
Chronic radiation fibrosis	Integumentary	Breast Neck	Long-term and late radiation effects (may develop years after completion of therapy). Fibrosis causes decreased ROM, tightness, discomfort	PT/OT Massage for myofascial release Trigger point injection Opioids
Lymphedema	Integumentary	Breast Pelvic tumors	Surgery or radiation may interfere with lymph drainage from affected limb; may be discomfort more than pain.	Compression garments PT for ROM Manual lymphatic drainage Diuretics are not helpful Opioids not likely to be helpful
Chronic arthralgias	Musculo-skeletal	Breast	Aromatase inhibitors, used to prevent recurrence of breast cancer, cause symmetrical pain aching or stiffness in shoulders, elbows, wrists, fingers, knees, ankles	Exercise PT/OT/Thermal/Rehabilitation Medicine Massage Acetaminophen NSAIDs Antidepressants: duloxetine, desipramine Anticonvulsants: pregabalin, gabapentin Change to another aromatase inhibitor For severe intensity, consider opioids primarily for functional improvement.
Scar pain from surgery or radiation	Integumentary	Breast All	Tissue fibrosis leading to pain and decreased ROM	Massage for scar release

Pain Syndrome	System	Type of Cancer	Cause of Pain	Treatment Options & Notes
Myofascial pain	Musculo-skeletal	Hematopoietic cell transplant All cancers may cause myalgias and arthralgias from deconditioning	High dose corticosteroids High dose cyclophosphamide Deconditioning Radiation fibrosis	Exercise, aerobic, stretching and strengthening PT/OT/Rehabilitation Medicine Thermal Massage Acupuncture Acetaminophen NSAIDs Antidepressants: duloxetine, nortriptyline Anticonvulsants: gabapentin, pregabalin Topical: lidocaine 5% patch, capsaicin cream Trigger point injections For severe intensity, consider opioids only for validated and demonstrated functional improvement.
Vertebral compression fractures	Skeletal	Ovarian failure from chemotherapy or surgery, prostate, all cancers at risk, especially GYN, prostate, myeloma, hematopoietic cell transplant	Painful vertebral compression fractures	Opioids (acute) NSAIDs PT/Rehabilitation Weight bearing exercise (subacute & chronic) Bisphosphonates
Avascular necrosis of major joints	Skeletal	Hematopoietic cell transplant, especially unrelated donor allogeneic transplant Acute lymphoblastic leukemia	High dose steroids can lead to painful (aseptic) degeneration of joint of such severity that joint replacement may be required in young adults	Opioids Exercise, especially swimming PT Thermal Off-weight joint with cane/crutches
Dyspareunia	Genital	Breast, ovarian, any cancer treatment causing ovarian failure	Decreased vaginal lubrication, vaginal stricture from pelvic surgery or radiation	Vaginal lubricants PT for Pelvic floor exercises and vaginal dilators Sexual therapy Low-dose vaginal estrogen cream #

There are no FDA approved medications specifically for chronic pain conditions in cancer survivors.

# Recommend contacting the oncologist prior to initiating vaginal estrogen cream, especially if patient had estrogen-receptor positive breast cancer.

- NSAIDs = non-steroidal anti-inflammatory agents (e.g. naproxen, ibuprofen).
- PT/OT = physical therapy or occupational therapy
- ROM = range of motion
- Thermal = hot packs, ice packs
- CBT = cognitive behavioral therapy

## Appendix F: Diagnosis-based Pharmacotherapy for Pain and Associated Conditions

Best Used For...	Adjuvant Drug	Key Points
Minor arthritis, backache, muscle and joint pain	Topical menthol, methyl salicylate, trolamine salicylate or capsaicin	May experience burning, stinging or itching sensations during and following application but high concentration capsaicin or repeat applications will produce a loss of responsiveness to stimuli. <b>Caution:</b> Wash hands or use gloves when handling capsaicin.
Minor to moderate pain	Acetaminophen (APAP)	APAP 325 mg + ibuprofen 200 mg provides better pain relief than oral opioids. <b>Caution:</b> Hepatotoxicity increases with dose, age, use of alcohol, and co-occurring liver disease. Keep to < 2 grams daily if at risk for hepatotoxicity. Some manufacturers have voluntarily revised their label to recommend a lower maximum of 3 grams daily.
Pain from spasticity (spinal cord injury or multiple sclerosis)	Tizanidine or baclofen	<b>Caution:</b> Do not abruptly discontinue baclofen due to potential for severe rhabdomyolysis and fever.
Neuropathic pain conditions (diabetic peripheral neuropathy, post-herpetic neuralgia, spinal cord injury, cauda equina syndrome, phantom limb pain, HIV neuropathy, chemotherapy-induced peripheral neuropathy, etc.)	Tricyclic antidepressants (amitriptyline, nortriptyline, doxepin, desipramine), serotonin norepinephrine reuptake inhibitors (duloxetine, venlafaxine), anticonvulsants (gabapentin, pregabalin)	Low dose TCAs and gabapentin are good first line therapy options especially helpful with sleep disturbance. <b>Caution:</b> Gabapentin and pregabalin can cause cognitive slowing, weight gain, and edema. Also, pregabalin is a controlled substance.
Trigeminal neuralgia	Carbamazepine	<b>Caution:</b> Monitor for hematologic (aplastic anemia, agranulocytosis) and dermatologic (toxic epidermal necrolysis, Stevens-Johnson syndrome) complications. Because there is a strong association between dermatologic complication and the presence of human leukocyte antigen (HLA-B*1502), the FDA and the manufacturers of carbamazepine recommend that patients with ancestry in genetically at-risk populations be screened for the presence of the HLA-B*1502 allele prior to initiating carbamazepine therapy.
Neuropathic pain condition + depression or anxiety	Tricyclic antidepressants (amitriptyline, nortriptyline, doxepin, desipramine) or serotonin norepinephrine reuptake inhibitors (duloxetine, venlafaxine)	<b>Caution:</b> Monitor for dose related QTc prolongation (TCAs > SNRIs). Also, SNRIs can provoke leg movement disorders.
Non-specific low back or nociceptive pain or pain from traumatic, infectious, or degenerative conditions, or pain from connective tissue disorders	Nonsteroidal anti-inflammatory drugs (naproxen, ibuprofen, meloxicam, diclofenac, etodolac, nabumetone, ketoprofen, piroxicam, sulindac, tolmetin, etc.)	Naproxen 500 mg or naproxen sodium 550 mg alone and ibuprofen 200 mg + acetaminophen 500 mg are as effective, or more effective than opioids. <b>Caution:</b> Monitor patients for potential renal, gastrointestinal (GI), and cardiac side effects. Risk increases with age and dose.

Best Used For...	Adjuvant Drug	Key Points
Fibromyalgia	Duloxetine, gabapentin or pregabalin	<b>Caution:</b> Serotonin syndrome has been reported with SNRIs (e.g. duloxetine) when taken alone or concurrently with other serotonergic agents (e.g. triptans, tramadol, fentanyl, TCAs, etc.)
Localized neuropathic pain (HIV polyneuropathy, postherpetic neuralgia)	Topical lidocaine or capsaicin	May experience burning, stinging or itching sensations during and following capsaicin application but high concentration or repeat applications will produce a loss of responsiveness to stimuli. <b>Caution:</b> Wash hands or use gloves when handling capsaicin.
Insomnia	<ul style="list-style-type: none"> <li>• Melatonin 1-5mg</li> <li>• Tricyclic antidepressants (TCAs)</li> <li>• Trazodone</li> <li>• Benzodiazepine receptor agonists or Z-drugs (e.g. zolpidem, zaleplon, zopiclone, eszopiclone)</li> </ul>	Melatonin side effects include drowsiness, dizziness, headache, nausea, and nightmares. <b>Caution:</b> Trazodone is not advised when patient is taking SSRIs or SNRIs. <b>Caution:</b> Z-drugs can potentially induce unsafe behaviors like sleep-driving or preparing and eating food when not fully awake; have limited value with reducing chronic pain.

## Appendix G: Patient Education Resources

Providing quality treatment for your patients is critical, and so is educating them about the risks of taking opioid medications. Resources that can help you provide this education are listed here.

Resource	Description
<p><b>Chronic Pain</b>  <a href="#">American Chronic Pain Association</a></p> <p><a href="#">Chronic Pain Self-Management Program</a></p> <p><a href="#">Substance Abuse and Mental Health Services Administration (SAMHSA)</a>            Evans Health Lab’s <a href="#">Advice for Patients Taking Opioids</a></p>	<p>Patients and their families can access plain-language fact sheets, worksheets, communication tools and videos on topics such as medications, pain management programs, and going to the ER. Addresses health literacy with tools for how to read an OTC label, and how to store medications safely.</p> <p>Find a local six-week workshop, developed by the Stanford Patient Education Research Center.</p> <p>Downloadable booklet <i>You Can Manage Your Chronic Pain to Live a Good Life</i></p> <p>Provides advice for people on, or about to start taking opioid medications, related to chronic non-cancer pain.</p>
<p><b>Fibromyalgia</b>  <a href="#">Fibromyalgia Information Foundation</a></p>	<p>Overview of fibromyalgia, diagnosis, treatment, preventive advice and new research discoveries. The site does mention the use of opioids and benzodiazepines for fibromyalgia, which is not supported by this guideline.</p>
<p><b>Headaches</b>  <a href="#">National Headache Foundation</a></p>	<p>Contains topic sheets, educational modules, and videos on all kinds of headaches. Useful for providers also; contains links to research.</p>
<p><b>Medications</b>            National Institute of Health’s <a href="#">Daily Med</a></p> <p><a href="#">UpToDate</a></p>	<p>Sponsored by the National Library of Medicine, this site contains information for professionals as well as patients on almost all drugs.</p> <p>This is a paid subscription service, which consumers are not likely to use directly. Providers who have access can download patient information on the basics of: narcotic pain medicines, prescription drug abuse, opioid use disorder, and alcohol and illegal drug use in pregnancy.</p>
<p><b>Stress and Mental Health</b>  <a href="#">Anxiety Disorders Association of America</a></p> <p><a href="#">National Institute of Mental Health</a></p> <p><a href="#">Depression Screening.org</a></p>	<p>Information for healthcare providers and consumers. Detailed information about anxiety disorders, how to find help, and tips for managing anxiety.</p> <p>Information on mental health topics including signs and symptoms, treatment, locating local services, and research.</p> <p>Confidential online depression screening test, symptoms and treatments, personal stories and sources of help.</p>
<p><b>Sleep</b>  <a href="#">National Sleep Foundation</a></p>	<p>General information about sleep health and safety, and sleep-related problems.</p>
<p><b>Setting Patient Health Goals</b>            Swedish’s <a href="#">Structuring Your Own Management of Pain (STOMP) brochure</a></p>	<p>Brochure is designed to help patient set health goals to alleviate pain and improve quality of life. It includes general information about pain, goal-setting ideas and steps to take to achieve those goals.</p>

Resource	Description
<p><b>Opioid Safety</b></p> <p>Washington State Department of Health's <a href="#">Take as Directed</a></p> <p><a href="#">The Addiction Technology Transfer Center Network</a></p>	<p>Includes possible risks from taking opioids, warning signs of drug abuse or addiction, tips on preventing overdoses and signs of overdose and problematic opioid use.</p> <p>A fact sheet with six tips for preventing others from stealing your prescription medicines; good for printing.</p>
<b>Books</b>	
<i>Treat Your Own Neck and Back</i> (5 <sup>th</sup> Ed.) by R. McKenzie	Patient handbook for common neck pain will help patients learn to relieve their problems and prevent recurrence of their symptoms in the future. It covers a step-by-step system of education, awareness, exercise and prevention.
<i>Managing Pain Before It Manages You</i> (3 <sup>rd</sup> Ed.) by M Caudill	Simple set of tools to help patients live with their pain more effectively and independently.
<i>Mind Over Mood: Change How You Feel by Changing the Way You Think</i> by D Greenberger and C Padesky	Step by step worksheets teach specific skills to conquer common mental health issues such as depression, anxiety, and low self-esteem.
<i>Thoughts and Feelings: Taking Control of Your Moods and Your Life</i> by M. McKay, M.Davis, and P.Fanning	Adapts the powerful techniques of cognitive behavioral therapy into a set of tools readers can use against anxiety, depression, and obsessiveness.
<i>The War on Pain</i> by S. Fishman & L. Berger	An introduction to interdisciplinary pain management that integrates traditional and alternative techniques.
<i>Heal Your Headache: The 1-2-3 Program for Taking Charge of Your Pain</i> by D. Buchholz & S.G. Reich	Information on how to avoid triggers and use preventative medications rather than pain relievers which can cause rebound headaches.
<i>Chronic Pain Solution: Your Personal Path to Pain Relief</i> by J.N. Dillard & L.A. Hirschman	Useful information on how to approach and relieve chronic pain.
<i>Snoring and Sleep Apnea: Sleep Well, Feel Better</i> by R. Pascualy	This book is for patients and health care professionals and covers causes, diagnosis, treatment, and surgical techniques.

## Appendix H: Clinical Tools and Resources

### Consultation Resources

The WA State Department of Health maintains a webpage specifically for pain management<sup>vi</sup> where the rules for opioid prescribing (including obtaining consultations with pain specialists) are referenced in five separate places, each for the different specialists who can prescribe opioids: MDs, DOs, PAs (within the MD or DO rules), ARNPs, DPMs, and Dentists. They are codified in Washington Administrative Code Chapter 246, and can also be found at the state’s legislative website ([www.leg.wa.gov](http://www.leg.wa.gov)).

UW School of Medicine and its academic medical centers offer a toll free consultation and referral service available 24 hours per day 7 days per week. This service links providers with a faculty physician with expertise in any particular area. To access these services visit, call 800.326.5300, email [medcon@u.washington.edu](mailto:medcon@u.washington.edu) or visit, <http://uwmedicine.washington.edu/Patient-Care/Referrals/Pages/MEDCON.aspx>. Click on “Refer a Patient.” The entire process can be done online, including transfer of records and images.

UW TelePain offers a weekly (with few seasonal exceptions) free teleconference where primary care providers can call and present complex pain management cases (with personally identifiable patient information redacted) and receive consultative advice from a multidisciplinary group of pain specialists. There is also a 20-30 minute didactic section on pain related topics before cases are presented. Visit: <http://depts.washington.edu/anesth/care/pain/telepain/index.shtml>.

### Mentoring Resources

Physician Clinical Support System has mentors available by phone or email to answer providers’ questions on methadone or buprenorphine. In addition, guidance on specific clinical questions and helpful tools can be downloaded from the website. There is no cost for this service. Once the provider registers at <http://pcssmat.org/mentoring/>, a mentor is assigned within 2 days.

UW offers a free online course called COPE-REMS that is designed to educate healthcare providers on how to better treat and manage patients with chronic pain in order to improve patient outcomes. Its goal is to increase knowledge and confidence among providers about how to best treat chronic pain, including whether and when to start, modify or stop opioid therapy. The course contributes to national health goals of preventing opioid misuse, abuse and overdose. It is aimed at physicians, registered nurses, ARNPs, physician assistants, psychiatrists, and other care managers who treat patients with chronic pain. Visit: <https://trainingexchange.org/our-programs/cope-rems>.

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<sup>vi</sup> <http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PainManagement>

## Treatment and Referral Resources

There are several treatment options available for opioid use disorder. A combination of medication and behavioral therapies has been found to be most successful (SAMHSA Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Program

[www.kap.samhsa.gov/products/trainingcurriculums/pdfs/tip43\\_curriculum.pdf](http://www.kap.samhsa.gov/products/trainingcurriculums/pdfs/tip43_curriculum.pdf)).

- Department of Social and Health Services (DSHS) Tool Kit to help address drug and alcohol issues in Medicaid patients <http://maa.dshs.wa.gov/pharmacy/ToolKit.htm>
- DSHS Division of Alcohol and Substance Abuse at 877-301-4557. A referral for treatment may be made to any one of the licensed opioid treatment programs (OTPs) in Washington State: <http://www.dshs.wa.gov/dbhr/dadirectory.shtml>
- A list of treatment centers certified by the Division of Behavioral Health and Recovery is available at [www.dshs.wa.gov/dbhr/dadirectory.shtml](http://www.dshs.wa.gov/dbhr/dadirectory.shtml).
- A partial list of physicians authorized by SAMHSA and the DEA to prescribe buprenorphine for treatment of opioid use disorder and treatment programs that also provide it can be found at: [http://buprenorphine.samhsa.gov/pls/bwns\\_locator/provider\\_search.process\\_query?alternative=C&HOICEG&one\\_state=WA](http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=C&HOICEG&one_state=WA)

## Sample Doctor-Patient Agreements for Chronic Opioid Use (links only)

L&I's Opioid Treatment Agreement in English <http://www.lni.wa.gov/Forms/pdf/F252-095-000.pdf> and Spanish <http://www.lni.wa.gov/Forms/pdf/F252-095-999.pdf>

HCA's Medicaid Chronic Pain Agreement <http://www.hca.wa.gov/medicaid/pharmacy/pages/toolkit.aspx>

## DSM 5 Criteria for Substance Use Disorder, by the American Psychiatric Association:

<http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf>

## Everyday Helpful Resources

- UW Department of Anesthesiology and Pain Medicine keeps a useful [Pain Medicine Provider Toolkit](#) on their website with educational and resource information.
- For tips on motivational interviewing, check out: *Motivational Interviewing in Health Care: Helping Patients Change Behavior* by Stephen Rollnick, William R. Mill, and Christopher C. Butler, Guilford Press 2007, (Review at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779641/>) .
- Swedish's pain management guide, [STOMP](#) (Structure your Own Management of Pain) is a helpful resource for patients with chronic pain to be more active in their care and improve their pain and function.

## **Emergency department guidelines help coordinate care with primary care providers**

The emergency department (ED) is a significant outpatient source of prescription opioids. Yet there has been little guidance on how to treat pain in the emergency department while minimizing the potential for overdose and abuse. The Washington Chapter of the American College of Emergency Physicians (WA-ACEP) has developed a set of guidelines that outline good prescribing practices for ED providers. The guidelines include a patient information brochure that explains to patients the purpose of the guidelines and the risks associated with prescription opioids. More information can be obtained at <http://www.washingtonacep.org/painmedication.html> and <http://here.doh.wa.gov/materials/pain-medication-guidelines/?searchterm=emergency%20department>.

