



CONTROLLED SUBSTANCES BOARD

Contact: Chad Zadrazil (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison
September 20, 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 description of the actions and deliberations of the Board.

AGENDA

9:30 A.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-3)**
- B. Approval of Minutes of July 13, 2016 (4-8)**
- C. Administrative Matters**
 - 1) Staff Updates
 - 2) Board Members
 - a. Yvonne Bellay – Dept. of Agriculture, Trade, and Consumer Protection Designee
 - b. Alan Bloom – Pharmacologist
 - c. Doug Englebert – Dept. of Health Services Designee
 - d. Franklin LaDien – Pharmacy Examining Board Designee
 - e. Gunnar Larson – Psychiatrist
 - f. Jeffrey Miller – Board of Nursing Designee
 - g. Jason Smith – Attorney General Designee
 - h. Wendy Pietz – Dentistry Examining Board Designee
 - i. Timothy Westlake – Medical Examining Board Designee
- D. Legislation and Rule Matters – Discussion and Consideration (9-54)**
 - 1) CSB 4 Relating to Prescription Drug Monitoring Program **(10-22)**
 - 2) CSB 2.40 Relating to Exclusion of [¹²³I]ioflupane **(23-25)**
 - 3) CSB 2.42 Relating to Furanyl Fentanyl **(26)**
 - 4) Scope for CSB 2.41 Relating to Butyryl Entanyl and Beta-Hydroxythiofentanyl **(27-28)**
 - 5) Affirmative Action Relating to Scheduling to Brivaracetam **(29-35)**
 - 6) Scheduling of Thiafentanil (Schedule II) **(36-42)**
 - 7) Scheduling of PB-22, SF-PB-22, AB-FUBINACA and ADB-PINACA **(43-46)**
 - 8) Scheduling of U-47700 **(47-54)**
 - 9) Update on Pending or Possible Rule-Making Projects

- E. **Statewide Standing Order for Naloxone – Discussion and Consideration (55-65)**
- F. **Controlled Substance Prescribing Guidelines Update – Discussion and Consideration**
- G. **Wisconsin State Coalition for Prescription Drug Abuse Reduction Update – Discussion and Consideration**
- H. **Prescription Drug Monitoring Program Operations – Discussion and Consideration**
 - 1) Operations Statistics **(66-68)**
 - 2) PDMP Account Suspension Proposed Process Diagram **(69-70)**
 - 3) Implementation of CSB 4.09 for integration purposes **(71)**
- I. **ePDMP Development – Discussion and Consideration (72)**
 - 1) Development Update
 - 2) Demonstration
- J. **Annual and Quarterly Reports – Discussion and Consideration**
 - 1) Quarterly PDMP Report: Wis. Stat. 961.385 (5) and (6) **(73-75)**
 - 2) PDMP User Satisfaction Survey
- K. **Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration**
- L. **Informational Items – Discussion and Consideration**
 - 1) Abuse Deterrence Article **(76-80)**
 - 2) CARA 2016 Article **(81-85)**
 - 3) Elephant Sedative Article **(86-88)**
 - 4) FDA Box Warning Release **(89-91)**
 - 5) Federal Action on Kratom **(92-93)**
- M. Discussion and Consideration of Items Received After Preparation of the Agenda:
 - 1) Introductions, Announcements, and Recognition
 - 2) Presentations of Petition(s) for Summary Suspension
 - 3) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
 - 4) Presentation of Final Decision and Order(s)
 - 5) Informational Item(s)
 - 6) DLSC Matters
 - 7) Status of Statute and Administrative Rule Matters
 - 8) Education and Examination Matters
 - 9) Credentialing Matters
 - 10) Practice Questions
 - 11) Legislation / Administrative Rule Matters
 - 12) Liaison Report(s)
 - 13) Speaking Engagement(s), Travel, or Public Relations Request(s)
 - 14) Consulting with Legal Counsel
- N. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), 440.205 and 961.385(2)(c) Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

O. Review of Medical Examiner and Toxicology Reports (94-135)

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

P. Voting on Items Considered or Deliberated on in Closed Session, If Voting is Appropriate

ADJOURNMENT

The next scheduled meeting is November 15, 2016.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
JULY 13, 2016**

PRESENT: Yvonne Bellay, Doug Englebert, Franklin LaDien, Gunnar Larson (*via GoToMeeting*), Jeffrey Miller (*via GoToMeeting, was excused from the meeting at 11:28 a.m.*), Wendy Pietz, Jason Smith, Timothy Westlake (*via GoToMeeting, joined the meeting at 9:31 a.m. and was excused at 10:41 a.m.*)

EXCUSED: Alan Bloom

STAFF: Chad Zadrazil – Managing Director; Andrea Magermans – Deputy Managing Director, Nilajah Hardin - Bureau Assistant; Sharon Henes - Administrative Rules Coordinator; and other DSPS Staff

CALL TO ORDER

Doug Englebert called the meeting to order at 9:30 a.m. A quorum of eight (8) members was confirmed.