EDs across the state have collaborated to take advantage of a visit tracking system used by every ED in the state to notify the emergency care provider of a patient's ED visit history. A randomized clinical trial of citywide ED care coordination performed by Washington State University and funded by the Centers for Disease Control shows the effectiveness of this approach. The trial demonstrated a statistically significant reduction in ED visits made by frequent users and a large reduction in opioid prescribing to these patients by ED providers. The results of this trial are pending publication. Coordinating ED care for frequent users is a promising approach to address high risk opioid prescribing from the ED.

## Appendix I: Guideline Development and AGREE II Criteria

### Guideline Development

The Washington State Agency Medical Directors' Group (AMDG), which sponsored this guideline, works to improve the health care purchased by Washington State by making evidence-based decisions that maximize the effectiveness, cost-effectiveness, and safety of the health care delivered to Washington residents, while reducing or preventing harm. The group consists of the medical directors and senior health policy staff from four Washington State agencies: Corrections, Health, Labor and Industries (for workers' compensation), and the Health Care Authority (for Medicaid and public employee benefits).

In April 2014, the AMDG invited state health officials, policy leaders, and health care providers specializing in pain medicine, psychiatry, family medicine, psychology, internal medicine, psychiatry, palliative care, and other fields to lend their expertise to the guideline process and content. This advisory committee had diverse interests, experience, and views, which made for robust discussions. Each member signed conflict of interest disclosures, and though some had financial arrangements with various companies, none posed a conflict of interest when contributing to this guideline. A complete list of their names and affiliations can be found in the [Acknowledgment](#) section.

The guideline was posted for public comment for four weeks; the comments were reviewed by agency staff and workgroup leads, and considered before the guideline became final. A list of these comments and responses is available on the AMDG website. Principal funding and resources for the guideline development were provided by state agencies and staff. In addition, contracted committee members received reimbursement for their formal committee time and travel, similar to other statutory evidence-based committees for Washington State.

### Research Methods and Decision-Making

The co-chairs of the opioid guideline committee designated several workgroups to review the evidence and make clinical recommendations for each section. The workgroups met at committee meetings or on their own in person or via webinars and exchanged information and views via email. Each workgroup was assigned an agency staff to support scheduling meetings and collating, editing and formatting workgroup product. The entire guideline advisory committee met in person three times to review guideline progress and, as much as possible, reach consensus on the final clinical recommendations.

Each workgroup did its own reviews of the evidence. A large proportion of recommendations are based on consensus of expert opinion due to lack of studies specific enough to guide a recommendation, workgroups did not summarize overall strength of recommendations.

## AGREE II Criteria

This guideline meets most of the specific criteria for the “Appraisal of Guidelines for Research and Evaluation,” (AGREE), which is the industry standard for ensuring its development followed a rigorous strategy, appropriate methodology, and high quality systematic development and implementation process. This standard was developed by the Canadian Institute of Health Research and is used by the United States Agency for Healthcare Research and Quality and the National Guideline Clearinghouse.

### DOMAIN 1: SCOPE AND PURPOSE

The overall objective(s) of the guideline is (are) specifically described; health question(s) covered by the guideline are specifically described; and population (patients, public etc.) to whom guideline is meant to apply is specifically described.

#### Opioids during acute/subacute phase, clinically meaningful improvements and alternative treatments

1. When should PMP be accessed?
  - a. At first opioid prescription?
  - b. At point of decision on chronic opioid therapy?
  - c. During monitoring?
  - d. For any emergency department opioid prescription?
2. Excluding trauma and surgery, what are indications and contraindications for acute, subacute, and chronic opioid use?
  - a. How does this relate to the new FDA labeling on ER/LA opioids?
  - b. Should mild-moderate conditions, such as musculoskeletal sprains and strains, fibromyalgia, headaches, etc. be contraindications to opioid use?
3. What is considered clinical meaningful improvement (CMI) in pain and function with opioid use?
  - a. What are the most reliable and valid publicly available brief instruments for tracking pain and function?
  - b. Which instruments, such as the PROMIS, may be best for tracking function, rather than pain interference with function?
  - c. Should the baseline for tracking CMI be measured at the start of opioid therapy, or at some other point?
4. What pharmacologic and non-pharmacologic treatments are effective initial treatments or as alternatives to opioid treatment for acute and subacute pain?
5. What pharmacologic and non-pharmacologic treatments are effective in preventing the transition from acute/subacute to chronic pain?
6. What pharmacologic and non-pharmacologic treatments are effective in treating chronic pain?

#### Opioids for perioperative pain

1. For patients undergoing elective surgery, what risk factors are there for difficult post-operative pain control?
2. For patients undergoing elective surgery, what pre-operative practices help improve pain control in the post-operative period?
3. For patients who are on COAT, what pre-operative recommendations should be given to improve management of post-operative pain?
  - a. What dose and/or duration of COAT signal post-op opioid tolerance concerns?
  - b. Should patients on high dose COAT be tapered before elective surgery?
  - c. How long would one expect opioid tolerance to persist?
4. What adjuncts are helpful for opioid sparing in the postoperative period in patients with (and, if different, without) opioid tolerance?
5. Is there a recommended dose range for managing post-surgical pain (either doses per se or % of baseline opioid requirement)?

6. Is there evidence to support the use of long-acting opioids for acute post-surgical pain?
7. Are high doses of post-operative opioids associated with adverse outcomes, such as development of refractory pain, tolerance, or overdose events? If so, how high?
8. By how many days after surgery should we expect patients to have returned to their COAT dose (or lower)?
9. If formal weaning is required to return to preoperative opioid doses, how long after surgery should this start and at what rate?

**When to discontinue chronic opioid therapy and initiate addiction treatment**

1. When should opioids be weaned?
  - a. Rate of taper (how much, how quickly)?
  - b. When adjunctive treatments may be indicated (e.g. behavioral treatment, more formal detox)?
  - c. What if the patient is not interested or willing?
2. In what circumstances should someone be weaned off entirely vs. tapered down to a lower dose?
3. How to proceed if weaning attempt(s) failed?
4. What resources are available in the community to help support providers and patients when tapering opioids?
5. What is the evidence on safety and efficacy for available treatments for addiction?
6. What precautions are necessary for treating chronic pain in patients with current or former substance use disorder?

What resources are available in the community to help support addiction recognition and treatment for providers and patients?

**DOMAIN 2: STAKEHOLDER INVOLVEMENT**

**The guideline development group includes individuals from relevant professional groups; the views and target preferences of the target population (patients, public, etc.) have been sought; and target users of the guideline are clearly defined.**

**Where found: Title, Introduction, Appendix I and Acknowledgements**

The Guidelines were developed in collaboration with a broad advisory group of the state’s academic leaders, pain specialists, and clinicians in both primary care and specialty areas in response to the growing epidemic of opioid-related unintentional overdoses. A list of participating clinicians and their affiliations can found in the Acknowledgements. The opioid guideline committee did not include public member although the public had an opportunity to comment on the guideline during the four-week public comment period. Public comments were reviewed by agency staff and workgroup leads, and responses were considered before the guideline became final. A list of these comments and responses is available on the AMDG website.

The main target population is primary care providers and any provider who treats patients with chronic pain. Primary care providers as well as specialists were included in the guideline advisory group, the names of which are documented in the acknowledgements section. A secondary target population is public and private payers in WA state. The statutory public/private Robert Bree Collaborative, representing all major health care sectors and payers in WA has preliminarily unanimously voted to endorse this guideline.

### DOMAIN 3: RIGOR OF DEVELOPMENT

Systematic methods were used to search for evidence; criteria for selecting the evidence are clearly described; strengths and limitations of the body of evidence are clearly described; health benefits, side effects and risk have been considered in formulating the recommendations; an explicit link between the recommendations and the supporting evidence; guideline has been externally reviewed by experts prior to its publication; and procedure for updating guideline is provided.

#### **Where found: Introduction, Uncertain Long-term Efficacy and Clear Evidence of Harm, Evidence for each section and Appendix I**

This is the 3<sup>rd</sup> edition of the AMDG interagency opioid guide. First published in 2007, the guideline is updated every 5 years or when there is substantial new evidence on COAT to warrant an update. Guideline development and all updates were done in collaboration with a broad advisory group of the state's academic leaders, pain experts, and clinicians in both primary care and specialty areas. The updates build upon the previous guideline.

A literature review was done in Medline – PUBMED. Searches began in March of 2014. Search terms included “opioids and chronic pain”, “chronic pain and treatment”, “opioid related adverse events”, “risk and dose and opioids”, “opioids and overdose and deaths”, and “chronic pain management”. The search was limited to English, humans, the last 10 years and in some cases, to systematic reviews and meta-analysis. Additional hand searches of relevant studies in reference lists were done. A search was also performed in the National Guideline Clearinghouse for relevant guidelines. Guidelines selected for review addressed the use of opioids in the treatment of chronic non-cancer pain. In addition, each workgroup did its own reviews of the evidence. A large proportion of recommendations are based on consensus of expert opinion due to lack of studies specific enough to guide a recommendation, workgroups did not summarize overall strength of recommendations. The following is a brief description of the literature search for the main topics:

#### **CMIF**

PubMed was searched for relevant studies on methodology and measuring pain and function. Key search terms included “meaningful improvement” and “pain” and “function” or “MCID” and “pain” and “function.” This search yielded 240 abstracts.

#### **Dosing threshold and adverse effects**

A literature review was done in Medline/ PUBMED. Searches began in March of 2014. Search terms included “opioids and chronic pain”, “chronic pain and treatment”, “opioid related adverse events”, “risk and dose and opioids”, “opioids and overdose and deaths” and “chronic pain management.”

#### **Alternatives to Opioids**

The evidence for this section is derived from systematic reviews of randomized trials published since the Chou et al (2007) review of RCTs for pharmacologic and non-pharmacologic treatments of acute, subacute, and chronic low back pain. Using key terms “chronic pain”, “randomized”, and “systematic review”, we reviewed 976 abstracts, 42 of which were relevant to this review. More recent reviews that incorporated older RCT results took precedence over older systematic reviews. In addition, we used key words “systematic review” and “cognitive behavioral therapy” and “chronic pain” to identify conditions other than chronic low back pain for which cognitive behavioral therapy may have been effective; we reviewed 586 abstracts, and included 8 additional studies.

#### **Acute and subacute phase**

PubMed was searched for randomized trials and systematic reviews of randomized trials, in the treatment of low back pain, headaches, and fibromyalgia. Key terms used included “systematic reviews” and “opioids” and either “low back pain” or “headaches” or “fibromyalgia”. The final numbers of articles used were: 7 of 180 for low back pain; 3 of 219 for headache; and 3 of 60 for fibromyalgia. A search of the literature on specific use of opioids during the subacute pain period yielded no randomized trials. In addition, the use of screening tests prior to starting COAT was covered in the 2010 AMDG guideline.

### **Perioperative period**

A number of reviews of the literature on perioperative pain treatment have been undertaken and published in the last few years including those from the American Pain Society, the American Society of Anesthesiologists, the Department of Defense, the Veterans Administration, and the Washington State Department of Labor and Industries. These guidelines as well as a PubMed search for additional reviews of this topic in the last 5 years, which yielded 560 articles, excluding 32 reviews concerning any single surgical procedure.

### **Chronic non-cancer pain**

The literature was reviewed in PubMed for studies since 2010. The committee also reviewed the opioid prescribing guidelines from other government agencies and public and private insurers.

### **Reducing or discontinuing COAT and treatment of opioid use disorder**

A search of the literature on opioid tapering yielded no randomized trials. In addition, treatment for withdrawal symptoms was covered in the 2010 AMDG guideline. A review of recent meta-analyses and systematic reviews and a few well-designed randomized clinical trials provided the basis for recommendations on the treatment of opioid use disorder.

### **Pregnancy and Neonatal Abstinence Syndrome**

A literature search in PubMed was conducting using text terms "pregnancy" and "opioid" and one of the following different terms to identify pertinent studies: "detoxification" or "neonatal abstinence" or "NSAID and oligohydramnios" or "adverse outcomes."

### **Children and Adolescents**

The literature was reviewed using Medline, years 1996 to present. Search terms were "opioid" and "chronic pain". The search returned 48 articles, none of which were used. Searches for "off label drug use in pediatrics" were more relevant and articles already familiar to the author were used.

### **Opioid Use in Older Adults**

A literature search was performed in October 2014, using PubMed and the search terms "opioids and older adults". Of 887 abstracts identified, 31 were examined in detail. Two other relevant guidelines were also included in the review.

### **Cancer Survivors**

PubMed searches limited to 5 years were performed in April 2014 and again in January 2015 using the search terms "cancer survivor" and "pain" revealing over 500 results, which were narrowed by "reviews", "systematic reviews" and "therapy" resulting in approximately 100 abstracts, of which 35 were examined in detail. In addition, the National Comprehensive Cancer Network (NCCN) 2015 Survivorship Guidelines reference list of 621 items was reviewed for additional relevant papers (Pam Davies).

A literature search was performed in April 2015 using PubMed and the search terms "cancer survivors and pain treatments (Dr. Fitzgibbon).

## **DOMAIN 4: CLARITY OF PRESENTATION**

**The recommendations are specific and unambiguous; different options for the management of the condition or health issues are clearly presented; and key recommendations are easily identifiable.**

### **Where found: Throughout the guideline**

- Recommendations are clearly identified and can be found within each clinical section
- Supporting evidence for recommendations are clearly documented
- Tables and algorithms are used to illustrate processes and decision making
- Appendices are used for more detailed references so key recommendations are not obscured.

#### DOMAIN 5: APPLICABILITY

The guideline describes facilitators and barriers to its application; provides advice and/or tools on how the recommendations can be put into practice; potential resources implication of applying the recommendations have been considered; and guideline presents monitoring or auditing criteria.

#### Where found: Within each section of the guideline, appendices, and on the AMDG website

The 2007 and 2010 AMDG opioid guidelines were widely diffused, both in WA state via the [AMDG website](#) and the [National Guideline Clearinghouse](#). All of the tools necessary for successful implementation of the prior guidelines can be accessed on the AMDG website, such as an app for opioid dosing calculation, and brief, validated publicly available screening instruments for risk assessment.

The statutory public/private Bree Collaborative, representing all major health care sectors and payers in WA state, has preliminarily and unanimously voted to endorse this guideline and are planning final endorsement at their July, 2015 quarterly meeting. As such, the guideline would become the standard for all residents in WA state.

The committee explicitly chose not to address in this guideline, issues such as resource limitations (e.g. access to pain specialists), inadequate reimbursement, and medicinal cannabis. Although important topics, the committee felt that these were beyond the scope and capacity of what they could effectively achieve and still have a clinically useful guideline. The authors are aware of potential barriers to the guideline's application, and the state agencies will continue to seek ways of communicating and educating providers about how to improve care through the use of this guideline. All recommendations were written to apply to the general population in Washington State, and are considered to be implementable by most providers.

#### DOMAIN 6: EDITORIAL INDEPENDENCE

The views of the funding body have not influenced the content of the guideline; and competing interest of the guideline development group members have been recorded and addressed.

#### Where found: Appendix I

Although funding and resources for the guideline development were supported by state agencies, the guideline was approved by advisory committee via a consensus process. Each committee member signed conflict of interest disclosures, and though some had financial arrangements with various companies, none posed a conflict of interest when contributing to this guideline. A complete list of their names and affiliations can be found in the [Acknowledgment](#) section.

# Acknowledgements

The Washington State Agency Medical Directors’ Group wishes to acknowledge the many individuals and groups from both the private and public sectors who provided crucial consultation and input to this guideline. Their clinical, scientific, and technical expertise helped ensure that this guideline would be relevant, accurate, and of practical use to prescribers. Every effort was made to create a guideline as evidence-based as possible. Where scientific evidence was insufficient or unavailable, the best clinical opinions and consensus of the advisory group were used.

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OTHER  
STATES  
CME

# CALIFORNIA

2190.5. (a) All physicians and surgeons shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. For the purposes of this section, this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, to be completed by December 31, 2006. All physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The board may verify completion of this requirement on the renewal application form.

(b) By regulatory action, the board may exempt physicians and surgeons by practice status category from the requirement in subdivision (a) if the physician and surgeon does not engage in direct patient care, does not provide patient consultations, or does not reside in the State of California.

(c) This section shall not apply to physicians and surgeons practicing in pathology or radiology specialty areas.

## Required CME on Pain Management and the Appropriate Treatment of the Terminally Ill

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Most California-licensed physicians are required to take, as a one-time requirement, 12 hours of CME on pain management and the appropriate care and treatment of the terminally ill. Pathologists and radiologists are exempted from this requirement. The courses or programs must be presented by an organization accredited to provide CME by the ACCME, the AMA, the IMQ/CMA, or the AAFP. In addition to accrediting CME providers, AMA, IMQ/CMA, and AAFP may also present CME programs that will be accepted.

The 12 units may be divided in any way that is relevant to the physician's specialty and practice setting. Acceptable courses may address either topic individually or both topics together. For example, one physician might take three hours of "pain management education" and nine hours of "the appropriate care and treatment of the terminally ill;" a second physician might opt to take six hours of "pain management" and six hours of "the appropriate care and treatment of the terminally ill;" a third physician might opt to take one 12-hour course that includes both topics. The Medical Board will accept any combination of the two topics totaling 12 hours.

Physicians must complete the mandated hours by their second license renewal date or within four years, whichever comes first.

The 12 required hours would count toward the 50 hours of approved CME each physician is required to complete during each biennial renewal cycle.

- [Currently Available Pain Management and End-of-Life Classes](#)

## Currently Available Pain Management and End-of-Life Classes

The following pain management and end-of-life courses meet the mandated one-time 12-hour requirement taken within four years of licensure or by the second renewal date. The Medical Board will accept courses or programs from an approved provider that address one or both topics. The 12 hours may be divided in any way that is relevant to the physician's specialty and practice setting. Acceptable courses may address either topic individually or both topics together. It is not necessary to send and/or fax your completed pain management and end-of-life certificates unless you are being audited.

### **2014 California Physician Update**

*InforMed | Self Study*

Developed by nationally recognized experts in pain management to meet California 12-hour requirement. Available online at [www.ca.cme.edu](http://www.ca.cme.edu) or in print by calling 800-237-6999.

### **COPE-REMS Training Program**

*University of Washington School of Medicine | Self Study*

Collaborative Opioid Prescribing Education for REMS uses a collaborative care model for the care and treatment of patients with chronic non-cancer pain. COPE-REMS is aimed at preventing opioid misuse and abuse and preventing deaths from opioid overdose.