ADOPTION OF AGENDA

Timothy Westlake joined the meeting at 9:31 a.m.

Amendments to the Agenda:

- *Move Item F: “Update on the Wisconsin State Coalition for Prescription Drug Abuse Reduction – Discussion and Consideration” and Item G: “Controlled Substance Prescribing Guidelines (2015 Act 269) – Discussion and Consideration” to occur immediately after Item C: “Administrative Matters”*

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES

March 15, 2016

MOTION: Franklin LaDien moved, seconded by Jeffrey Miller, to approve the minutes of March 15, 2016 as published. Motion carried unanimously.

April 20, 2016

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to approve the minutes of April 20, 2016 as published. Motion carried unanimously.

June 9, 2016

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to approve the minutes of June 9, 2016 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Liaison Appointments

Prescription Drug Monitoring Program (PDMP) Liaison

2016 LIAISON APPOINTMENTS	
PDMP Liaison	Timothy Westlake (Alternate: Wendy Pietz)

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to affirm the Chair’s appointment of the PDMP Liaison and alternate. Motion carried unanimously.

WAUPACA COUNTY DISTRICT ATTORNEY’S REQUEST REGARDING FURANYL

MOTION: Timothy Westlake moved, seconded by Franklin LaDien, to approve the Scope Statement on CSB 2 relating to Additions to Schedules in Chapter 961 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.

MOTION: Wendy Pietz moved, seconded by Yvonne Bellay, to authorize the Chair to approve the emergency rule draft of CSB 2 relating to Additions to Schedules in Chapter 961 for submission to the Governor’s Office and Publication. Motion carried unanimously.

DEA REGISTRATION REQUIREMENT GUIDANCE REQUEST

MOTION: Wendy Pietz moved, seconded by Jeffrey Miller, to request DSPS staff draft a letter on behalf of the Chair in response to the request for guidance from the Wisconsin Veterinary Medical Association. Motion carried unanimously.

Timothy Westlake was excused from the meeting at 10:41 a.m.

ePDMP DEVELOPMENT UPDATE

ASAP Format Identification

MOTION: Wendy Pietz moved, seconded by Franklin LaDien, to utilize software version 4.2 of the American Society for Automation in Pharmacy (ASAP) for the PDMP in Wisconsin. Motion carried unanimously.

Survey of Users

MOTION: Franklin LaDien moved, seconded by Wendy Pietz, that ePDMP Survey questions are reviewed by Wendy Pietz and Timothy Westlake prior to the release of the survey. Motion carried unanimously.

Jeffrey Miller was excused from the meeting at 11:28 a.m.

LEGISLATION AND RULE MATTERS

Adopt Clearinghouse Rule 15-068 Relating to the Exclusion of Naloxegol from Scheduling

MOTION: Wendy Pietz moved, seconded by Franklin LaDien, to approve the Adoption Order for Clearinghouse Rule 15-068 Relating to the Exclusion of Naloxegol from Scheduling. Motion carried unanimously.

Adopt Clearinghouse Rule 15-083 Relating to Special Use Authorization Measurements

MOTION: Yvonne Bellay moved, seconded by Wendy Pietz, to approve the Adoption Order for Clearinghouse Rule 15-083 Relating to Special Use Authorization Measurements. Motion carried unanimously.

Scope for CSB 2.40 Relating to Exclusion of [¹²³I]ioflupane

MOTION: Franklin LaDien moved, seconded by Wendy Pietz, to approve the Scope Statement on CSB 2.40 relating to Exclusion of [¹²³I]ioflupane 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.

Affirmative Action Order Relating to Butyryl Fentanyl and Beta-Hydroxythiofentanyl

MOTION: Wendy Pietz moved, seconded by Yvonne Bellay, to affirm the rescheduling of Butyryl Fentanyl and Beta-hydroxythiofentanyl to Schedule I to take effect on July 18, 2016 to allow for publication in the Administrative Register. Motion carried unanimously.