### **Extended-Release and Long-Acting (ER/LA) Opioids: Assessing Risks, Safe-Prescribing**

*University of Nebraska Medical Center | Webinar*

For more information, contact the Federation of State Medical Boards at [kalfred@fsmb.org](mailto:kalfred@fsmb.org) or (817) 868-5160

## **IMQ Online CME**

*Institute for Medical Quality | Self Study*

For a full list of courses available, visit their website at: <https://imq.inreachce.com/>

## **Internet Drug Sellers: What Providers Need to Know**

*University of Nebraska Medical Center | Webinar*

For more information, visit the Federation of State Medical Board's website at:  
<http://www.fsmb.org/policy/education-meetings/>

## **Pain Management and End-of-Life Care**

*California Society of Anesthesiologists | Self Study*

More information at: [www.csahq.org](http://www.csahq.org)

## **SCOPE of Pain: Safe and Competent Opioid Prescribing Education**

*Boston University School of Medicine | Self Study*

For more information, visit: <http://www.scopeofpain.com/>

## **UC Davis Pain Management Series**

*University of California, Davis | Self Study*

Pain Management and the Appropriate Care and Treatment of the Terminally Ill. More information at:

[http://ucdmc.ucdavis.edu/cme/distance\\_education/webevents/UCD\\_Pain/UCD-Pain\\_index.html](http://ucdmc.ucdavis.edu/cme/distance_education/webevents/UCD_Pain/UCD-Pain_index.html) or call 1-866-263-4338.

## **UC Davis' eDoctoring Online Training Program**

*University of California, Davis | Self Study*

More information at: [http://edoc.ucdavis.edu/Public\\_site/](http://edoc.ucdavis.edu/Public_site/)

# Virtual Lecture Hall

*Virtual Lecture Hall | Self Study*

For a full list of courses available, visit their website at:  
<http://www.vlh.com/shared/courses/all.cfm?stateid=6>.

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# KENTUCKY

Section 5. (1) For each three (3) year continuing education cycle beginning on January 1, 2015, a licensee who is authorized to prescribe or dispense controlled substances within the commonwealth at any time during that cycle shall complete at least four and one-half (4.5) hours of approved continuing education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects. A licensee may satisfy this requirement by completing a single approved program of four and one-half (4.5) hours or longer or by completing multiple approved programs for a total of four and one-half (4.5) hours or longer for that cycle.

(2) Each physician licensed to practice medicine or osteopathy within the Commonwealth of Kentucky who is authorized to prescribe or dispense controlled substances within the commonwealth from July 20, 2012 through the end of the three (3) year continuing education cycle beginning on January 1, 2012 and ending on December 31, 2014 shall complete at least four and one-half (4.5) hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects on or before December 31, 2014. The licensee may satisfy this requirement by completing a single approved program of four and one-half (4.5) hours or longer or by completing multiple approved programs for a total of four and one-half (4.5) hours or longer for this cycle.

(3) Each physician licensed to practice medicine or osteopathy within the Commonwealth of Kentucky who is authorized to prescribe or dispense controlled substances during the calendar years 2013 and 2014, but not during any portion of 2012, shall complete at least three (3) hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects on or before December 31, 2014. The licensee may satisfy this requirement by completing a single approved program of three (3) hours or longer or by completing multiple approved programs for a total of three (3) hours or longer for those two (2) years.

(4) Each physician licensed to practice medicine or osteopathy within the Commonwealth of Kentucky who is authorized to prescribe or dispense controlled substances during calendar year 2014, but not during any portion of 2012 or 2013, shall complete at least one and one-half (1.5) hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects on or before December 31, 2014. The licensee may satisfy this requirement by completing a single approved program of one and one-half (1.5) hours or longer or by completing multiple approved programs for a total of one and one-half (1.5) hours or longer for that calendar year.

(5)(a) To qualify as approved continuing education under this section, the educational program shall have been approved in advance for the specified number of continuing education hours by the board.

(b) The board may approve an educational program that:

1. Consists of a live presentation;
2. Is presented by a live or recorded webinar; or
3. Is presented through an online module.

(c) The board shall maintain a current listing of approved continuing education programs on its official Web site, [www.kbml.ky.gov](http://www.kbml.ky.gov).

(6)(a) In order to lawfully prescribe or dispense controlled substances within the Commonwealth of Kentucky, a licensee shall complete the required number of continuing education hours for each period designated in this section.

(b) Failure to complete the required number of continuing education hours for the required period or to submit the required written verification within the time specified shall constitute a violation of KRS 311.595(9) and (12), which shall constitute an immediate danger to the public health, safety, or welfare, for the purposes of KRS 311.592 and 13B.125.

(c) If the board determines that a licensee has failed to complete the required continuing education hours within the time specified or has failed to provide the written verification of completion within the time specified, the appropriate inquiry panel or its chair shall promptly issue an emergency order restricting that licensee from prescribing or dispensing controlled substances within the Commonwealth of Kentucky until the licensee has completed the required continuing education hours for that period and has provided written verification of completion to the board.

(d) An emergency order restricting a licensee from prescribing or dispensing controlled substances within the Commonwealth of Kentucky issued pursuant to paragraph (c) of this subsection shall remain valid and in effect until the board has received written verification that the licensee has successfully completed the required continuing education hours for the time period specified. Upon receipt of the written verification, the panel or its chair shall immediately issue an order terminating the emergency order issued pursuant to this section.

(e) If a licensee who is affected by an emergency order issued pursuant to this section requests an emergency hearing pursuant to KRS 13B.125(3), the hearing officer conducting the emergency hearing shall affirm the emergency order if presented with written notification on board letterhead stating that the board has not received the required written verification that the licensee completed the required continuing education hours for the continuing medical education cycle by the deadline date for the cycle.

(7) If a licensee prescribes or dispenses a controlled substance within the Commonwealth of Kentucky during any period after the licensee has failed to complete the required continuing education hours within the time specified or has failed to provide written verification of completion within the time specified, each instance of prescribing or dispensing of a controlled substance shall constitute a separate violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(1)(b), and shall serve as the basis for disciplinary sanctions pursuant to KRS 311.595.

## Kentucky Board of Medical Licensure (/)

Kentucky Board of Medical Licensure (/Pages/default.aspx) / Continuing Medical Education

- Allied Health (</ah/Pages/default.aspx>)
- Board Information (</board/Pages/default.aspx>)
- Document Search (</search/Pages/default.aspx>)
- Grievances (</grievances/Pages/default.aspx>)
- House Bill 1 (</hb1/Pages/default.aspx>)
- KAR KRS Search (</search/Pages/KAR-KRS-Search.aspx>)
- Newsletter (</newsletter/Pages/default.aspx>)
- Pain Management Facility (</pain-management-facility/Pages/default.aspx>)
- Physician Licensure (</physician/Pages/default.aspx>)
- Substance Abuse Resources (</substance-abuse/Pages/default.aspx>)
- Update Address (</address/Pages/default.aspx>)
- Continuing Medical Education (</Pages/Continuing-Medical-Education.aspx>)
- Other Links (</Pages/Other-Links.aspx>)
- Ebola Information (</Pages/Ebola-Information.aspx>)
- Verification-Duplicate ID (</Pages/Verification-Duplicate-ID.aspx>)

## Continuing Medical Education

If you have questions pertaining to information on this page, contact Teresa Kleinhenz (502) 429-7932 or by email [teresa.kleinhenz@ky.gov](mailto:teresa.kleinhenz@ky.gov) (<mailto:teresa.kleinhenz@ky.gov>).

### HB 1 Approved CME

Federation of State Medical Boards - Responsible Opioid Prescribing A Clinician's Guide  
(<http://fsmb.org/books>)

Free Opioid Prescribing Training From Boston University  
(</Documents/CME%20Free%20Opioid%20Prescribing%20Training%20From%20Boston%20University>)

pdf)

InforMed- Kentucky Update For Physicians (Self Study) (/Documents/CME%20InforMed.pdf)

FSMB Risk Evaluation and Mitigation Strategy (REMS) activity for extended-release (ER) and long-acting (LA) opioid medications

(/Documents/CME%20FSMB%20Risk%20Evaluation%20and%20Mitigation%20Strategy%20%28REMS%29.pdf)

Operation Unite Taped CME (<http://www.cecentral.com/addictionky>)

Prescription Opioids: Risk Management and Strategies For Safe Use  
(<http://www.netce.com/courseoverview.php?courseid=1085>)

Central Appalachia Inter-Professional Pain Education Collaborative  
(<http://www.cecentral.com/caipec>)

## Approved Pediatric Abusive Head Trauma CME

Norton HealthCare (<http://www.nortonhealthcare.com/pediatric-abusive-head-trauma>)

Understanding Abusive Head Trauma and Child Physical Abuse From CeCentral  
(<http://www.cecentral.com/activity/11445>)

## CME Facts

### What is Continuing Medical Education?

Continuing Medical Education consists of educational activities, which serve to maintain, develop, or increase the knowledge, skills, and professional performance, and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

### What are the CME requirements?

In accordance with Board regulation 201 KAR 9:310, as of January 1, 1994, all physicians who maintain an active Kentucky medical or osteopathic license are required to complete 60 hours of CME every three years, with 30 hours being certified in AMA or AOA Category 1 by an organization accredited by the Accreditation Council on Continuing Medical Education or the AOA Council on Continuing Medical Education. The remaining hours may be in Category I or Category II hours. State specific CME hours are defined below:

- HB 1 (passed in 2012) requires a minimum of 4.5 hours required for physicians who are authorized to prescribe or dispense controlled substances in Kentucky. Please reference HB 1 CME here (</Documents/CME-Important%20HB%201%20CME%20Reminder.pdf>) .
- HB 157 (passed on 2014) requires pediatricians, radiologists, family practitioners, and emergency medicine and urgent care physicians to complete 1 hour of training on this subject that is approved by the Board prior to December 31, 2017. Information can be found on this page under the Approved Pediatric Abusive Head Trauma CME above.
- Primary care physicians, who are granted licensure after July 1, 1996, are required to successfully complete a 3 hour domestic violence training course within 3 years of the date of initial licensure.

# MARYLAND

## CME MANDATE

**Please Note:** The Board will accept any one credit CME related to opioid prescribing (pain management, substance abuse, et cetera). As a resource, the Board has compiled a chart of courses (see the link below) for its physician and physician assistant licensees. This list is not exhaustive. Licensees may select a course offered through another source, as long as the course is related to opioid prescribing.

The one credit must be earned by all physician and physician assistant licensees, regardless of specialty, prescribing authority, workplace setting, or location in or out of state.

For physicians with licenses expiring on September 30 in 2015 or 2016, the credit must be earned in the current renewal cycle. A prior CME, related to opioid prescribing, already taken during this current renewal cycle will fulfill the mandate. For physician assistants, the credit must be earned during the current renewal cycle (the renewal period for renewal applications to be submitted in 2017).

Licensees are not required to send to the Board documentation of completion of the one credit. The Board audits a random sampling of renewing licensees, and only at the time of an audit would an individual licensee need to produce CME certificates.

- **Board Approved Continuing Education Resources**

**Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses**

<b>Education Provider or Accredited Provider</b>	<b>Course Title</b>	<b>Location(s)</b>	<b>Live or Online Course</b>	<b>Course Format or Duration &amp; (Credits)</b>	<b>Additional Information</b>
<b>American Academy of Addiction Psychiatry (and other partner organizations)</b>  <a href="http://www.pcssmat.org">www.pcssmat.org</a>	Various activities	N/A	Online	Various training modules and webinars  (1 AMA PRA Category 1 Credit™)	<ul style="list-style-type: none"> <li>• Advertised cost: Free</li> <li>• PCSS-MAT = Providers’ Clinical Support System for Medication Assisted Treatment</li> <li>• AAAP is the lead organization in a collaborative effort for this project</li> </ul>
<b>American Academy of Pain Medicine</b>  <a href="http://www.painmed.org">www.painmed.org</a>	Essential Tools for Treating the Patient in Pain™	N/A	Online	16 Modules (Valid to 6/16/16) 4 Additional Modules (Valid to 7/24/17)  (AMA PRA Category 1 Credits™ are offered)	<ul style="list-style-type: none"> <li>• Advertised cost: \$49 per module for members; \$69 per module for non-members</li> <li>• Per the Website, AAPM is accredited by the Accreditation Council for Continuing Medical Education (ACCME)</li> </ul>
<b>American Academy of Physician Assistants</b>  <a href="https://cme.aapa.org">https://cme.aapa.org</a>	Managing Pain Patients Who Abuse Prescription Drugs	N/A	Online	Test-and-teach Case  (1.75 AAPA Category 1 CME credits)	<ul style="list-style-type: none"> <li>• Advertised cost: Free; supported by the National Institute on Drug Abuse (NIDA)</li> <li>• Another course, Safe Prescribing for Pain, is available (1.25 AAPA Category 1 CME credits)</li> </ul>

***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board’s mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\* Other opioid prescribing-related activities are available on Medscape.org. Licensees may choose to select a course or activity offered through another source, as long as the course or activity is related to opioid prescribing. Additional information on accredited CME/CE also can be found on [www.er-la-opioidrems.com](http://www.er-la-opioidrems.com).

\*\* The FSMB Directory was updated in July 2015.

**Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses**

<b>Education Provider or Accredited Provider</b>	<b>Course Title</b>	<b>Location(s)</b>	<b>Live or Online Course</b>	<b>Course Format or Duration &amp; (Credits)</b>	<b>Additional Information</b>
<b>American Pain Society</b> www.americanpainsociety.org	REMS for ER/LA Opioid Analgesics: The Keys to Safe Use	N/A	Online	One article  (Maximum of 2 AMA PRA Category 1 Credits™; maximum of 2 AAPA hours of Category 1 credits)	<ul style="list-style-type: none"> <li>This article is a certified CME/CE activity available on Medscape.org*</li> <li>Per its Website, APS is accredited by ACCME</li> </ul>
<b>Audio Digest Foundation</b> www.audio-digest.org	Various educational activities	N/A	Online	Various activities  (Maximum of 2 AMA PRA Category 1 Credits™ for each enduring material)	<ul style="list-style-type: none"> <li>Per the Website, the Foundation is accredited by ACCME</li> </ul>
<b>Boston University, School of Medicine</b> www.opioidprescribing.com/overview	Safe and Effective Opioid Prescribing for Chronic Pain	N/A	Online	Various Modules (Various expiration dates)  (AMA PRA Category 1 Credits™ are offered)	<ul style="list-style-type: none"> <li>Per the Website, registration is required for CME credit; Boston University School of Medicine is accredited by ACCME</li> </ul>
<b>Boston University, School of Medicine</b> www.scopeofpain.com	SCOPE of Pain (Safe and Competent Opioid Prescribing Education)	N/A	Online	3 Modules  (Maximum of 3 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>Per the Website, registration needed to begin online training; Boston University School of Medicine is accredited by ACCME</li> <li>A free, live event is scheduled in Linthicum, Maryland on October 17, 2015; up to 4.5 AMA PRA Category 1 Credits™ are available</li> </ul>

***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board's mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\* Other opioid prescribing-related activities are available on Medscape.org. Licensees may choose to select a course or activity offered through another source, as long as the course or activity is related to opioid prescribing. Additional information on accredited CME/CE also can be found on www.er-la-opioidrems.com.

\*\* The FSMB Directory was updated in July 2015.

**Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses**

<b>Education Provider or Accredited Provider</b>	<b>Course Title</b>	<b>Location(s)</b>	<b>Live or Online Course</b>	<b>Course Format or Duration &amp; (Credits)</b>	<b>Additional Information</b>
<b>Case Western Reserve University,</b> School of Medicine  <a href="http://casemed.case.edu/cme">http://casemed.case.edu/cme</a>	Intensive Course in Controlled Substance Management (Pain, Anxiety, Insomnia)	Cleveland, Ohio	Live	4 days (Scheduled in December 2015, February 2016, and June 2016)  (Maximum of 31.5 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Advertised cost: \$1,200</li> <li>• Per its Website, Case Western Reserve University, School of Medicine is accredited by ACCME</li> <li>• This course is listed in the FSMB's Directory of Assessment and Remedial Education Programs**</li> </ul>
<b>Center for Personalized Education for Physicians (CPEP)</b>  <a href="http://www.cpepdoc.org">http://www.cpepdoc.org</a>	Prescribing Controlled Drugs	Denver	Live	December 9-11, 2015  (Maximum of 22.75 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Advertised cost: \$2,525</li> <li>• Per the CPEP Website, this activity was planned and implemented in accordance with requirements and policies of ACCME through the joint providership of Memorial Hospital University of Colorado Health and CPEP; majority of the course materials originally developed by Vanderbilt (see Vanderbilt entry)</li> </ul>
<b>Federation of State Medical Boards</b>  <a href="http://www.fsmb.org">www.fsmb.org</a>	Extended-Release and Long-Acting (ER/LA) Opioids: Assessing Risks, Safe Prescribing	N/A	Online	6 Modules  (AMA PRA Category 1 Credits™ are offered)	<ul style="list-style-type: none"> <li>• Per the activity Website, all modules must be completed to receive credit</li> </ul>

***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board's mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\* Other opioid prescribing-related activities are available on Medscape.org. Licensees may choose to select a course or activity offered through another source, as long as the course or activity is related to opioid prescribing. Additional information on accredited CME/CE also can be found on [www.er-la-opioidrems.com](http://www.er-la-opioidrems.com).

\*\* The FSMB Directory was updated in July 2015.

**Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses**

<b>Education Provider or Accredited Provider</b>	<b>Course Title</b>	<b>Location(s)</b>	<b>Live or Online Course</b>	<b>Course Format or Duration &amp; (Credits)</b>	<b>Additional Information</b>
<b>Federation of State Medical Boards</b>  <a href="http://www.fsmb.org">www.fsmb.org</a>	Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain	N/A	Online	One activity (Expiration 2/28/16)          (Maximum of 1 AMA PRA Category 1 Credit™ available)	<ul style="list-style-type: none"> <li>• Advertised cost: Free; activity is provided by the University of Nebraska Medical Center and the FSMB</li> <li>• Per the course information, the University of Nebraska Medical Center, Center for Continuing Education, is accredited by ACCME</li> <li>• A second activity is available: Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office</li> </ul>
<b>Harvard Medical School</b>  <a href="http://cmeonline.med.harvard.edu">http://cmeonline.med.harvard.edu</a>	Pain Management for the Outpatient	N/A	Online	Approx. 2 hours (Expiration 7/16/16)       (2 AMA PRA Category 1 Credits™ for physicians)	<ul style="list-style-type: none"> <li>• Advertised cost: \$40</li> <li>• Per its Website, Harvard Medical School is accredited by ACCME</li> <li>• Other courses are available</li> </ul>
<b>Johns Hopkins University, School of Medicine</b>  <a href="http://www.hopkinsmedicine.org">http://www.hopkinsmedicine.org</a>	Pain Action Consulting Team (PACT): A Mentoring Model CME	N/A	Online	Approx. 30 minutes (Valid for credit through 8/28/15)       (Maximum of 0.5 AMA PRA Category 1 Credits™ for physicians)	<ul style="list-style-type: none"> <li>• This activity is available on Medscape.org; a second activity is available for another half credit (valid through 3/20/16)</li> <li>• Per the Medscape Website, Johns Hopkins University School of Medicine is accredited by ACCME</li> </ul>

***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board's mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\* Other opioid prescribing-related activities are available on Medscape.org. Licensees may choose to select a course or activity offered through another source, as long as the course or activity is related to opioid prescribing. Additional information on accredited CME/CE also can be found on [www.er-la-opioidrems.com](http://www.er-la-opioidrems.com).

\*\* The FSMB Directory was updated in July 2015.

**Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses**

<b>Education Provider or Accredited Provider</b>	<b>Course Title</b>	<b>Location(s)</b>	<b>Live or Online Course</b>	<b>Course Format or Duration &amp; (Credits)</b>	<b>Additional Information</b>
Maryland State Medical Society <b>(MedChi)</b>  https://medchi.inreachce.com	Various courses	N/A	Online	Various activities  (1 or 2 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Various costs advertised</li> </ul>
NIH: <b>National Institute on Drug Abuse</b>  www.drugabuse.gov	Safe Prescribing For Pain	N/A	Online	One activity  (1.25 CME/CE credits on Medscape Education; 1.25 AAPA Category 1 CME Credits on AAPA's Learning Central)	<ul style="list-style-type: none"> <li>• Per its Website, this course was developed by NIDA and Medscape Education with funding from the White House Office of National Drug Control Policy</li> <li>• Additional courses are available</li> </ul>
<b>PACE</b> University of California, San Diego  www.paceprogram.ucsd.edu	Physician Prescribing Course	San Diego, California	Live	3 days (Scheduled in October 2015)  (Maximum of 27 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Advertised cost: \$1,800</li> <li>• PACE = Physician Assessment and Clinical Education</li> <li>• Per the Website, the University of California, San Diego, School of Medicine is accredited by ACCME</li> <li>• This course is listed in the FSMB's Directory of Assessment and Remedial Education Programs</li> </ul>

***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board's mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\* Other opioid prescribing-related activities are available on Medscape.org. Licensees may choose to select a course or activity offered through another source, as long as the course or activity is related to opioid prescribing. Additional information on accredited CME/CE also can be found on www.er-la-opioidrems.com.

\*\* The FSMB Directory was updated in July 2015.

**Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses**

<b>Education Provider or Accredited Provider</b>	<b>Course Title</b>	<b>Location(s)</b>	<b>Live or Online Course</b>	<b>Course Format or Duration &amp; (Credits)</b>	<b>Additional Information</b>
<b>Professional Boundaries, Inc.</b> (PBI)  www.professionalboundaries.com	Opioids, Pain Management & Addiction	> Atlanta > Chicago > Houston > Irvine, California > Orlando, Florida	Live	2 days (Numerous dates scheduled in 2015 and 2016)  (21 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Advertised cost: \$1,695</li> <li>• Per the PBI Website, the University of California, Irvine School of Medicine is the provider of CME and is accredited by ACCME</li> </ul>
<b>Substance Abuse and Mental Health Services Administration</b>  www.samhsa.gov	Substance Use in Adults and Adolescents: Screening, Brief Intervention and Referral to Treatment (SBIRT)	N/A	Online	One activity  (1.75 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Advertised cost: Free</li> <li>• The activity can be accessed via a link from the SAMHSA Web site to Medscape (Medscape.org)</li> </ul>
<b>University of Florida,</b> College of Medicine  http://cme.ufl.edu	Prescribing Controlled Drugs: Critical Issues and Common Pitfalls of Misprescribing	Gainesville, Florida	Live	3 days (Scheduled in September and November 2015)  (AMA PRA Category 1 Credits™ are offered)	<ul style="list-style-type: none"> <li>• Advertised cost: \$2,500</li> <li>• This course is based on the one originally developed by Vanderbilt (see Vanderbilt entry)</li> <li>• Per its Website, the University of Florida is accredited by ACCME</li> </ul>

***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board's mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\* Other opioid prescribing-related activities are available on Medscape.org. Licensees may choose to select a course or activity offered through another source, as long as the course or activity is related to opioid prescribing. Additional information on accredited CME/CE also can be found on www.er-la-opioidrems.com.

\*\* The FSMB Directory was updated in July 2015.

## Board Approved Courses: Pain Management / Substance Abuse and Addiction Courses

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Education Provider or Accredited Provider	Course Title	Location(s)	Live or Online Course	Course Format or Duration & (Credits)	Additional Information
<b>Vanderbilt University,</b> School of Medicine  www.cme.vanderbilt.edu	Prescribing Controlled Drugs	Nashville, Tennessee	Live	3 days (Scheduled in August, September, and November 2015)  (Maximum of 21.75 AMA PRA Category 1 Credits™)	<ul style="list-style-type: none"> <li>• Advertised cost: \$2,500</li> <li>• Per its Website, Vanderbilt University is accredited by ACCME</li> <li>• This course is listed in the FSMB's Directory of Assessment and Remedial Education Programs</li> </ul>

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***This list is not exhaustive and was updated on 8/17/15. Any one credit of CME related to opioid prescribing (pain management, substance abuse, addiction, etc.) from a course or online activity will meet the Board's mandate. Note that some courses or activities may have additional sponsors, grant sources, affiliations, or other accreditation information.***

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\*\* The FSMB Directory was updated in July 2015.

# NEW MEXICO

**TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING**  
**CHAPTER 10 MEDICINE AND SURGERY PRACTITIONERS**  
**PART 14 MANAGEMENT OF PAIN WITH CONTROLLED SUBSTANCES**

**16.10.14.1 ISSUING AGENCY:** New Mexico Medical Board, hereafter called the board.

[16.10.14.1 NMAC - N, 1/20/03; A, 4/3/05]

**16.10.14.2 SCOPE:** This part applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration.

[16.10.14.2 NMAC - N, 1/20/03; A, 9/28/12]

**16.10.14.3 STATUTORY AUTHORITY:** These rules are promulgated pursuant to and in accordance with the Medical Practice Act, Sections 61-6-1 through 61-6-35 NMSA 1978 and the Pain Relief Act, Sections 24-2D-1 NMSA through 24-2D-6.

[16.10.14.3 NMAC - N, 1/20/03; A, 9/28/12]

**16.10.14.4 DURATION:** Permanent

[16.10.14.4 NMAC - N, 1/20/03]

**16.10.14.5 EFFECTIVE DATE:** January 20, 2003, unless a later date is cited at the end of a section.

[16.10.14.5 NMAC - N, 1/20/03]

**16.10.14.6 OBJECTIVE:** It is the position of the board that practitioners have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed for that purpose. When such medicines and drugs are used, they should be prescribed in adequate doses and for appropriate lengths of time after a thorough medical evaluation has been completed.

[16.10.14.6 NMAC - N, 1/20/03; A, 4/3/05]

**16.10.14.7 DEFINITIONS:**

**A.** “Addiction” is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and, craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

**B.** “Acute pain” means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and is generally time-limited.

**C.** “Chronic pain” means pain that persists after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. “Chronic pain” does not, for purpose of the Pain Relief Act requirements, include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

**D.** “Clinical expert” means a person who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

**E.** “Drug abuser” means a person who takes a drug or drugs for other than legitimate medical purposes.

**F.** “Pain” means acute or chronic pain or both.

**G.** “Physical dependence” means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

**H.** “Prescription monitoring program” means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.

**I.** “Therapeutic purpose” means the use of pharmaceutical and non-pharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

**J.** “Tolerance” means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.  
[16.10.14.7 NMAC - N, 1/20/03; A, 9/28/12]

**16.10.14.8 REGULATIONS:** The following regulations shall be used by the board to determine whether a health care practitioner’s prescriptive practices are consistent with the appropriate treatment of pain.

**A.** The treatment of pain with various medicines or controlled substances is a legitimate medical practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

**B.** The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substance abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A practitioner shall be familiar with and employ screening tools as appropriate, as well as the spectrum of available modalities, in the evaluation and management of pain. The practitioner shall consider an integrative approach to pain management.

(3) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan shall include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(4) The practitioner shall discuss the risks and benefits of using controlled substances with the patient or surrogate or guardian, and shall document this discussion in the record.

(5) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized shall be recorded. Prescriptions for opioids shall include indications for use. For chronic pain patients treated with controlled substance analgesic(s), the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. As part of a written agreement, chronic pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.

(6) The management of patients needing chronic pain control requires monitoring by the attending or the consulting practitioner. The practitioner shall periodically review the course of treatment for chronic pain, the patient’s state of health, and any new information about the etiology of the chronic pain at least every six months. In addition, a practitioner shall consult, when indicated by the patient’s condition, with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control.

(7) If, in a practitioner’s medical opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

**C.** Pain management for patients with substance use disorders shall include:

- (1) a contractual agreement;
- (2) appropriate consultation;
- (3) drug screening when other factors suggest an elevated risk of misuse or diversion; and
- (4) a schedule for re-evaluation at appropriate time intervals at least every six months.

**D.** The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medical indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner’s treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient’s pain for its duration while effectively addressing other aspects of the patient’s functioning, including physical, psychological, social, and work-related factors.

**E.** The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection.

**F.** A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Medical Practice Act or board rules.

[16.10.14.8 NMAC - N, 1/20/03; A, 4/3/05; A, 9/28/12; A, 2/14/13]

**16.10.14.9 PHYSICIAN, PHYSICIAN ASSISTANTS AND ANESTHESIOLOGIST ASSISTANTS**

**TREATED WITH OPIATES:** Physicians, physician assistants or anesthesiologist assistants who have chronic pain and are being treated with opiates shall be evaluated by a pain clinic or, by an M.D. or D.O. pain specialist, and must have a complete, independent neuropsychological evaluation, as well as clearance from their physician, before returning to or continuing in practice. In addition, they must remain under the care of a physician for as long as they remain on opiates while continuing to practice.

[16.10.14.9 NMAC - N, 4/3/05; A, 9/28/12]

**16.10.14.10 PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS:** The intent of the New Mexico medical board in requiring participation in the PMP is to assist practitioners in balancing the safe use of controlled substances with the need to impede illegal and harmful activities involving these pharmaceuticals.

**A.** A health care practitioner who holds a federal drug enforcement administration registration and a New Mexico controlled substance registration shall register with the board of pharmacy to become a regular participant in PMP inquiry and reporting.

**B.** A health care practitioner shall, before prescribing, ordering, administering or dispensing a controlled substance listed in Schedule II, III or IV, obtain a patient PMP report for the preceding 12 months when one of the following situations exists:

(1) the patient is a new patient of the practitioner, in which situation a patient PMP report for the previous 12 months shall only be required when Schedules II, III, and IV drugs are prescribed for a period greater than 10 days; and

(2) during the continuous use of opioids by established patients a PMP shall be requested and reviewed a minimum of once every six months.

[16.10.14.10 NMAC - N, 9/28/12; A, 2/14/13]

**16.10.14.11 PAIN MANAGEMENT CONTINUING EDUCATION:** This section applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids. Pursuant to the Pain Relief Act, in order to ensure that all such health care practitioners safely prescribe for pain management and harm reduction, the following rules shall apply.

**A. Immediate requirements effective November 1, 2012.** Between November 1, 2012 and no later than June 30, 2014, all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids, shall complete no less than five continuing medical education hours in appropriate courses that shall include:

- (1) an understanding of the pharmacology and risks of controlled substances,
- (2) a basic awareness of the problems of abuse, addiction and diversion,
- (3) awareness of state and federal regulations for the prescription of controlled substances,
- (4) management of the treatment of pain, and

(5) courses may also include a review of this rule (16.10.14 NMAC) the applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval.

Practitioners who have taken continuing medical education hours in these educational elements between July 1, 2011 and November 1, 2012, may apply those hours toward the required five continuing medical education hours described in this subsection.

**B. Triennial requirements for physicians.** Beginning with the July 1, 2014 triennial renewal date, as part of the 75 continuing medical education hours required during each triennial renewal cycle, all New Mexico medical board physician licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit five continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the three-year period immediately preceding the triennial renewal date. The five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of the required continuing medical education hours in pain management in either

the triennial cycle in which these hours are completed, or the triennial cycle immediately thereafter.

**C. Biennial requirements for physician assistants.** Beginning with the July 1, 2014 biennial renewal date, in addition to the NCCPA certification required during each biennial renewal cycle pursuant to 16.10.15.16 NMAC, all New Mexico medical board physician assistant licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit three continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the two-year period immediately preceding the renewal date. Three of the five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of these required three continuing medical education hours in pain management in either the biennial cycle in which these hours are completed, or the biennial cycle immediately thereafter. Any or all three of these hours may also be applied to satisfy NCCPA requirements for certification.

**D. Biennial requirements for anesthesiologist assistants.** Beginning with the July 1, 2014 biennial renewal date, all New Mexico medical board anesthesiologist assistant licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit three continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the two-year period immediately preceding the renewal date. Three of the five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of these required three continuing medical education hours in pain management in either the biennial cycle in which these hours are completed, or the biennial cycle immediately thereafter.

**E. Requirements for new licensees.** All New Mexico medical board licensees, whether or not the New Mexico license is their first license, who hold a federal drug enforcement administration registration and license to prescribe opioids, shall complete five continuing medical education hours in pain management during the first year of licensure. These five continuing medical education hours completed prior to the first renewal may be included as part of the hours required in Subsections B, C or D, above.

**F.** The continuing medical education requirements of this section may be included in the total continuing medical education requirements set forth at 16.10.4.8 NMAC, 16.10.15.16 NMAC and 16.10.19.15 NMAC.

[16.10.14.11 NMAC - N, 9/28/12; A, 2/14/13]

**16.10.14.12 NOTIFICATION:** In addition to the notice of procedures set forth in the State Rules Act, Section 14-4-1 et seq NMSA 1978, the board shall separately notify the following persons of the Pain Relief Act and Part 14 of the New Mexico medical board rule, 16.10.14 NMAC;

**A.** health care practitioners under its jurisdiction; and

**B.** a health care practitioner being investigated by the board in relation to the practitioner's pain management services.

[16.10.14.12 NMAC - N, 9/28/12]

**HISTORY OF 16.10.14 NMAC:** [RESERVED]

## **PAIN MANAGEMENT CME**

Appropriate courses may include a review of NM Medical Board Rule 16.10.14 NMAC on pain management; an understanding of the pharmacology and risks of controlled substances, a basic awareness of the problems of abuse, addiction and diversion, and awareness of state and federal regulations for the prescription of controlled substances.

To have a course approved, send the course curriculum to:

NM Medical Board  
2055 S. Pacheco Street, Bldg. 400  
Santa Fe, NM 87505  
FAX: 505-476-7233  
EMAIL: nmbme@state.nm.us

### **BELOW IS A LIST OF EXAMPLES OF CME COURSES THAT HAVE BEEN APPROVED AS MEETING THE REQUIREMENTS SET FORTH IN 16.10.14 NMAC.**

**This list is broken up into “scheduled CME” and “continuous CME”**

#### **Scheduled:**

**IHS Essential Training on Pain and Addiction** – Webinar is presented by Indian Health Services in partnership with UNM ECHO program. Training dates: April 28, 2016, June 29, 2016, August 25, 2016, October 25, 2016, and December 15, 2016. There is no cost or travel required. To pre-register go to: <https://surveyMonkey.com/r/EssentialsPreRegistration>. For more detailed information the flyer for the webinar is attached to the end of this document.

**Opioids and The Overdose Epidemic: Clinical Tools for Safety and Success** – Saturday, May 7, 2016, 8:30 – 4:30, Santa Fe Convention Center, 201 W. Marcy Street. For information please contact [SantaFePreventionAlliance@gmail.com](mailto:SantaFePreventionAlliance@gmail.com).

#### **Continuous:**

**Get SMART (Safe Means of Administering the Right Therapy)** – Presented by John’s Hopkins University and DKBmed, LLC. The program offers up to 3 CME/MOC/CE credits and focuses on best practices when using opioid therapy for the management of patients with Chronic Pain. [www.DKBmed.com/smart](http://www.DKBmed.com/smart)

**Pain Management and the FDA REMS Blueprint for Prescriber Education** – Presented by INFORMED. Developed by experts to provide 5 AMA Category 1 Credits in the New Mexico Medical Board mandatory content area of pain management. 1-800-237-6999. <http://www.nm.cme.edu>.

**American Academy of Addiction Psychiatry**- Buprenorphine in the Treatment of Opioid Dependence. <http://www.aaap.org/annual-meeting/addictions-treatment-course/>

**Annual Pain Management Symposium** – Presented by the Cleveland Clinic. <http://www.clevelandclinicmeded.com/live/courses/pain/default.asp>

**California Academy of Physician Assistants**- Controlled Substances Education Courses.

**California Medical Board -**

[http://www.mbc.ca.gov/Licensees/Continuing\\_Education/Pain\\_Management\\_Classes.aspx](http://www.mbc.ca.gov/Licensees/Continuing_Education/Pain_Management_Classes.aspx)

**California Society of Anesthesiologists** – Pain Management and End of Life Care

<http://www.csahq.org/cme2/course.php?course=3>

**John Hopkins University School of Medicine**- Pain Management Virtual Congress

<http://www.paincarelive.com>.