Proposals for Amending CSB 4 Relating to Prescription Drug Monitoring Program (Acts 266, 267 and 268)

MOTION: Wendy Pietz moved, seconded by Franklin LaDien, to authorize Chair to approve the emergency rule draft of CSB 4 relating to Prescription Drug Monitoring Program (Acts 266, 267 and 268) for submission to the Governor's Office and Publication and the corresponding preliminary rule draft for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CLOSED SESSION

MOTION: Yvonne Bellay moved, seconded by Wendy Pietz, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85 (1)(b), Stats.); to consider closing disciplinary investigation with administrative warning (ss.19.85(1)(b), 440.205, and 961.385(2)(c) Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and, to confer with legal counsel (s.19.85(1)(g), Stats.). Doug Englebert, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Yvonne Bellay-yes, Doug Englebert-yes; Franklin LaDien-yes; Gunnar Larson-yes; Wendy Pietz-yes; Jason Smith-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:19 p.m.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay , to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 12:56 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Wendy Pietz moved, seconded by Yvonne Bellay, to affirm all motions made in closed session. Motion carried unanimously.

DELIBERATION ON ISSUANCE OF ORDER SUSPENDING ACCESS TO THE PRESCRIPTION DRUG MONITORING PROGRAM

MOTION: Yvonne Bellay moved, seconded by Wendy Pietz, to request DSPS staff draft a policy regarding the suspension of access for users of the PDMP for the Board's review at the next meeting. Motion carried unanimously.

16 CSB 002

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to issue an Order to maintain the suspension of access of C.R., R.Ph., to the Prescription Drug Monitoring Program, pursuant to Wis. Stat. § 961.385(2)(c), and Wis. Admin. Code CSB 4.09(3)(a), and to refer this matter to the Pharmacy Examining Board for review, pursuant to Wis. Stat. § 961.385(2)(c), and Wis. Admin. Code CSB 4.13(2). Motion carried unanimously.

MOTION: Wendy Pietz moved, seconded by Franklin LaDien, to authorize the PDMP Liaison to lift the suspension of access to the Prescription Drug Monitoring Program in the matter of C.R., R.Ph. in accordance with the terms of the Order. Motion carried unanimously.

16 CSB 003

MOTION: Jason Smith moved, seconded by Wendy Pietz, to issue an Order to maintain the suspension of access of J.B., R.Ph., to the Prescription Drug Monitoring Program, pursuant to Wis. Stat. § 961.385(2)(c), and Wis. Admin. Code CSB 4.09(3)(a), and to refer this matter to the Pharmacy Examining Board for review, pursuant to Wis. Stat. § 961.385(2)(c), and Wis. Admin. Code CSB 4.13(2). Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Jason Smith, to authorize the PDMP Liaison to lift the suspension of access to the Prescription Drug Monitoring Program in the matter of J.B., R.Ph. in accordance with the Order. Motion carried unanimously.

ADJOURNMENT

MOTION: Yvonne Bellay moved, seconded by Jason Smith, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 12:58 p.m.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 8 September 2016 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: Controlled Substances Board			
4) Meeting Date: 20 Sept. 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. CSB 4 Relating to Prescription Drug Monitoring Program 2. CSB 2.40 Relating to Exclusion of [¹²³I]ioflupane 3. CSB 2.42 Relating to Furanyl Fentanyl 4. Scope for CSB 2.41 Relating to Butyryl entanyl and Beta-Hydroxythiofentanyl 5. Affirmative Action Relating to Scheduling of Brivaracetam 6. Scheduling of Thiafentanil (Schedule II) 7. Scheduling of PB-22, SF-PB-22, AB-FUBINACA and ADB-PINACA 8. Scheduling of U-47700 9. Update on pending and possible rulemaking projects	
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 (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed: 			
11) Authorization			
<i>Sharon Henes</i>		<i>8 September 2016</i>	
Signature of person making this request		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.			

TEXT OF RULE

SECTION 1. CSB 4.01 is amended to read:

CSB 4.01 Authority and scope. The rules in this chapter are adopted under authority in ss. 227.11 (2) (a) and 961.385, Stats., for the purpose of creating a prescription drug monitoring program to collect and ~~maintain~~ disclose information relating to the prescribing and dispensing of monitored prescription drugs.

SECTION 2. CSB 4.02 (1) and (2) are amended to read:

CSB 4.02 (1) “Access” means to have the ability to view ~~PDMP information through an account established with the board~~ relevant monitored prescription drug history reports, audit trails, and PDMP data as authorized by s. 4.09.

(2) “Administer” has the meaning given in s. ~~450.01 (1)~~ 961.385 (1) (a), Stats.