**MedRisk Management** –Pain Management Strategies for the Office Based Practitioner- various online courses presented by Medical Risk Management, Inc. <http://www.medrisk.com>

**MedScope** – Various online courses including **Improving the Assessment of Pain-**

<http://www.medscape.org>

**Opioid Abuse and Dependence**- online Course #9696, presented by CME Resource

<http://www.netCE.com>

**Opioids and Addictions** - presented by ECHO Telemedicine Conferences-

<http://echo.unm.edu/clinics/clinic-pain.html>

**Pain Management** - Reducing Risk, Protecting Patients-DVD/CD set offered by NM Medical Society\*  
For order form please refer to:

[http://www.nmms.org/sites/default/files/images/2014\\_12\\_4\\_dvd\\_2\\_order\\_form.pdf](http://www.nmms.org/sites/default/files/images/2014_12_4_dvd_2_order_form.pdf)

**Pain Management and the FDA REMS Blueprint for Prescriber Education**-presented by INFORMED

<http://www.nm.cme.edu>

**Pain Management Self-Assessment Module (SAM)** – Presented by the American Board of Family Medicine <http://www.theabfm.org> - Must have or create an account with the ABFM to search available CME.

**NetCE.com**– continuously offers Pain Management CME. An example of a previously approved course was **CME Palliative Care and Pain Management at the End of Life-** online, Course #9738, presented by CME Resource <http://www.netCE.com>

**Prescribers' Clinical Support For Opioid Therapies** – Online modules <http://www.pcass-o.org>

**Risk Management Consult: Pain Management** – Presented by Medical Protective.

<http://medpro.medrisk.com/>.

**Safe and Competent Opioid Prescribing Education (SCOPE)** – Presented by Boston University, available at <http://www.scopeofpain.com> \*This program awards 3 hours of CME.

**Safe Opioid Prescribing** – Presented by Pri-Med <http://www.pri-med.com>

**Tele-Scan-Echo-Pain Management** Walter Reed National Military Medical Center.

**University of Arizona HSC - Improving Outcomes in Chronic Pain** – online @ <http://www.vlh.com> - - Must have or create an account with Virtual Lecture Hall to search available CME.

**UpToDate** – online at [www.uptodate.com](http://www.uptodate.com) - The following courses have been approved and are ongoing:

- Treatment of opioid abuse and dependence
- Opioid withdrawal in the emergency setting
- Substance use disorder: Principles for recognition and assessment in general medical care
- Medically supervised opioid withdrawal during treatment for addiction
- Acute opioid intoxication in adults
- Prescription drug abuse and addiction: Clinical features, epidemiology and contributing factors

### **Other Resources**

AMA-CME-<http://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education.page>

American Academy of Pain Management- [www.aapainmanage.org](http://www.aapainmanage.org)- web-based tutorials and didactics

American Academy of Pain Medicine- [www.painmed.org](http://www.painmed.org)

American Pain Society- [www.ampainsoc.org](http://www.ampainsoc.org)- web-based tutorials and didactics

California Society of Addiction Medicine (415) 764-4855 [www.csam-asam.org](http://www.csam-asam.org); [csam@csam-asam.org](mailto:csam@csam-asam.org) ; NetCE.Com- [www.netce.com](http://www.netce.com)

PainEdu.org- [www.painedu.org](http://www.painedu.org)

Peerview- [www.peerviewpress.com](http://www.peerviewpress.com)- web-based tutorials and didactics

**OHIO**

## **4731-10-02 Requisite hours of continuing medical education for license renewal or reinstatement.**

(A) The respective CME program requirements certified by the Ohio state medical association, the Ohio osteopathic association or the Ohio podiatric medical association and approved by the board shall consist of two categories, category 1 and category 2.

(1) Category 1 and category 2, CME shall be defined and identified within the programs certified by the respective state medical associations and approved by the board.

(2) In a two year CME period, a licensee shall be required to earn a total of one hundred hours of CME, of which a minimum of forty hours shall be category 1 as certified by their respective state professional associations and approved by the board. Certification is a process whereby the Ohio state medical association, the Ohio osteopathic medical association and the Ohio podiatric medical association define their respective CME program requirements for periodic submission to the board for approval. The board may approve each association's CME program requirements which consist of CME courses and activities that are deemed acceptable for completing the requisite hours of CME by each licensee.

(3) When undertaking a CME program, a licensee shall be responsible for ascertaining from the sponsor or co-sponsor whether the CME program will be credited toward the category 1 or category 2 requirement.

(B) The board shall keep on file copies of the program requirements of the various state professional associations.

(C) If a licensee has not completed the requisite hours of CME, a licensee is not eligible for license renewal or license reinstatement until such time as the requisite hours have been completed. Any CME undertaken after the end of a renewal period and utilized for purposes of renewing or reinstating a suspended license cannot also be utilized to meet the CME requirement of the current CME period.

(D) Licensees and applicants who are not working in the medical profession or who are retired from practice but wish to renew or reinstate their licenses shall meet the CME requirements of section [4731.281](#) of the Revised Code and this chapter of the Administrative Code.

Eff 6-8-98; 2-28-03

Rule promulgated under: RC [119.03](#)

Rule authorized by: RC [4731.05](#), [4731.281](#), [4731.295](#)

Rule amplifies: RC [4731.22](#), [4731.281](#), [4731.291](#), [4731.292](#), [4731.293](#), [4731.294](#), [4731.295](#), [4731.296](#)

Replaces: Part of 4731-10-01, 4731-10-03, 4731-10-06

R.C. [119.032](#) review dates: 11/18/2002 and 03/25/2006

4731-29-01 Standards and procedures for the operation of a pain management clinic.

(C) Each physician who provides care at a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.



[Resources](#) >> Prescription Drug Abuse

## Prescription Drug Abuse

### Treatment Guidelines

### Continuing Education

### Resources

The OSMA is working with a number of partners across the state to inform physicians on effective pain management and the issue of prescription drug abuse and diversion in Ohio. Physicians who own and/or work in pain management clinics must complete at least 20 hours of category 1 continuing medical education (CME) in pain medicine every two years. The education must include at least one course that addresses the potential for addiction. The pain management courses will be accepted toward a physician's category 1 education requirement. There are a number of live and online courses that will help you meet these requirements. Click the link below to see a few options in this area. We will update this page with pain management CME opportunities as they become available.

- [American Medical Association Pain Management Series](#)
- [American Academy of Family Physicians Pain Management CME Podcasts](#)
- [American Society of Addiction Medicine Live Online CME Training](#)
- [Prescribers' Clinical Support System for Opioid Therapies](#)

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# OREGON

**847-008-0075**

## **Mandatory Pain Management Education**

- (1) All licensees of the Oregon Medical Board, except the licensees listed in section (2) of this rule, must complete mandatory continuing medical education (CME) in the subjects of pain management and/or the treatment of terminally ill and dying patients as follows:
  - (a) A one-hour pain management course specific to Oregon provided by the Pain Management Commission of the Department of Human Services; and
  - (b) A minimum of six continuing medical education credit hours in the subjects of pain management and/or the treatment of terminally ill and dying patients. Any combination of CME coursework focusing on pain management and/or treatment of terminally ill and dying patients may be used to fulfill this requirement.
- (2) Licensees holding the following types of licenses are not required to meet this requirement:
  - (a) Lapsed license;
  - (b) Limited License;
  - (c) Telemedicine license;
  - (d) Teleradiology license; or
  - (e) Telemonitoring license.
- (3) The required CME must be completed after January 1, 2000, and before January 2, 2009.
- (4) Licensees must be prepared to provide documentation of CME if requested by the Board.
- (5) All applicants granted a license after January 2, 2009, except those granted a license listed in section (2), must obtain the required CME coursework no later than 12 months after the date the Board granted licensure.
- (6) Licensees who wish to reactivate to a status requiring completion of this CME who have not previously completed the required CME must obtain the required coursework no later than 12 months after the date the Board approved reactivation.
- (7) The continuing medical education hours in pain management and/or the treatment of terminally ill or dying patients may be used to fulfill the continuing medical education hours required for registration renewal under 847-008-0070.

# Pain Management Commission



## Oregon Pain Management Commission

# Oregon Pain Management Commission

About Us

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Meetings

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### Pain Education Program

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Required Module

### Reports

### Resources for Consumers

### Resources for Health Professionals

CEUs, Events, Conferences

### Coordinator's Message

Archives

Health Evidence Review Commission

Oregon Health Policy & Research

Oregon Health Authority

The Oregon Pain Management Commission is currently taking applications/ interest forms to fill two voluntary healthcare member positions to serve on the commission. One of those positions to be filled will represent dental healthcare. To learn more about this opportunity and to obtain information about the formal application process please contact [pmc.info@state.or.us](mailto:pmc.info@state.or.us).



[Subscribe](#) to receive email notification of meetings and updates.



## Pain Management Module – Required Continuing Education

The Oregon Pain Management Commission provides Oregon specific training required for certain licensed health care professionals as directed by ORS 413.590. Completion of the pain management module *Advancing Pain Management in Oregon* fulfills this requirement.

To complete the module:

- Please use MS Internet Explorer as your browser.
- The module is available in two formats to make it more accessible to users and persons with disabilities.
  - If you choose the PDF version, please download the latest version of [Adobe Reader](#). Bookmarks have been added for ease in navigating.
  - The MS Word (.doc) version contains an index to aid in navigating the module.
- Complete the module.
- After you have read the module, you will be able to complete a survey and to print a certificate of completion. There is no test required for the module. Please save your printed certificate for your own records in case you are audited by your licensing board. And you're done! This completes your requirements with the OPMC.

### Advancing Pain Management in Oregon

[PDF version](#) | [MS Word version](#) Updated 3/12/2013

If you are unable to create/print the certificate, please email [PMC.Info@state.or.us](mailto:PMC.Info@state.or.us) the following:

- Full name
- Professional designation (MD, RN, DMD, etc.)
- License number
- Module completion date
- Please allow 48-72 hours.

### A Note about Continuing Education Hours

In addition to the Module, you are required to complete six (6) additional continuing education hours in pain or palliative care. Your licensing board, not the OPMC, has oversight of the proper required CEU accreditation. If you have questions regarding the additional 6 CEUs please contact your licensing board. For your convenience, we have compiled a list of [Pain CEU Resources](#).

### OPMC News



#### Next meeting

4/28/2016 1:00-4:00 pm

### News

[OPB Story: "Integrative Care for OHP Pain Sufferers: Less drugs, more options"](#)

[Unwanted Drug Drop Off Sites](#)

[Partner for Quality Care publication: Safe and Effective Care for Low Back Pain](#)

[Best Advice for People Taking Opioid Medication](#)

Agencies A to Z  
Oregon Administrative Rules  
Oregon Revised Statutes  
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About Oregon.gov



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OHA ADA Notice  
File Formats  
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Site Map  
Web Site Feedback

image to get a free download of the reader from Adobe.



# SOUTH CAROLINA

## **SECTION 40-47-40.** Continuing professional education.

The continued professional competency of a physician holding a permanent license must be demonstrated in the following manner:

(1) For renewal of a permanent license initially issued during a biennial renewal period, compliance with all educational, examination, and other requirements for the issuance of a permanent license is sufficient for the first renewal period following initial licensure.

(2) For renewal of an active permanent license biennially, documented evidence of at least one of following options during the renewal period is required:

(a) forty hours of Category I continuing medical education sponsored by the American Medical Association, American Osteopathic Association, or another organization approved by the board as having acceptable standards for courses it sponsors, at least thirty hours of which must be related directly to the licensee's practice area, and at least two (2) hours of which may be related to approved procedures of prescribing and monitoring controlled substances listed in Schedules II, III, and IV of the schedules provided for in Sections 44-53-210, 44-53-230, 44-53-250, and 44-53-270, and must be received from a statewide organization recognized by the Accreditation Council for Continuing Medical Education to recognize and accredit organizations in South Carolina offering continuing medical education or from a statewide organization approved to provide continuing medical education by its national organization which is accredited by the Accreditation Council for Continuing Medical Education. Each renewal form submitted pursuant to Section 40-47-41 must include a certificate of participation with the prescribing and monitoring education requirement issued by the organization from which the education was received;

(b) certification of added qualifications or recertification after examination by a national specialty board recognized by the American Board of Medical Specialties or American Osteopathic Association or another approved specialty board certification;

(c) completion of a residency program or fellowship in medicine in the United States or Canada approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association;

(d) passage of the Special Purpose Examination or Comprehensive Osteopathic Medical Variable Purpose Examination; or

(e) successful completion of a clinical skills assessment program approved by the board, such as the Institute for Physician Evaluation or the Center for Personalized Education for Physicians.

Continuing Medical Education for Prescribing and Monitoring Controlled Substances

Approved by the Board at its January 13, 2015 meeting and revised at its May 6, 2015 meeting

Service Area: Licensure, Physicians

Subject: Continuing Medical Education for Prescribing and Monitoring Controlled Substances

In accordance with S.C. Code Ann. § 40-47-10(I)(1) of the 1976 Code of Laws of South Carolina, as amended, the South Carolina Board of Medical Examiners has adopted the following statement as guidance for physicians in the practice of medicine under the South Carolina Medical Practice Act and the Principles of Medical Ethics as adopted by the Board.

Effective June 6, 2014, S.C. Code Ann. § 40-47-40(2)(a) was amended to read as follows:

(2) For renewal of an active permanent license biennially, documented evidence of at least one of following options during the renewal period is required:

(a) forty hours of Category I continuing medical education sponsored by the American Medical Association, American Osteopathic Association, or another organization approved by the board as having acceptable standards for courses it sponsors, at least thirty hours of which must be related directly to the licensee's practice area, and at least two (2) hours of which may be related to approved procedures of prescribing and monitoring controlled substances listed in Schedules II, III, and IV of the schedules provided for in Sections [44-53-210](#), [44-53-230](#), [44-53-250](#), and [44-53-270](#), and must be received from a statewide organization recognized by the Accreditation Council for Continuing Medical Education to recognize and accredit organizations in South Carolina offering continuing medical education or from a statewide organization approved to provide continuing medical education by its national organization which is accredited by the Accreditation Council for Continuing Medical Education. Each renewal form submitted pursuant to Section [40-47-41](#) must include a certificate of participation with the prescribing and monitoring education requirement issued by the organization from which the education was received;"

The South Carolina Board of Medical Examiners provides guidance for acceptable prescribing courses for meeting the requirement. The Accreditation Council for Continuing Medical Education (ACCME) provides standardization, oversight, and certification of CME hours by numerous professional organizations throughout the United States. Likewise, the

American Osteopathic Association provides national standardization, oversight, and certification of AOA approved CME hours through the Council on Continuing Medical Education (CCME). For the purposes of the 2 hour requirement listed above, an ACCME or AOA CCME-approved course in prescribing and monitoring controlled substances is required. Offerings that fulfill this requirement include but are not limited to CME hours in controlled substance prescribing sponsored by the Federation of State Medical Boards, (e.g. “*Responsible Opioid Prescribing, A Clinician’s Guide*” by Scott M. Fishman, MD) the South Carolina Medical Association, other professional organizations with ACCME or AOA CCME certified CME (e.g. AAFP, ACP), and any FDA-REMS (Risk Evaluation and Mitigation Strategy) compliant CME courses.

GO



## New CME Course Requirement

By: SCMA

Friday, January 23, 2015

**CME for Prescribing and Monitoring Controlled Substances:  
Mandatory for All South Carolina Licensed Physicians by the SC Legislature  
Available at No Cost for our Physician Community**

As you are aware, the South Carolina Prescription Monitoring Program (PMP), also known as Senate Bill 840, was signed into law on June 6, 2014. Through this statute, South Carolina licensed physicians are required to obtain two continuing medical education credit hours related to the approved procedures of prescribing and monitoring controlled substances listed in Schedules II, III, and IV.

As outlined by the legislature, the two hour **requirement must be met** before the end of the current license renewal cycle which is **June 30, 2015** and the SCMA is approved by statute to offer this course.

The SCMA recognizes the critical need for more education on prescription abuse and monitoring in our state. Because our leadership knows it is important for physicians to be at the forefront of understanding the complexities of this law, immediately after understanding this new requirement, the SCMA developed an approved CME course designed specifically for South Carolina licensed physicians.

To make adherence to this requirement easier for our physician community, the SCMA is offering this approved course on prescribing and monitoring controlled substances **for free** to SC licensed physicians.

To receive your two CME credit hours prior to June 30, please visit: [www.scmmedical.org/content/mycmehome](http://www.scmmedical.org/content/mycmehome). Click *Take a CME Course*, follow the prompts to register, complete the course, and print a CME certificate for your records.

We will send this important information to all South Carolina licensed physicians by US Mail in the next few weeks. For questions, please contact our Director of Education, Sharron Kelley, by email at [s.kelly@scmedical.org](mailto:s.kelly@scmedical.org) or phone at 1-800-327-1027, extension 173 or directly at 803-612-4104.

**FEATURED COURSE:**

Medical Certification for Commercial Drivers

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Please Enter your email address below. If your email address is not found in our records we will ask for you to register an email address and username with us so you can leave comments on our site. **NOTICE:** Once you have registered and been verified you can just enter your email address to add comments.

Email Address:

SUBMIT EMAIL

## 1 Comments

Sunday, May 10, 2015

**jhkopp**

"Where is the link "Take a CME Course"?"

# TENNESSEE

## 0880-02-.19 CONTINUING MEDICAL EDUCATION.

### (1) Hours Required, Waiver, and Exemptions

(a) All licensees must complete forty (40) hours of continuing medical education courses during the two (2) calendar years (January 1 - December 31) that precede the licensure renewal year.

(b) Unless exempt under T.C.A. 63-1-402(c), all licensees holding a current Tennessee license shall complete a minimum of two (2) of the forty (40) required hours of continuing education related to controlled substance prescribing, which must include instruction in the Department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol and may include topics such as medicine addiction, risk management tools, and other topics approved by the Board.

(c) The Board approves a course for only the number of hours contained in the course. The approved hours of any individual course will not be counted more than once in a calendar year toward the required hourly total regardless of the number of times the course is attended or completed by any individual.

(d) Waiver - The Board may waive the requirements of these rules in cases where illness, disability, or other undue hardship beyond the control of the licensee prevents a licensee from complying. Requests for waivers must be sent in writing to the Board prior to the expiration of the calendar year in which the continuing medical education is due.

(e) Exemptions: 1. Anyone whose license is in the retired or inactive status pursuant to rule 0880-02-.10 (1) and/or (2) is exempt from the requirements of these continuing medical education rules. 2. Anyone who obtains licensure in the same calendar year as successful completion of the USMLE Step 3 is exempt from the provisions of these continuing medical education rules but only for the calendar year in which licensure is issued.

(2) Proof of Compliance - All licensees must retain independent documentation of completion of all continuing medical education hours and compliance with the provisions of these rules.