SECTION 3. CSB 4.02 (2m), (3s), (4m) and (5m) are created to read:

CSB 4.02 (2m) “Agent” has the meaning given in s. 961.385 (1) (ab), Stats.

(3s) “Audit trail” means the log that contains information about each time the PDMP system discloses PDMP data and monitored prescription drug history reports.

(4m) “Business day” has the meaning given in s. 961.385 (1) (ad), Stats.

(5m) “Deliver” or “delivery” has the meaning in s. 961.385 (1) (ae), Stats.

SECTION 4. CSB 4.01 (7) is amended to read:

CSB 4.02 (7) “Dispense” has the meaning given in s. ~~450.01 (7)~~ 961.385 (1) (af), Stats.

SECTION 5. CSB 4.01 (11c) and (11n) are created to read:

CSB 4.01 (11c) “Healthcare Professional” means a pharmacist, practitioner, registered nurse licensed under s. 441.06, Stats., substance abuse counselor, as defined in s. 440.88 (1) (b), or individual authorized under s. 457.02 (5m) to treat alcohol or substance dependency or abuse as a specialty.

(11n) “Law enforcement agency” has the meaning given in s. 165.77 (1) (b), Stats.

SECTION 6. CSB 4.01 (11r) and (12) (a) 1. are amended to read:

CSB 4.01 (11r) “Managing pharmacist” ~~has the meaning given in s. Phar 1.02 (6)~~ means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

4.01 (12) (a) 1. A controlled substance included in s. ~~961.385 (1)~~ 961.385 (1) (ag), Stats.

SECTION 7. CSB 4.01 (11w) and (12m) are created to read:

CSB 4.01 (11w) “Medical coordinator” means a person who medically coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

(12m) “Monitored prescription drug history report” means all of the following information about a patient, practitioner, or dispenser compiled by the PDMP system and disclosed as authorized in ss. 4.09 and 4.11:

- (a) PDMP data.
- (b) Reports submitted to the program pursuant to s. 961.37, Stats.
- (c) Information submitted to the program by a healthcare professional.
- (d) Information from the analytics platform.

SECTION 8. CSB 4.01 (13) is amended to read:

CSB 4.01 (13) “Patient” has the meaning given in s. ~~450.01 (14)~~ 961.385 (1) (aj), Stats.

SECTION 9. CSB 4.01 (14) is repealed.

SECTION 10. CSB 4.01 (15) (intro.) and (a) are consolidated, renumbered CSB 4.01 (15) and amended to read:

CSB 4.01 (15) “PDMP information data” ~~means any of the following: The data the information compiled and stored~~ analyzed by the ~~board~~ PDMP system from dispensing data submitted to it by dispensers.

SECTION 11. CSB 4.01 (15) (b) is repealed.

SECTION 12. CSB 4.01 (15b) and (15e) are created to read:

CSB 4.01 (15b) “PDMP system” means the web-based application and analytics platform that facilitates the submission of dispensing data and the access to and the obtaining of relevant monitored prescription drug history reports and relevant PDMP data.

(15e) “Personally identifiable information” means information that can be associated with a particular patient through one or more identifiers or other information or circumstances.

SECTION 13. CSB 4.01 (15g), (15r), (16), (17) and (18) are amended to read:

CSB 4.01 (15g) “Pharmacist” has the meaning given in s. 961.385 (1) (aL), Stats. For the purposes of this program, the board recognizes a pharmacist licensed by another state that engages in the practice of pharmacy within the contiguous borders of this state as a person authorized to engage in the practice of pharmacy.

(15r) “Pharmacist delegate” means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing ~~PDMP information~~ monitored prescription drug history reports, audit trails or PDMP data.

(16) “Pharmacy” ~~means any place of practice licensed by~~ has the board under ss. 450.06 or 450.065 meaning given in s. 961.385 (1) (an), Stats., including a pharmacy that chooses to solely dispense to animal patients.

(17) “Practitioner” has the meaning given in s. 961.385 (1) (ar), Stats. For the purposes of this program, the board recognizes a practitioner licensed by another state that engages in the practice of their credentialed profession within the contiguous borders of this state as a person authorized to prescribe and administer drugs.

(18) “Practitioner delegate” means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing ~~PDMP information~~ monitored prescription drug history reports, audit trails or PDMP data.

SECTION 14. CSB 4.01 (21m) is created to read:

CSB 4.01 (21m) “Prosecutorial unit” has the meaning given in s. 978.001 (2), Stats.

SECTION 15. CSB 4.03 (2) is repealed.

SECTION 16. CSB 4.04 (1) (b), (d) and (e) are repealed.