(a) This documentation must be retained for a period of four (4) years from the end of the calendar year in which the continuing medical education was acquired.

(b) This documentation must be produced for inspection and verification, if requested in writing by the Division during its verification process.

(c) Documentation verifying the licensee's completion of the continuing medical education hours may consist of any one (1) or more of the following:

1. Original certificates or photocopies of original certificates from course providers verifying the licensee's attendance and/or completion of hours.
2. Original letters or photocopies of original letters from course providers verifying the licensee's attendance and/or completion of hours.
3. Documentation from the American Academy of Family Physicians (hereafter AAFP) indicating acquired continuing medical education hours.

(3) Acceptable Continuing Education - To be utilized for satisfaction of the continuing education requirements of this rule, the continuing education hours must comply with both of the following:

(a) They must be sponsored by an organization accredited as a sponsor of continuing medical education by either the Accrediting Council for Continuing Medical Education (ACCME) or by a state medical association recognized by the ACCME as an intrastate accreditor of sponsors of continuing medical education; and

(b) They must be designated or certified by the accrediting sponsor as meeting the criteria for Category 1 continuing medical education credit of the American Medical Association's Physician's Recognition Program; or be designated by the AAFP as meeting the criteria of the AAFP's prescribed credit: or

(c) If a licensee provides disciplinary case review at the request of the Department, and submits a written report of his or her conclusions regarding such disciplinary case review, the reviewing licensee shall receive one (1) hour of continuing medical education credit for each hour spent reviewing the materials and preparing the report. A maximum of ten (10) hours credit shall be awarded for reviewing disciplinary case materials during the two (2) calendar years (January 1 – December 31) that precede the licensure renewal year.

#### (4) Violations and Disciplinary Orders

(a) Any licensee who fails to obtain the required continuing medical education hours or otherwise comply with the provisions of these rules will be subject to disciplinary action.

(b) Continuing medical education hours obtained as a result of compliance with the terms of Board Orders in any disciplinary action or obtained pursuant to licensure or renewal restriction/conditions mandated by the Board shall not be credited toward the continuing medical education hours required to be obtained in any calendar year

## **General Continuing Education Requirements for Medical Doctors**

By Board Rule, all licensees are required to complete forty (40) hours of continuing medical education courses during the two (2) calendar years (January 1 – December 31) preceding their licensure renewal year. All licensees (unless exempt under TENN. CODE ANN. § 63-1-402(c)) shall complete a minimum of two (2) of the forty (40) required hours of continuing education in controlled substance prescribing, which must include instruction in the Department's Chronic Pain Guidelines on opioids, benzodiazepines, barbiturates and carisoprodol and may include topics such as medicine addiction, risk management tools and other topics approved by the Board.

This rule change follows the enactment of TENN. CODE ANN. § 63-1-402 which requires that all prescribers who hold a current federal drug enforcement administration (DEA) license and who prescribe controlled substances shall be required to complete a minimum of two (2) hours of continuing education related to controlled substance prescribing to include instruction in the Department's Chronic Pain Guidelines. The statute's effective date was July 1, 2014.

### **The result of these changes is as follows:**

Prescriber licensees with a DEA registration who are renewing in 2015 and all subsequent years must complete two (2) hours of controlled substance prescribing to include instruction in the Department's Chronic Pain Guidelines. These credits should be earned by December 31, 2014.

Licensees who do not prescribe and do not have a DEA registration who are renewing in 2015, must complete one hour of continuing education in prescribing practices by December 31, 2014. These licensees will have to complete the two hours of controlled substance prescribing CME as a condition of their 2017 and all subsequent renewals (unless they are exempt under TENN. CODE ANN. § 63-1-402(c)).

All licensees of the Board of Medical Examiners who are renewing in 2016 or subsequent years, must complete two hours of controlled substances prescribing CME which must include instruction in the Department's Chronic Pain Guidelines, unless the licensee is exempt under TENN. CODE ANN. § 63-1-402(c).

### **The following licensees are exempt under TENN. CODE ANN. § 63-1-402(c):**

- Veterinarians;
- Providers practicing at a registered pain management clinic as defined in TENN. CODE ANN. § 63-1-301; and
- Medical doctors and osteopathic physicians who are board certified by the ABMS, AOA, ABPS in one or more of the following specialties or subspecialties:
  - Pain management;
  - Anesthesiology;
  - Physical medicine and rehabilitation;
  - Neurology; or
  - Rheumatology.

**Failure to comply with continuing education requirements may result in disciplinary action against the licensee or registrant. The disciplinary action will be reported on the Department of Health license verification web site.**

By signing the renewal application form, licensees affirm that they have met this requirement. The Department of Health audits licensees to determine and confirm compliance.



# 2016 Tennessee Chronic Pain Guidelines Symposia

\* Certified for 3.0 AMA PRA Category 1 Credits™ \*

## Cost FREE!

\*Refreshments & CME/CE credit included

## Health Care Providers (Will vary by location)

Mitchell Mutter, M.D.  
Todd Bess, Pharm.D.  
Elizabeth Lund, RN, MSN  
Stephen Loyd, M.D.  
Linda Johnson, APN  
Jim Montag, PA-C  
Michael O'Neil, Pharm.D.  
Tommy Farmer, TBI

## Locations

Johnson City  
Knoxville  
Hardin County  
Upper Cumberland  
Sullivan County  
Jackson

## Time

5:30 Refreshments  
6-9 Conference

## Dates

April 2016-Nov. 2016

## Please Visit

[www.etsu.edu/com/cme](http://www.etsu.edu/com/cme)

to Register and find exact locations of symposia

## Please join us!

The Tennessee Department of Health would like to present you an opportunity to attend our 2016 Tennessee Chronic Pain Guidelines Symposia to receive **FREE AMA PRA Category 1 Credits™** in various locations throughout Tennessee.

**Objective:** To better educate health care professionals in the State of Tennessee and prepare them with the best methods of professional practice relating to Tennessee Chronic Pain Guidelines

**Target Audience:** All health care professionals including physicians, nurse practitioners, physician assistants, pharmacists, etc.

### Key Topics:

- Discuss updated Tennessee Chronic Pain Guidelines
- Address overprescribing in Tennessee
- Addiction Panel
- Opioid Epidemic
- Efforts to improve the CSMD
- Regulations for various health care professional boards

## A word from Dr. Mutter...

“Prescriptions for opioids and benzodiazepines peaked in 2012. Since then, we have shown a steady decline in prescriptions and morphine equivalents (MME). However, outcomes have not declined. Neonatal abstinence has plateaued and overdose deaths continue to rise. The Tennessee Department of Health will share data and future efforts, and seek your stakeholder input.”

*Mitchell Mutter, M.D., Medical Director of Special Projects  
Tennessee Department of Health*

### Accreditation and designation:



This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Quillen College of Medicine, East Tennessee State University and the Tennessee Department of Health. The Quillen College of Medicine, East Tennessee State University is accredited by the ACCME to provide continuing medical education for physicians. The Quillen College of Medicine, East Tennessee State University designates this live activity for a maximum of 3.0 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**CNE Credit:** Up to 2.75 continuing nursing education contact hours will be offered for this conference. East Tennessee State University College of Nursing is an approved provider of continuing nursing education by the Tennessee Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation. **This educational event may contain nursing pharmacology credits that may be used to fulfill your pharmacology nursing CE requirement.**

The ETSU College of Nursing implements a \$15 certificate fee per conference. This fee covers the following: cost for being a provider of nursing contact hours, supplies, and nursing education coordinator's time for completing necessary paperwork for each conference, reports, study for renewal of being a provider, and attending meetings. If you would like to claim Nursing Contact Hours, please [click here](#). Questions? Contact [ETSUCNE@etsu.edu](mailto:ETSUCNE@etsu.edu).

# UTAH

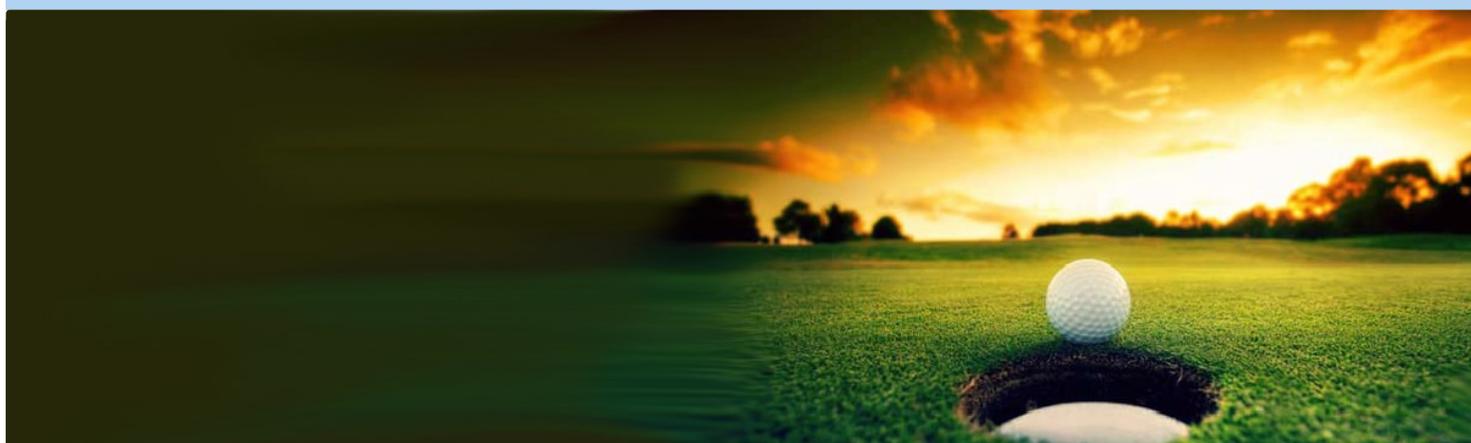
## **58-37-6.5 Continuing education for controlled substance prescribers.**

- (1) For the purposes of this section:
  - (a) "Controlled substance prescriber" means an individual, other than a veterinarian, who:
    - (i) is licensed to prescribe a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act; and
    - (ii) possesses the authority, in accordance with the individual's scope of practice, to prescribe schedule II controlled substances and schedule III controlled substances that are applicable to opioid narcotics, hypnotic depressants, or psychostimulants.
  - (b) "FDA" means the United States Food and Drug Administration.
  - (c) "M.D." means a physician and surgeon licensed under Title 58, Chapter 67, Utah Medical Practice Act.
  - (d) "D.O." means an osteopathic physician and surgeon licensed under Title 58, Chapter 68, Utah Osteopathic Medical Practice Act.
- (2) Beginning with the licensing period that begins after January 1, 2014, as a condition precedent for license renewal, each controlled substance prescriber shall complete at least four continuing education hours per licensing period that satisfy the requirements of Subsections (3) and (4).
- (3) As provided in Subsection 58-37f-402(8), the online tutorial and passing the online test described in Section 58-37f-402 shall count as 1/2 hour of continuing professional education under Subsection (2) per licensing period.
- (4) A controlled substance prescriber shall complete at least 3.5 hours of continuing education hours in one or more controlled substance prescribing classes, except dentists who shall complete at least 2 such hours, that satisfy the requirements of Subsections (5) and (7).
- (5) A controlled substance prescribing class shall:
  - (a) satisfy the division's requirements for the continuing education required for the renewal of the controlled substance prescriber's respective license type;
  - (b) be delivered by an accredited or approved continuing education provider recognized by the division as offering continuing education appropriate for the controlled substance prescriber's respective license type; and
  - (c) include a postcourse knowledge assessment.
- (6) An M.D. or D.O. completing continuing professional education hours under Subsection (4) shall complete those hours in classes that qualify for the American Medical Association Physician's Recognition Award Category 1 Credit.
- (7) The 3.5 hours of the controlled substance prescribing classes under Subsection (4) shall include educational content covering the following:
  - (a) the scope of the controlled substance abuse problem in Utah and the nation;
  - (b) all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published July 9, 2012, or as it may be subsequently revised;
  - (c) the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing;
  - (d) patient record documentation for controlled substance and opioid prescribing; and
  - (e) office policies, procedures, and implementation.
- (8)
  - (a) The division, in consultation with the Utah Medical Association Foundation, shall determine whether a particular controlled substance prescribing class satisfies the educational content requirements of Subsections (5) and (7) for an M.D. or D.O.
  - (b) The division, in consultation with the applicable professional licensing boards, shall determine whether a particular controlled substance prescribing class satisfies the educational content

requirements of Subsections (5) and (7) for a controlled substance prescriber other than an M.D. or D.O.

- (c) The division may by rule establish a committee that may audit compliance with the Utah Risk Evaluation and Mitigation Strategy (REMS) Educational Programming Project grant, that satisfies the educational content requirements of Subsections (5) and (7) for a controlled substance prescriber.
- (9) A controlled substance prescribing class required under this section:
  - (a) may be held:
    - (i) in conjunction with other continuing professional education programs; and
    - (ii) online; and
  - (b) does not increase the total number of state-required continuing professional education hours required for prescriber licensing.
- (10) The division may establish rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to implement this section.

Repealed and Re-enacted by Chapter 450, 2013 General Session



# UMPAC GOLF TOURNEY

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**!** Required Course for License Renewal

## EDUCATION FOR CONTROLLED SUBSTANCE PRESCRIBERS

In Utah, legislation was passed that requires health care providers licensed to prescribe controlled substances to complete 3.5 hours of Department of Occupational and Professional Licensing (DOPL) approved continuing education on Schedule II and III controlled substances that are applicable to opioid narcotics, hypnotic depressants, and psychostimulants. (Utah Code Section 58-37-6.5) This required education is intended to reduce the negative effects of controlled substances in Utah.

The UMA Foundation course, CONTROLLED SUBSTANCES: EDUCATION FOR THE PRESCRIBER, is approved by DOPL and available online. You may take the course in one sitting or incrementally and at your convenience from work, home, or any location with internet access. Click here to get instructions on how to begin the registration process or to re-access the course.

**Note:** In addition to this course, DOPL requires controlled substance prescribers to complete the thirty-minute Controlled Substance Database (CSD) tutorial and examination. This is the same DOPL course that you have already been taking every two years for licensure renewal.

## HYDROCODONE COMBO PRODUCTS NOW SCHEDULE II DRUGS

The Drug Enforcement Administration (DEA) recently published a final rule (PDF) in the Federal Register rescheduling hydrocodone combination products to Schedule II of the Controlled Substances Act (CSA). The DEA's rationale for the move is to combat prescription drug abuse. As these drugs were previously in Schedule III, this change has dramatically increased the restrictions on prescribing and dispensing practices for hydrocodone combination products. The rule went into effect October 6, 2014. UMA members should identify patients being treated with hydrocodone combination products and change prescribing practices to conform to the drugs' more restrictive Schedule II requirements.

This change will affect prescription refills as follows: As of October 6, 2014, Hydrocodone combination prescriptions may not authorize any refills. A new prescription must be written by the prescriber if the patient requires continued therapy.

## 2016 UMA PHYSICIANS OF UTAH DIRECTORY IN PRODUCTION

The 2016 Physicians of Utah Directory will be published soon and sent to all members who have an email address on file. The directory will again be available in an electronic format, accessible either on the UMA website to members, and as a PDF file available for sale to the public. Members will be able to access the file for free by logging in to the website and clicking the "Physician Referral Directory" link under the Membership tab. Each UMA member is granted a single concurrent user license to use the Directory file. Members who wish to share the file with other users (office staff, etc.) can purchase additional licenses for 1/2 the regular price. Non-members will be able to purchase a license for the Directory for \$70/license.

## EVENT CALENDAR

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### Controlled Substance Course Info

### APRIL

27 | Utah Regional Health Care Innovation Day, Salt Lake City, UMAF (6.0)

28 | NICU Advanced Skills, Salt Lake City, UUCME (3.0)

### MAY

6-7 | 15th Annual Utah Dermatology Society Meeting, Springdale, UMAF (TBD)

12-15 | 8th Annual Perioperative Echocardiography Review Course, Salt Lake City, UUCME (28)

# VERMONT

## DEPARTMENT OF HEALTH BOARD OF MEDICAL PRACTICE

### SECTION VII CONTINUING MEDICAL EDUCATION RULES

#### PART 22 RULES REGARDING CONTINUING MEDICAL EDUCATION

##### 22.1 INTRODUCTION AND DEFINITIONS

- (a) Copies of the statute concerning continuing medical education for physicians, 26 V.S.A. § 1400(b), are accessible online, and hard copies may be obtained from the Department of Health, Board of Medical Practice.
- (b) These Rules pertaining to continuing medical education for physicians are adopted under authority of 26 V.S.A. § 1351(e) and 26 V.S.A. § 1400.
- (c) These are rules specifically regarding the requirement for physicians licensed by the Board of Medical Practice to complete continuing medical education (“CME”) during each two-year licensing period in order to be eligible to renew their license for the following two-year licensing period.
- (d) The words and phrases that are defined in 26 V.S.A. § 1311 shall have the same meaning here as assigned to them there.
- (e) The terms “hour” and “credit” are both used with respect to continuing medical education. The term hour means an hour of activity that has been approved as qualifying to count toward satisfaction of the requirement for continuing medical education. The term credit is also used as a measure of approved continuing medical education activity, and equals an hour of approved activity.
- (f) “Palliative care” refers to specialized medical care that is focused on relief from the pain and symptoms of a serious medical condition.

##### 22.2 MINIMUM EDUCATION REQUIREMENT – HOURS AND SUBJECTS

- (a) Except as provided in the following subparagraph, each physician applying for renewal of a license to practice medicine must certify that he or she has completed at least thirty hours of qualifying CME during the most recent two-year licensing period, naming the subject, sponsor, date, location, and hours or credits for each activity. During the initial licensing period that the requirement is in effect, training during the six months preceding the licensing period may be used to satisfy CME requirements; training completed during the period June 1, 2012 through November 30, 2012 will count as training completed December 1, 2012 through November 30, 2014. The licensee is not required to file documentation of CME that verifies

completion at the time that it is reported, however it is the licensee's responsibility to retain documentation for four years from the time the information is submitted to the Board. The Board may audit records of CME for up to four years from the time of submission; a licensee is required to promptly submit documentation of CME completion in response to a request from the Board.