SECTION 17. CSB 4.04 (2) (b),(e) and (i) and (4) are amended to read:

CSB 4.04 (2) (b) The ~~dispenser identifier, if available~~ dispenser’s DEA registration number.

(e) The NDC number ~~or the name and strength~~ of the monitored prescription drug.

(i) The ~~practitioner identifier, if available~~ practitioner’s DEA registration number.

(4) ~~A~~ The board may refer a dispenser and dispenser delegate, if applicable, who that fail to compile dispensing data as required by sub. (2) may be subject to disciplinary action by the appropriate licensing or regulatory board that issued for discipline, or the license under which the dispenser is authorized to dispense monitored prescription drugs appropriate law enforcement agency for investigation and possible prosecution.

SECTION 18. CSB 4.05 (1) (intro) is amended to read:

CSB 4.05 (1) Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data ~~through an account with the board.~~ to the PDMP in any of the following ways:

SECTION 19. CSB 4.05 (1) (a) and (b) are created to read:

CSB 4.05 (1) (a) As a file that complies with the data standards identified in version 4 and release 2 of ASAP implementation guide for prescription monitoring programs.

(b) Using the prescription record entry functions of the PDMP system.

SECTION 20. CSB 4.05 (1) (note) is repealed and recreated to read:

NOTE: The guide for dispensers which specifies the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs and other electronic formats identified by the board may be obtained online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

SECTION 21. CSB 4.05 (2) and (3) are repealed.

SECTION 22. CSB 4.05 (4) is repealed and recreated to read:

CSB 4.05 (4) The board may refer a dispenser and dispenser delegate that fail to submit dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution.

SECTION 23. CSB 4.06 (1), (2), (3) and (5) are amended to read:

CSB 4.06 (1) A dispenser shall submit dispensing data to the board ~~within 7 days~~ PDMP no later than 11:59 p.m. of dispensing a the next business day after the monitored prescription drug is dispensed.

(2) If a dispenser does not dispense a monitored prescription drug ~~for 7 days on a business day,~~ the dispenser shall submit no later than 11:59 p.m. of the next business day a zero report to the ~~board~~ PDMP that accounts for each 7-day period during business day on which the dispenser did not dispense a monitored prescription drug.

(3) If a dispenser is not able to submit dispensing data ~~within 7 days of dispensing or a monitored prescription drug~~ zero report before 11:59 p.m. of the next business day as required by ~~sub.~~ subs. (1) or (2), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser is not able to submit dispensing data or a zero report because of circumstances beyond its control.

(b) The dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data or zero report.

(5) ~~A~~ The board may refer a dispenser and dispenser delegate, if applicable, who that fail to submit dispensing data or a zero report as required by subs. (1) and (2), or be granted an emergency waiver under sub. (3), or a dispenser and a dispenser delegate, if applicable, that who submit false information to the board may be subject PDMP to disciplinary action by the appropriate licensing or regulatory board that issued for discipline, or the license under which the dispenser is authorized to dispense monitored prescription drugs appropriate law enforcement agency for investigation and possible prosecution.

SECTION 24. CSB 4.07 is repealed and recreated to read:

CSB 4.07 Correction of dispensing data. A dispenser shall electronically correct dispensing data in the PDMP system within 5 business days of discovering an omission, error, or inaccuracy in previously submitted dispensing data.

SECTION 25. CSB 4.08 (2m) is created to read:

CSB 4.08 (2m) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is compounded, packaged or labeled in preparation for delivery but is not delivered.

SECTION 26. CSB 4.09 is repealed and recreated to read:

CSB 4.09 Access to monitored prescription drug history reports and PDMP data about a patient.

(1) Healthcare professionals may access relevant monitored prescription drug history reports or PDMP data about a patient for any of the following reasons:

- (a) The healthcare professional is directly treating or rendering assistance to the patient.
- (b) The healthcare professional is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient.

(2) Pharmacist delegates and practitioner delegates may access relevant monitored prescription drug history reports and PDMP data about a patient for any of the following reasons:

- (a) A pharmacist or practitioner who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.
- (b) A pharmacist or practitioner who is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.

(3) A healthcare professional may only disclose a monitored prescription drug history report about a patient obtained pursuant to sub. (1) in the following situations:

- (a) To the patient as part of treating or rendering assistance to the patient.
- (b) To another healthcare professional or a medical coordinator for consultation about the health of the patient or as part of treating or rendering assistance to the patient.
- (c) To a law enforcement agency as required by s. 146.82, Stats.

SECTION 27. CSB 4.093 is created to read:

CSB 4.093 Monitored prescription drug history reports, audit trails and PDMP data about healthcare professionals.

- (1) Practitioners may access relevant monitored prescription drug history reports, audit trails, and PDMP data about themselves and their practitioner delegates.
- (2) Healthcare professionals may access audit trails about themselves and their practitioner delegates or pharmacist delegates.
- (3) Medical coordinators may access monitored prescription drug history reports, PDMP data, and audit trails about a healthcare professional whom the medical coordinator coordinates, directs, or supervises or for whom the medical coordinator establishes standard operating procedures that contain no personally identifiable information about a patient if the medical coordinator is conducting any of the following activities:
 - (a) Evaluating the job performance of the healthcare professional.
 - (b) Performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines for the healthcare professional.
- (4) To obtain access to monitored prescription drug history reports, audit trails, and relevant PDMP data as authorized in sub. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall do one of the following:
 - (a) Create an account with the PDMP system.
 - (b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with which the board exchanges monitored prescription drug history reports or PDMP data pursuant to s. CSB 4.14.
 - (c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.
 - (d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.
- (5) To obtain access to monitored prescription drug history reports, audit trails, and PDMP data about a healthcare professional, a medical coordinator shall create an account with the PDMP system.

SECTION 28. CSB 4.097 is created to read:

CSB 4.097 Deny, suspend, revoke or otherwise restrict or limit access.

- (1) The board may deny, suspend, revoke or otherwise restrict or limit a healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's access to monitored prescription drug history reports, PDMP data, and audit trails for any of the following reasons:

- (a) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is suspected of attempting to access, accessing, or disclosing a monitored prescription drug history report, PDMP data, or audit trail in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.
 - (b) The healthcare professional is no longer licensed in this state or in another state and recognized by this state as a person to whom the board may grant access pursuant to s. CSB 4.09 or 4.093.
 - (c) The board, or other licensing board, or regulatory agency takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.
 - (d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.
 - (e) The federal department of justice, drug enforcement administration takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.
 - (f) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.
 - (g) The pharmacist delegate or practitioner delegate is no longer delegated the task of accessing monitored prescription drug history reports or PDMP data.
 - (h) The medical coordinator no longer coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.
- (2) The board may temporarily suspend access to monitored prescription drug history reports, PDMP data, and audit trails upon discovering circumstances that indicate a healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator has performed any of the actions identified in sub. (1) (a).

SECTION 29. CSB 4.10 (1) (intro) is amended to read:

CSB 4.10 (1) A pharmacist dispenser, healthcare professional, pharmacist delegate, practitioner, or practitioner delegate, or medical coordinator may request that the board review any of the following:

SECTION 30. CSB 4.10 (1) (a) is repealed.

SECTION 31. CSB 4.10 (1) (c), (2) (intro) and (a), (3), (6), and (7) is amended to read:

CSB 4.10 (1) (c) The denial, suspension, revocation or other restriction or limitation imposed on the pharmacist's, healthcare professional's, pharmacist delegate's, practitioner's, or practitioner delegate's, or medical coordinator's account pursuant to s. CSB ~~4.09 (3)~~ 4.09 (5).

(2) To request a review, the pharmacist dispenser, health care professional, pharmacist delegate, practitioner, or practitioner delegate, or medical coordinator shall file a written request

with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

(a) The ~~pharmacist's~~ dispenser's, healthcare professional's, pharmacist delegate's, practitioner's, or practitioner delegate's, or medical coordinator's name and address, including street address, city, state and ZIP code.

(3) The board shall conduct the review at its next regularly scheduled meeting and notify the ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, practitioner, or practitioner delegate, or medical coordinator of the time and place of the review.

(6) The board shall provide the ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, practitioner, or practitioner delegate, or medical coordinator with an opportunity to submit written documentation, make a personal appearance before the board and present a statement. The board may establish a time limit for making a presentation. Unless otherwise determined by the board, the time for making a personal appearance shall be 20 minutes.

(7) If the ~~pharmacist~~ dispenser, healthcare professional, pharmacist delegate, practitioner, or practitioner delegate, or medical coordinator fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

SECTION 32. CSB 4.105 is created to read:

CSB 4.105 Practitioners' requirement to review monitored prescription drug history reports. (1) Practitioners shall review relevant PDMP data or the monitored prescription drug history report about a patient before the practitioner issues a prescription order for the patient unless any of the following conditions are met:

- (a) The patient is receiving hospice care, as defined in s. 50.94 (1) (a).
- (b) The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.
- (c) The monitored prescription drug is lawfully administered to the patient.
- (d) The practitioner is unable to review the patient's monitored prescription drug history reports before issuing a prescription order for the patient due to an emergency.
- (e) The practitioner is unable to review the patient's records under their program because the PDMP system is not operation or due to other technological failure that the practitioner reports to the board.