- (b) For physicians licensed in Vermont for the first time during the most recent two-year licensing period, if licensed in Vermont for less than one year, there is no requirement for CME at the time of the first renewal. If licensed for one year or more during that initial period of Vermont licensure, the licensee shall complete at least 15 hours of approved CME activity and those 15 hours shall include any subject-specific CME required by these rules.
- (c) Time is calculated from the date the license was approved by the Board until the date of expiration. Any physician who has not completed the required continuing medical education shall submit a make-up plan with his or her renewal application, as specified in these rules.
- (d) Except for required subjects that are mandated by these rules, all CME hours completed in satisfaction of this requirement shall be designed to assure that the licensee has updated his or her knowledge and skills in his or her own specialties and also has kept abreast of advances in other fields for which patient referrals may be appropriate. A licensee's "own area of practice" shall not be interpreted narrowly; it is acknowledged that training in many other fields may be reasonably related to a practitioner's own specialties.
- (e) **Required Subject: Hospice, Palliative Care, Pain Management.** 26 V.S.A. § 1400(b) mandates that the Board of Medical Practice shall require licensees to provide "evidence of current professional competence in recognizing the need for timely appropriate consultations and referrals to assure fully informed patient choice of treatment options, including treatments such as those offered by hospice, palliative care, and pain management services." Accordingly, all licensees who are required under these rules to complete CME shall certify at the time of each renewal that at least one of the hours of qualifying CME activity has been on the topics of hospice, palliative care, or pain management services.
- (f) **Required Subject: Prescribing Controlled Substances.** All licensees who are required to certify completion of CME and who prescribe controlled substances shall certify at the time of each renewal that at least one of the hours of qualifying CME activity has related to the topic of safe and effective prescribing of controlled substances. Each licensee who is registered with the U.S. Drug Enforcement Agency (D.E.A.) and who holds a D.E.A. number to prescribe controlled substances, or who has submitted a pending application for one, is presumed to prescribe controlled substances.

- (g) Licensees who are not in active practice shall still complete CME, including all required subjects, to be relicensed. For purposes of subsection (b), a physician not in active practice may consider his or her last area of practice as the area of practice to which activity shall relate, or the activity may relate to a new area of practice he or she intends to pursue.
- (h) Licensees who are members of the armed forces and who are subject to a mobilization and/or deployment for all or part of a licensing cycle will be treated the same as licensees who are licensed for the first time during a licensing cycle. To wit, a licensee whose military mobilization/deployment covers a year or more is not required to complete CME for that cycle. A licensee whose military duties during the two-year cycle total less than one year shall be required to meet the CME requirement of at least 15 hours, including any required subjects.
- (i) A licensee who allows his or her license to lapse by not timely applying for renewal shall certify completion of all CME that would have been required had he or she remained licensed in order to be granted a renewal license.

### **22.3 QUALIFYING CONTINUING MEDICAL EDUCATION ACTIVITIES**

- (a) Only CME activities that are approved for American Medical Association Physician's Recognition Award Category 1 Credit (AMA PRA Category 1 Credit™) qualify as approved Vermont CME.
- (b) Credit for providing training. The Board accepts all AMA PRA Category 1 Credit™ activity. The AMA PRA program grants two hours of credit for each hour of training presented by a physician. The Board recognizes those credits the same as the AMA PRA program.

### **22.4 MAKE-UP PLANS**

- (a) Any physician who has not completed the minimum number of hours of CME, or who has not completed the required subject-specific training, as of the deadline for submission of license renewal applications, will not be granted a renewal license unless the application includes an acceptable make-up plan signed by the licensee. The Board Executive Director is authorized to review and determine if make-up plans are acceptable.
- (b) An acceptable make-up plan must include a timeline for making up all CME that needs to be completed to satisfy the requirements of these Rules. The timeline shall identify the approved activities that the licensee plans to attend. The licensee may later substitute activities, but the plan shall indicate that it is the licensee's good faith

intent to complete the activities listed at the time of submission. A licensee shall have up to one hundred twenty (120) days to complete the CME make-up plan.

- (c) Any licensee who will not complete a make-up plan within the time specified by the plan shall contact the Board at least 30 days in advance of the date on which the period will end to notify the Board and submit a revised plan and request for extension of time. The request for extension of time must include an explanation of the reasons why the licensee was unable to complete the required training in accordance with the plan. Extensions of the make-up plan period are limited to 90 days, during which the licensee shall complete the required CME. Further extensions will be granted only for good cause shown, for reasons such as: serious illness of the licensee or a family member; death of an immediate family member; significant personal hardship, such as a house fire; significant and ongoing medical staff shortage during the make-up period; or similarly compelling reasons. The Board may delegate to the Board Executive Director the authority to approve requests to extend the time for a make-up plan in accordance with these rules. Any request for extension not granted by the Executive Director shall be considered by the Board.
- (d) CME activity completed as part of a make-up plan does not count toward satisfaction of the requirement to complete CME during that current licensing cycle; activity may only be counted once. If a multi-hour activity is performed partly in satisfaction of a make-up plan and partly for the CME requirement associated with the current licensing cycle, the licensee shall clearly document the allocation.

#### **22.5 FAILURE TO CERTIFY COMPLETION OF REQUIRED CME, FILE A MAKE-UP PLAN, OR COMPLETE A MAKE-UP PLAN**

- (a) A licensee who has failed to submit certification of completion of CME as required by law and these rules, or who having failed to certify completion of CME has failed to submit a make-up plan with his or her renewal application, will be notified of such failure and have not more than 15 days from receipt of notice to file with the Board either his or her certification of completion of CME or a make-up plan.
- (b) A licensee who fails to file a certificate of completion of CME at the end of a make-up period, or to file a request for an extended make-up period, shall be notified of such failure and have not more than 15 days from receipt of notice to file with the Board either a certificate of completion of CME or another request for extension of time in which to make up CME.
- (c) A licensee who submits a certificate of completion at the time of submission of the license renewal application, or who has filed an acceptable make-up plan with the renewal application and is in the make-up period, or who having failed to complete the first make-up plan has received approval from the Board for an extended make-up period that has not yet expired, is in good standing with respect to CME requirements.

- (d) Any licensee not in good standing with respect to CME requirements is subject to investigation by the Board for unprofessional conduct.

## Vermont M.D. License CME Requirement Update

The last edition of our newsletter included an article "[Vermont M.D. License Renewal Now Requires CME](#)" on the new requirement for completing CME as a requirement for renewal of your license when it expires on November 30, 2014. The Board continues to receive questions about the new CME rules, so we will try to address some of those here.

***I am a [Insert name of profession: radiologist, pathologist, etc.]. Do I have to take a safe prescribing course?***

The answer is that it depends. It doesn't matter if you see patients, or not. It doesn't matter what your specialty is. The only fact that matters for determining if you must take a safe prescribing course is whether you have, or have applied for, a DEA registration number. If you have one or have a pending application, you must take a course on prescribing. If you do not have a DEA number, have not applied for one, and will not be applying for one before November 30, 2014, then you do not need to meet the requirement for a prescribing course to renew your license.

***Do I have to take the Board of Medical Practice course on safe and effective prescribing of opioids?***

No. The Board has partnered with Boston University Medical School to offer a [course on opioid prescribing](#) on three different occasions, and we hope to offer it again this year. The course satisfies the requirement, but you are not required to take that particular course. Any course on prescribing that qualifies for AMA PRA Category 1™ credit will meet the requirement. BU offers a free, online course that meets the requirement.

***Is there a special course on hospice, palliative care, and pain management that I must take?***

Every licensee who is required to complete CME for renewal must have at least one hour of CME on at least one of those topics, but there is no specific course that must be taken. This subject requirement is taken directly from the statute that established the CME requirement. Any course that has at least one hour on any of those subjects, or on a combination of them, and that qualifies for AMA PRA Category 1™ credit will meet the requirement.

***Will I have to submit documentation of my CME activities when I apply to renew my license?***

No, you will only need to certify that you meet the applicable CME requirement. The rules do not make submission of documentation a requirement. However, each licensee should retain documentation. The Rules allow for auditing compliance, in which case the licensee will have to provide CME documentation. At the time of renewal, the licensee certifies compliance and is subject to being audited, but it is not mandatory to submit documentation at that time.

If you have more questions about the CME requirements, please refer to the [CME article from the 2013 newsletter](#) or contact the Board.

**Vermont Board of Medical Practice**  
PO Box 70, Burlington VT 05402-0070  
802-657-4220  
(within VT: 800-745-7371)  
medicalboard@state.vt.us  
[http://healthvermont.gov/hc/  
med\\_board/bmp.aspx](http://healthvermont.gov/hc/med_board/bmp.aspx)

## CME Requirements

### CONTINUING MEDICAL EDUCATION REQUIREMENTS

Successful completion of a minimum of 50 hours of continuing medical education satisfactory to the Board during the preceding two year period is required for the biennial renewal of a medical license. Beginning July 1, 2008, at least thirty (30) hours of the hours must be related to the physician's area or areas of specialty.

Continuing medical education satisfactory to the Board means:

- A. Continuing medical education designated as Category I by the American Medical Association or the American Academy of Family Physicians, or
- B. Medical education courses or lectures in medicine taught to medical students, residents, or licensed physicians, or serving as a preceptor to medical students or residents: Provided, that no more than twenty hours of the required fifty hours of continuing medical education in this category will be considered satisfactory to the Board.
- C. Sitting for and passing a certification or recertification examination of one of the ABMS member boards, and receiving certification or recertification from said board, or providing documentation of successful involvement in maintenance of certification from said ABMS member board during the two years subsequent to the last medical license renewal in West Virginia: Provided, that a physician may not count more than forty-seven hours in this category toward the required fifty hours of continuing medical education: Provided, however, that any physician who timely provides to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period may count fifty hours in this category toward the required fifty hours of continuing medical education. Certification, recertification, or current successful involvement in maintenance of certification from any board other than one of the ABMS member boards does not qualify the recipient for any credit hours of continuing medical education.
- D. Beginning May 1, 2014, unless a physician has completed and timely provided to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every physician as a prerequisite to license renewal shall complete a minimum of three hours of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period, which three such hours may be provided only by a Board-approved program. Said three hours shall be part of the fifty total hours of continuing education required and not three additional hours.

THERE ARE NO OTHER TYPES OF CATEGORIES OF CONTINUING MEDICAL EDUCATION SATISFACTORY TO THE BOARD.

## Approved Best Practice Prescribing and Drug Diversion Training

Course Name	Sponsor	Location / Date
Appalachian Addiction and Prescription Drug Abuse Conference (Includes Naloxone CME)	West Virginia Medical Professionals Health Program / West Virginia State Medical Association	Embassy Suites, Charleston, WV October 20-22, 2016
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Northern West Virginia Rural Health Education Center <a href="mailto:donna.steigleder@nwvrhec.org">donna.steigleder@nwvrhec.org</a>	Wheeling, WV June 9, 2016 (site to be announced)
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Northern West Virginia Rural Health Education Center <a href="mailto:donna.steigleder@nwvrhec.org">donna.steigleder@nwvrhec.org</a>	Judge Black Annex, Parkersburg, WV May 19, 2016
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Northern West Virginia Rural Health Education Center <a href="mailto:donna.steigleder@nwvrhec.org">donna.steigleder@nwvrhec.org</a>	Davis Medical Center, Elkins, WV – May 5, 2016
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Northern West Virginia Rural Health Education Center <a href="mailto:donna.steigleder@nwvrhec.org">donna.steigleder@nwvrhec.org</a>	United Hospital Center, Bridgeport, WV April 27, 2016
Opioid Prescribing: Safe Practices, Saving Lives on day 1 of the 64 <sup>th</sup> Annual Scientific Assembly	American Academy of Family Physicians	Embassy Suites, Charleston, WV April 14-16, 2016
The Treatment of Pain and Addiction Utilizing Education and Proper Prescribing	West Virginia University Office of Continuing Education, West Virginia Medical Professionals Health Program, West Virginia State Medical Association and West Virginia Osteopathic Medical Association	ONLINE COURSE March 4, 2016
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Southeastern Area Health Education Center	WV School of Osteopathic Medicine Mid-Winter Seminar, Embassy Suites, Charleston, WV January 31, 2016 9:00 a.m. – 12:00 p.m.

Special Family Medicine Grand Rounds: Opioid Prescribing/Prescribing Naloxone for Lay Use Workshop	Joan C. Edwards School of Medicine	September 10, 2015
Prescribing Opioids and Preventing Drug Diversion/Naloxone: The West Virginia Requirements, #91600	CME Resources	ONLINE COURSE (Written Course Book, Not Audio) July, 2015
Appalachian Addiction and Prescription Drug Abuse Conference (Includes Naloxone CME)	West Virginia Medical Professionals Health Program / West Virginia State Medical Association	Embassy Suites, Charleston, WV September 24-26, 2015
Extended Release/Long Acting Opioid Therapies: Balancing Primary Care Education, Patient Access NS Public Health Issues	West Virginia Academy of Family Physicians	Embassy Suites, Charleston, WV April 16, 2015
Management of Chronic Nonmalignant Pain and Access to Opioid Antagonists	Robert Michaels, M.D. WVU Eastern Division Annual Faculty Development and Research Day	September 23, 2015
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Southern Area Health Education Center	West Virginia School of Osteopathic Medicine, Lewisburg, WV February 24 & 26, 2015
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Community Care of West Virginia/Northern West Virginia Rural Health Education Center <a href="mailto:donna.steigleder@nwvrhec.org">donna.steigleder@nwvrhec.org</a>	Bridgeport – Jan 16, 2015 Parkersburg – Feb. 13, 2015 Wheeling – March 27, 2015 Elkins - April 17, 2015 Flatwoods – May 8, 2015
Management of Chronic Nonmalignant Pain	Robert Michaels, M.D. WVU	September 2014
Best Practice Prescribing/Drug Diversion Lecture	Family Medicine Foundation of West Virginia	September, 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Southeastern Area Health Education Center	Med-Surg. Group, Inc. Beckley, WV June 19, 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Southeastern Area Health Education Center	West Virginia School of Osteopathic Medicine Alumni Center June 17, 2014 3:00 p.m.- 6:00 p.m.
Prescribing Opioids and Preventing Drug Diversion: The West Virginia Requirements, #91600	CME Resources	ONLINE COURSE (Written Course Book, Not Audio) June 2014

Appalachian Addiction and Drug Abuse Conference	West Virginia Medical Professionals Health Program/West Virginia State Medical Association	Embassy Suites, Charleston, WV October 2014
Between Treatment and Abuse: Assisting the Healthcare Professional in Facing the Opioid Crisis	Marshall University School of Pharmacy/St. Mary's Medical Center	SMMC, Huntington, WV June 10, 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Community Care of West Virginia/Northern West Virginia Rural Health Education Center	Wheeling Park Ballroom, Wheeling, WV June 27, 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Eastern Area Health Education Center/Grant Memorial Hospital	Kaposey's, Petersburg May 22, 2014 5:30 PM – 8:30 PM
WVAPA Spring CME Conference	West Virginia Association of Physician Assistants	Oglebay Resort, Wheeling, WV April 11-13, 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Southeastern Area Health Education Center	Beckley ARH Hospital May 2, 2014 Two sessions - Noon – 3:00 PM, 3:30 – 6:00 PM
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Community Care of West Virginia/Northern West Virginia Rural Health Education Center	Parkersburg, WV April 25, 2015
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Community Care of West Virginia/Northern West Virginia Rural Health Education Center	Elkins, WV May 30, 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Community Care of West Virginia/Northern West Virginia Rural Health Education Center	WVU, Morgantown, WV March 28, 2014
Drug Diversion and Best Practices for Prescribing Controlled Substances	West Virginia University Office of Continuing Education	ONLINE COURSE January 2014
ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care	Community Care of West Virginia/Northern West Virginia Rural Health Education Center	Bridgeport, WV January 31, 2014
Best Practice Prescribing/Drug Diversion Lecture	Family Medicine Foundation of West Virginia	November 2013
Drug Diversion & Best Practice Prescribing of Controlled Substances Course	WVU School of Nursing	October 2013

Appalachian Addiction and Drug Abuse Conference	West Virginia Medical Professionals Health Program/West Virginia State Medical Association	September 2013
Best Practice Prescribing of Controlled Substances and Drug Diversion Training	West Virginia State Medical Association	ONLINE COURSE July 2013
Special Family Medicine Grand Rounds: Opioid Prescribing Workshop	Joan C. Edwards School of Medicine	April 2013
Prescribing Opioids for Chronic Pain: Balancing Safety and Efficacy	WVU Health Sciences Center	March 2013
Drug Diversion Training and Best Practice Prescribing of Controlled Substances	Raleigh Co. Medical Society	April 2013
Extended Release/Long Acting Opioid Therapies: Balancing Primary Care Education, Patient Access NS Public Health Issues	West Virginia Academy of Family Physicians	April 2013

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## TITLE 11 LEGISLATIVE RULE BOARD OF MEDICINE

### SERIES 6 CONTINUING EDUCATION FOR PHYSICIANS AND PODIATRISTS

#### **§11-6-1. General.**

- 1.1. Scope. -- These legislative rules address requirements for continuing education satisfactory to the Board for physicians and podiatrists.
- 1.2. Authority. -- W. Va. Code §30-3-12 and § 30-1-7a.
- 1.3. Filing Date. -- May 6, 2013.
- 1.4. Effective Date. -- May 6, 2013.

#### **§11-6-2. Definitions.**

- 2.1. "ABMS" means American Board of Medical Specialties.
- 2.2. "Board" means the West Virginia Board of Medicine.
- 2.3. "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three (3) continuous months. For purposes of this rule, "chronic pain" does not include pain associated with a terminal condition or illness or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition or illness.
- 2.4. "Controlled substances" means drugs that are classified by federal or state law in Schedules I, II, III, IV or V, as defined in W. Va. Code § 60-2-204 through 212.
- 2.5. "Drug diversion training and best practice prescribing of controlled substances training" means training which includes all of the following:
  - a. Drug diversion, including West Virginia statistics on prescription drug abuse and resulting deaths.
  - b. Epidemiology of chronic pain and misuse of opioids.
  - c. Indication for opioids in chronic pain treatment including general characteristics, toxicities and drug interactions.