(2) Reviews of reports or other information not provided by the board as part of the program that summarize or analyze PDMP data do not satisfy the requirement to review relevant PDMP data under sub. (1).

(3) The board may refer a practitioner that fails to review relevant monitored prescription drug history reports or PDMP data about a patient prior to issuing a prescription order for that patient to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution.

SECTION 33. CSB 4.11 (title), (1) and (2) (intro) and (c), (5) (intro), (a) and (c), (6) (intro), (a) and (c), (7) (intro), (a) and (c), (8) (intro), (a) and (c), (9), and (10) are amended to read:

CSB 4.11 Methods of obtaining ~~PDMP information~~ monitored prescription drug history reports.

(1) The board shall disclose ~~dispensing data~~ the monitored prescription drug history report about a patient to the patient if he or she does all of the following:

- (a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification or mails to the department copies of two forms of valid proof of identity, one of which is valid government-issued photographic identification.
- (b) Makes a request for the ~~dispensing data~~ monitored prescription drug history reports about the patient on a form provided by the board. If the request is mailed, the form shall be notarized.

(2) The board shall disclose ~~dispensing data~~ the monitored prescription drug history report about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

- (c) Makes a request for the ~~dispensing data~~ monitored prescription drug history report on a form provided by the board.

(5) The board shall disclose the minimum necessary amount of ~~PDMP~~ information ~~necessary in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser~~ to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

- (a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.
- (c) Makes a request for the ~~PDMP information~~ monitored prescription drug history report through its PDMP system account ~~with the board.~~

(6) The board shall disclose the minimum necessary amount of ~~PDMP~~ information ~~necessary in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser~~ to designated staff of the department who is charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

- (a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.
- (c) Makes a request for the ~~PDMP information~~ monitored prescription drug history report through its PDMP system account ~~with the board.~~

(7) The board shall disclose the minimum necessary amount of ~~dispensing data~~ necessary information in a monitored prescription drug history report about a patient or patient address to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(c) Makes a request for the ~~dispensing data~~ monitored prescription drug history report through its PDMP system account ~~with the board~~.

(8) The board shall disclose the minimum necessary amount of ~~dispensing data~~ necessary information in a monitored prescription drug history report about a patient to a coroner, deputy coroner, medical examiner, or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(c) Makes a request for the ~~dispensing data~~ monitored prescription drug history report through its PDMP system account with the board.

(9) The board may disclose ~~de-identified~~ PDMP data without personally identifiable information which does not and cannot that could be reasonably used to identify any ~~patient upon written request~~ healthcare professional, practitioner delegate, pharmacist delegate, or dispenser for public health and research purposes.

(10) The board shall disclose the minimum necessary amount of ~~PDMP~~ information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a law enforcement authority ~~in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records~~ agency or prosecutorial unit if the designated staff does all of the following:

(a) Creates an account with the ~~board on a form provided by the board~~ PDMP system.

(b) Provides a ~~lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that~~ documentation demonstrating the law enforcement agency or prosecutorial unit is entitled to the information under s. 146.82 (2)

(a) ~~11., Stats~~ engaged in one of the following activities:

1. An active and specific investigation or prosecution of a violation of any state or federal law involving a monitored prescription drug and that the PDMP data being requested is reasonably related to that investigation or prosecution.
2. The monitoring of a patient as part of a drug court, as defined in s. 165.955 (1).

(c) Makes a request for ~~PDMP information~~ the monitored prescription drug history report through its account with the ~~board~~ PDMP system.

SECTION 34. CSB 4.11 (10) (c) (note) is repealed.

SECTION 35. CSB 4.12 (title) and (1) are amended to read:

CSB 4.12 Use of PDMP ~~information~~ data by the board and department.

(1) The board shall develop and maintain a PDMP database to store dispensing data and PDMP ~~information~~ data in a secure environment and an encrypted format.

SECTION 36. CSB 4.12 (2) is repealed.

SECTION 37. CSB 4.12 (2m) is created to read:

CSB 4.12 (2m) The board shall develop and maintain a PDMP system to facilitate all of the following:

- (a) The submission of dispensing data to the PDMP database.
- (b) The creation of monitored prescription drug history reports about specific patients, practitioners, and dispensers.
- (c) The access to and the obtaining of monitored prescription drug history reports and PDMP data.