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d. Examination of patient evaluation and risk assessment and tools to assess risk and monitor benefits.

e. Initiation and ongoing management of chronic pain patient treated with opioid based therapies, including treatment objectives; monitoring and periodic review; referrals and consultations; informed consent; prescription of controlled substance agreements, urine screens and pill counts; patient education on safe use, storage and disposal of opioids; discontinuation of opioids for pain due to lack of benefits or increased risks; documentation and medical records.

f. Case study of a patient with chronic pain.

g. Identification of diversion and drug seeking tactics and behaviors.

h. Best practice methods for working with patients suspected of drug seeking behavior and diversion.

i. Compliance with controlled substances laws and rules.

j. Registration with and use of the West Virginia Controlled Substances Monitoring Program established in West Virginia Code Chapter 60A, Article 9.

k. Maintenance of a record of attendance of each individual who successfully completes the drug diversion training and best practice prescribing of controlled substances training.

2.6. "Maintenance of certification" means an ongoing process of education and assessment for the twenty four (24) member boards of the ABMS board certified physicians to improve practice performance in six (6) core competencies: professionalism, patient care and professional skills, medical knowledge, practice based learning and improvement, interpersonal and communication skills, and systems based practice.

2.7. "Opioid" means natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include, but are not limited to, codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl.

2.8. "Reactivation" means a return to active status of a license which has been in an expired, lapsed, surrendered or suspended status for more than one (1) year immediately preceding the request for reactivation.

2.9. "Suspended license" for purposes of this rule means a license suspended on a non-disciplinary basis under the provisions of West Virginia Code § 30-3-12 for failure to timely provide required continuing education to the Board.

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### **§11-6-3. Continuing Education Satisfactory to the Board.**

3.1. Physicians. -- Beginning July 1, 1993, successful completion of a minimum of fifty (50) hours of continuing medical education satisfactory to the Board during the preceding two (2) year period is required for the biennial renewal of a medical license. Beginning July 1, 2008, at least thirty (30) hours of the required fifty (50) hours must be related to the physician's area or areas of specialty.

3.2. In order to acquire continuing medical education satisfactory to the Board, a physician may:

3.2.1. Take continuing medical education designated as Category I by the American Medical Association or the American Academy of Family Physicians, or

3.2.2. Teach medical education courses or lecture to medical students, residents, or licensed physicians, or serve as a preceptor to medical students or residents: Provided, that a physician may not count more than twenty (20) hours in this category toward the required fifty (50) hours of continuing medical education.

3.2.3. Sit for and pass a certification or recertification examination of one of the ABMS member boards, and receive certification or recertification from said board, or provide documentation of successful involvement in maintenance of certification from said ABMS member board during the two (2) years subsequent to the last medical license renewal in West Virginia: Provided, that a physician may not count more than forty seven (47) hours in this category toward the required fifty (50) hours of continuing medical education: Provided, however, that any physician who timely provides to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period may count fifty (50) hours in this category toward the required fifty (50) hours of continuing medical education. Certification, recertification, or current successful involvement in maintenance of certification from any board other than one of the ABMS member boards does not qualify the recipient for any credit hours of continuing medical education.

3.3. Beginning May 1, 2014, unless a physician has completed and timely provided to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every physician as a prerequisite to license renewal shall complete a minimum of three (3) hours of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period, which three (3) such hours may be provided only by a Board-approved program. Said three (3) hours shall be part of the fifty (50) total hours of continuing education required and not three (3) additional hours.

There are no other types or categories of continuing medical education satisfactory to the Board.

3.4. Podiatrists. -- Beginning July 1, 1993, successful completion of a minimum of fifty (50) hours of continuing podiatric education satisfactory to the Board during the preceding two (2)

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year period is required for the biennial renewal of a podiatric license. Beginning July 1, 2008, at least thirty (30) hours of the hours must be related to the podiatrist's area or areas of specialty.

3.5. In order to acquire continuing podiatric education satisfactory to the Board a podiatrist may:

3.5.1. Take continuing podiatric education approved by the Council on Podiatric Medical Education, or

3.5.2. Take continuing podiatric education given under the auspices of the podiatry colleges in the United States, or

3.5.3. Take continuing medical education designated as Category I by the American Medical Association or the American Academy of Family Physicians.

3.5.4. Take continuing podiatric education given under the auspices of the West Virginia Podiatric Medical Association.

3.5.5. Teach podiatric education courses or lectures in podiatry taught to podiatric students, residents, or licensed podiatrists, or serve as a preceptor to podiatric students or residents: Provided, that a podiatrist may not count more than twenty (20) hours in this category toward the required fifty (50) hours of podiatric education.

3.6. Beginning May 1, 2014, unless a podiatrist has completed and timely provided to the Board a Board-developed certification waiver form attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every podiatrist as a prerequisite to license renewal shall complete a minimum of three (3) hours of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period. Said three (3) hours shall be part of the fifty (50) total hours of continuing education required and not three (3) additional hours.

There are no other types or categories of continuing podiatric education satisfactory to the Board.

3.7. Hours; Physicians and Podiatrists. -- For the purposes of this section, one (1) clock hour of attendance equals one (1) hour of continuing education.

### **§11-6-4. Certification of Successful Completion of Continuing Education Requirements.**

4.1. Certification. -- Every applicant for licensure renewal shall timely submit to the Board a certification of the successful completion of a minimum of fifty (50) hours of continuing education satisfactory to the Board during the preceding two (2) year period. If an applicant fails to submit such certification in a timely fashion the applicant's license shall automatically expire.

4.2. Form of Certification. -- The Board shall imprint on its biennial renewal application forms a certification requiring the applicant's signature and the date after an attestation to the truth and correctness of the applicant's statements pertaining to the successful completion of the required continuing education. The certification shall include a statement that any license issued from the

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application is based on the truth of the applicant's statements and that if false information is submitted in the application, such an act constitutes good cause for the revocation of the applicant's license to practice in the State of West Virginia.

4.3. Timely Submission of Certification. -- In order for a certification to be submitted to the Board in a timely fashion, the certification must be received in the Board offices before the first day of July of the year of renewal of the license.

### **§11-6-5. Written Documentation of Successful Completion of Continuing Education Requirements.**

5.1. Audits. -- The Board may conduct such audits and investigations as it considers necessary to determine if licensees are complying with continuing education requirements and if the statements made on the Board's renewal application forms as to continuing education are accurate.

5.2. When Written Documentation Requested. -- Any licensee is required to provide supporting written documentation of the successful completion of the continuing education certified as received on the biennial renewal application form, if the Board requests such written documentation in writing. The licensee shall provide the Board with the written documentation so that it is received by the Board within thirty (30) days of the licensee's receipt of the written request.

5.3. Automatic Expiration of License. -- When a licensee's license automatically expires for failure to timely submit to the Board a certification of successful completion of a minimum of fifty (50) hours of continuing education satisfactory to the Board, the license shall remain expired until such time as the certification, as set forth in section 4 of this rule, is received by the Board and until such time as all supporting written documentation is submitted to and approved by the Board.

5.4. Failure or Refusal to Provide Written Documentation. -- Failure or refusal of a licensee to provide written documentation requested by the Board as set forth in section 5.2 of this rule is prima facie evidence of renewing a license to practice medicine or podiatry by fraudulent misrepresentation and the licensee is subject to disciplinary proceedings under W. Va. Code §30-3-14.

5.5. Inactive License. -- Beginning July 1, 1993, in the case of a licensee who holds an inactive license and who makes a written request to the Board for an active license, the licensee shall submit written documentation of successful completion of a minimum of fifty (50) hours of continuing education as required in section 3 of this rule. The Board shall not consider a request for a change from an inactive to an active license until all written documentation accompanied by a certification in accordance with section 4 of this rule is submitted to and approved by the Board.

5.6. Expired, Lapsed, Surrendered, or Suspended License. -- Beginning June 1, 2013, in the case of a former licensee who makes a written request to the Board for reactivation of a license, the

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former licensee shall submit written documentation of successful completion of a minimum of fifty (50) hours of continuing education as required in section 3 of this rule: Provided, in order for reactivation to be granted by the Board, the former licensee shall not be required by the Board to submit such written documentation for more than fifty (50) hours obtained during each of the two (2) full and complete renewal cycles immediately preceding the reactivation request.

## Chapter Med 13

## CONTINUING MEDICAL EDUCATION FOR PHYSICIANS

Med 13.01 Authority and purpose.  
 Med 13.02 Continuing medical education required; waiver.  
 Med 13.03 Acceptable continuing medical educational programs.

Med 13.04 Physician postgraduate training program; length of service.  
 Med 13.05 Evidence of compliance.  
 Med 13.06 Audit.

**Med 13.01 Authority and purpose.** The rules in this chapter are adopted by the medical examining board pursuant to the authority delegated by ss. 15.08 (5) (b), 227.11 (2) and 448.13, Stats., and govern the biennial training requirements for physicians as provided under s. 448.13, Stats.

**History:** Cr. Register, February, 1977, No. 254, eff. 3-1-77; am. Register, March, 1979, No. 279, eff. 4-1-79; correction made under s. 13.93 (2m) (b) 7., Stats., Register, May, 1989, No. 401; am. Register, May, 1997, No. 497, eff. 6-1-97; am. Register, December, 1999, No. 528, eff. 1-1-00.

**Med 13.02 Continuing medical education required; waiver.** (1) Each physician required to complete the biennial training requirements provided under s. 448.13, Stats., shall, in each second year at the time of making application for a certificate of registration as required under s. 448.07, Stats., sign a statement on the application for registration certifying that the physician has completed at least 30 hours of acceptable continuing medical educational programs within the 2 calendar years immediately preceding the calendar year for which application for registration is made.

(2) A physician may apply to the board for waiver of the requirements of this chapter on grounds of prolonged illness or disability or other similar circumstances, and each case will be considered individually on its merits by the board.

**History:** Cr. Register, February, 1977, No. 254, eff. 3-1-77; am. (1), Register, March, 1979, No. 279, eff. 4-1-79; am. (1), February, 1981, No. 302, eff. 3-1-81; am. Register, May, 1997, No. 497, eff. 6-1-97; am. Register, December, 1999, No. 528, eff. 1-1-00.

**Med 13.03 Acceptable continuing medical educational programs.** The board shall accept the following in satisfaction of the biennial training requirement provided under s. 448.13, Stats.:

(1) (a) *Program approval.* Educational courses and programs approved in advance by the board may be used for credit, except that the board may approve for credit completed programs and courses conducted in other countries.

(b) *Physicians.* The board recognizes only those educational programs recognized as approved at the time of the physician's attendance by the council on medical education of the American medical association, or the American osteopathic association, or the accreditation council for continuing medical education or may recognize program providers outside the United States unless any of the foregoing have been previously disapproved by the board. The board will accept attendance at and completion of programs accredited as the American medical association's or the American osteopathic association's "Category I" or an equivalent as fulfilling the requirements of this chapter for continuing medical education. One clock hour of attendance shall be deemed to equal one hour of acceptable continuing medical education.

(2) (a) The board shall accept for continuing medical education credit, voluntary, uncompensated services provided by physicians specializing in psychiatry in assisting the department of health services in the evaluation of community outpatient mental health programs, as defined in s. 51.01 (3n), Stats., and approved by the department of health services according to rules promulgated under s. 51.42 (7) (b), Stats. Four hours of assistance, including hours expended in necessary training by the department

of health services, shall be deemed to equal one hour of acceptable continuing medical education for the purposes of this chapter.

(b) Physicians wishing to apply for continuing medical education credit under this subsection shall register in advance with the board and shall notify the board on forms provided by the board of the dates and the total number of hours in any biennium for which the applicant will be available to provide assistance. Referrals shall be made to the department of health services in the order received pursuant to requests for assistance received from that department by the medical examining board and by the psychology examining board.

**Note:** Forms are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

**History:** Cr. Register, February, 1977, No. 254, eff. 3-1-77; am. Register, February, 1981, No. 302, eff. 3-1-81; renum. Med 13.03 to be 13.03 (1) and am., cr. (intro.), (2), Register, November, 1995, No. 479, eff. 12-1-95; r. and recr. (1), Register, May, 1997, No. 497, eff. 6-1-97; r. (1) (c), Register, December, 1999, No. 528, eff. 1-1-00; correction in (2) made under s. 13.92 (4) (b) 6., Stats., Register November 2011 No. 671.

**Med 13.04 Physician postgraduate training program; length of service.** The board will accept postgraduate training in a program approved by the board under the provisions of s. Med 1.02 (3), as fulfilling the requirements of this chapter for continuing medical education for physicians. Three consecutive months of such postgraduate training shall be deemed to equal 30 hours of acceptable continuing medical education for the purposes of this chapter.

**History:** Cr. Register, February, 1977, No. 254, eff. 3-1-77; am. Register, March, 1979, No. 279, eff. 4-1-79; am. Register, May, 1997, No. 497, eff. 6-1-97.

**Med 13.05 Evidence of compliance.** (1) PHYSICIANS. The board will accept as evidence of compliance by physicians with the requirements of this chapter, as original documents or verified copies thereof, any or all or any combination of the following:

(a) Certification by either the providing institution or organization or the American medical association or the American osteopathic association, or components thereof, of attendance at and completion of continuing medical education programs approved under the provisions of s. Med 13.03 (1) (a).

(b) A "Physician's Recognition Award" of the American medical association or a certificate of continuing medical education from the American academy of family physicians awarded not more than 12 months prior to the beginning of the calendar year for which application for registration is being made.

(c) Certification by a chief of service or head of department or director of medical education of the providing facility of appointment to and satisfactory participation in a postgraduate training program approved under the provisions of s. Med 13.04.

(2) RETENTION REQUIREMENT. Evidence of compliance shall be retained by each physician through the biennium for which 30 hours of credit are required for registration.

**History:** Cr. Register, February, 1977, No. 254, eff. 3-1-77; am. (1) (intro.) and r. and recr. (2), Register, February, 1981, No. 302, eff. 3-1-81; am. (1) (intro.), (a) and (2), cr. (1m), Register, May, 1997, No. 497, eff. 6-1-97; r. (1m), am. (2), Register, December, 1999, No. 528, eff. 1-1-00.

**Med 13.06 Audit.** The board shall conduct a random audit of licensees on a biennial basis for compliance with the continuing

education requirement stated in s. [Med 13.02 \(1\)](#). The board may require any physician to submit evidence of compliance with the continuing education requirement to the board during the biennium for which 30 hours of credit are required for registration to audit compliance.

**History:** Cr. [Register, February, 1981, No. 302, eff. 3-1-81](#); am. [Register, May, 1997, No. 497, eff. 6-1-97](#); am. [Register, December, 1999, No. 528, eff. 1-1-00](#); [CR 14-033](#); am. [Register May 2015 No. 713, eff. 6-1-15](#).

# Opioid Prescribing Guideline Outline

**Scope and purpose of the guideline:** To help providers make informed decisions about acute and chronic pain treatment -pain lasting longer than three months or past the time of normal tissue healing. The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. Although not specifically designed for pediatric pain, many of the principals upon which they are based could be applied there, as well.

Opioids pose a potential risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

## 1) Identify and treat the cause of the pain, use non-opioid therapies

Use non-pharmacologic therapies (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) and non-opioid pharmacologic therapies (such as acetaminophen and anti-inflammatories) for acute and chronic pain. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

## 2) Start low and go slow

When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

## 3) Close follow-up

Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or discontinue opioids, if needed.

## What's included in the guideline?

The guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, treating the cause of the pain, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the guideline include:

### 1) Determining when to initiate or continue opioids

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

### 2) Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

### 3) Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder

## Opioid Guideline Outline

1. In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 7 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults.
2. Prescribing of opioids is discouraged in patients concurrently taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already extremely high increases in annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.
3. A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.
  - a. Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.
  - b. Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.
  - c. Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.
4. Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:
  - a. Medical history and physical examination targeted to the pain condition
  - b. Nature and intensity of the pain
  - c. Current and past treatments, with response to each treatment
  - d. Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal disease, sleep apnea, COPD, etc.)
  - e. Effect of pain on physical and psychological functioning
  - f. Personal and family history of substance abuse
  - g. History of psychiatric disorders associated with opioid abuse (bipolar, ADD/ADHD, sociopathic, borderline, untreated/severe depression)
  - h. Medical indication(s) for use of opioids
5. Opioids should not necessarily be the first choice in treating acute or chronic pain.
  - a. Acute pain: Evidence for opioids is weak. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments should be attempted prior to initiating opioid therapy. Although opioids could be simultaneously prescribed if it is apparent from the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.
  - b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (tricyclic antidepressant, serotonin/norepinephrine re-uptake inhibitor, anticonvulsant, etc.) should be attempted.
  - c. Chronic pain: Evidence for opioids is poor. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) should be utilized. Multiple meta-analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates

dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. Note: There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior.

- d. Patients unwilling to accept non-pharmacological and/or nonnarcotic treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

6. Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be weaned or discontinued.

7. Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating chronic opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

- a. Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).
- b. Components of ongoing assessment of risk include:
  - i. Review of the Prescription Drug Monitoring Program (PDMP) information
  - ii. Periodic urine drug testing – at least yearly in low risk cases, more frequently if evidence of increased risk (including chromatography) is strongly recommended
  - iii. Periodic pill counts – at least yearly and low risk cases, more frequently if evidence of increased risk
  - iiii. Violations of the opioid agreement

8. All patients on chronic opioid therapy should have informed consent consisting of:

- a. Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death
- b. Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects

9. Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long-acting agents for a majority of the daily dose.

10. Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented (see #7.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and clear and compelling documentation to support such dosing should be present on the chart.

11. The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other

opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse.

12. The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. Finally, methadone can have a potent effect on prolonging the QTc, predisposing susceptible patients to potentially fatal arrhythmias.

13. Prescribing of opioids is very strongly discouraged for patients abusing illicit drugs. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.

14. During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks. During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.

15. Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:

- a. History of overdose (a relative contraindication to chronic opioid therapy)
- b. Opioid doses over 50 MMEs/day
- c. Clinical depression
- d. Evidence of increased risk by other measures (behaviors, family history, PDMP, UDS, risk questionnaires, etc.)

The recommended dose is 0.4 mg for IM or intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives. Family members can be prescribed naloxone for use with the patient.

16. All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner should be able to assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an addiction treatment center which is willing to accept the patient. Simply discharging a patient from the provider's practice after prescribing the medication that led to the complication of opioid use disorder is not considered acceptable.

17. Terms to avoid

- a. Addiction-- This is a term which carries a very negative stigma and is therefore much more preferable to use "opioid use disorder."
- b. Drug-seeking-- This term can have a very negative stigma. It is preferable to use the term "aberrant opioid behavior."
- c. Opioid dependency--This has been used as a synonym for addiction prior to the DSM-V and is often confused with physiologic dependence. The more precise term is "opioid use disorder."