SECTION 38. CSB 4.12 (3) is repealed and recreated to read:

CSB 4.12 (3) The board shall maintain audit trails that contain all of the following information:

- (a) A log of dispensing data submitted to the PDMP database by each dispenser.
- (b) A log of persons to whom the Board has granted direct access to the PDMP system under s. CSB 4.093 (4) (a) and a log of each time a person attempts to access PDMP data or a monitored prescription drug history report.
- (c) A log of prescription monitoring programs operated by a relevant agency in another jurisdiction with which the board exchanges PDMP data pursuant to s. CSB 4.14 and a log of each time a person from another jurisdiction attempts to access PDMP data.
- (d) A log of pharmacies or other entities at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a pharmacy or other entity attempts to access PDMP data or a monitored prescription drug history report.
- (e) A log of hospitals or other entities at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a hospital or other entity attempts to access PDMP data or a monitored prescription drug history report.

- (f) A log of monitored prescription drug history reports and PDMP data disclosed pursuant to s. CSB 4.11, including the name of the person to whom the information was disclosed.
- (g) A log of requests for PDMP data or monitored prescription drug history reports even when no information was disclosed.

SECTION 39. CSB 4.12 (4), (4g), (4r), and (5) are repealed.

SECTION 40. CSB 4.12 (6) (intro) and (a) are amended to read:

CSB 4.12(6) ~~Board and department staff~~ Staff assigned administrative duties over the PDMP, vendors, and other agents of the board shall only have access to the minimum amount of PDMP ~~information data~~ necessary for all of the following purposes:

- (a) The design, implementation, operation, and maintenance of the program, including the PDMP database and PDMP system, as part of the assigned duties and responsibilities of their employment.

SECTION 41. CSB 4.12 (6) (am) is created to read:

CSB 4.12 (6)(am) The operation of an analytics platform that provides data cleansing and standardization, data integration, advanced analytics, and alert management capabilities as part of the PDMP database and PDMP system.

SECTION 42. CSB 4.12 (6) (c) is amended to read:

CSB 4.12 (6) (c) Evaluating and responding to legitimate requests for ~~PDMP information~~ monitored prescription drug history reports, audit trails, and PDMP data.

SECTION 43. CSB 4.12 (6) (cg) and (cr) are created to read:

CSB 4.12 (6) (cg) Preparing monitored prescription drug history reports, audit trails, and PDMP data for the board to determine whether suspicious or critically dangerous conduct or practices has occurred or is occurring pursuant to s. CSB 4.15.

- (cr) Conducting a review of the program as required by s. 961.385 (5), Stats.

SECTION 44. CSB 4.13 is amended to read:

CSB 4.13 Confidentiality of PDMP ~~information~~ records. (1) The dispensing data, PDMP ~~information~~ data, audit trails, and monitored prescription drug history reports maintained, ~~by the board, department or a vendor contracting with the department which is submitted to, maintained~~ created, or stored as a part of the program ~~is~~ are not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses or a person whose delegate discloses dispensing data, PDMP ~~information~~ data, audit trails, or monitored prescription drug history reports in violation

of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records, may be ~~subject to disciplinary action by~~ referred to the appropriate licensing or regulatory board that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties for discipline, or the appropriate law enforcement agency for investigation and possible prosecution.

SECTION 45. CSB 4.14 (title) and (1) (intro) are amended to read:

CSB 4.14 Exchange of PDMP information data. (1) The board may exchange PDMP ~~information data~~ with a prescription monitoring program operated by a relevant agency in another state or jurisdiction if the prescription monitoring program satisfies all of the following conditions:

SECTION 46. CSB 4.15 (1) and (5) (intro) are amended to read:

CSB 4.15 (1) The board may review dispensing data, monitored prescription drug history reports, PDMP information data, and data compiled pursuant to s. CSB 4.12 to determine whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.

(5) Upon determining that circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, practitioner, or patient, the Board may disclose ~~PDMP information~~ monitored prescription drug history reports, audit trails, and PDMP data to any of the following:

SECTION 47. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.40 relating to exclusion of [¹²³I]ioflupane.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: s. 961.11 (4), Stats.

Explanation of agency authority:

961.11(4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

Related statute or rule: N/A

Summary of, and comparison with, existing or proposed federal regulation:

On September 11, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [¹²³I]ioflupane from schedule II of the federal Controlled Substances Act. The scheduling action was effective September 11, 2015.

Plain language analysis:

The Controlled Substances Board did not receive an objection to excluding [¹²³I]ioflupane as a schedule II under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on October 13, 2015 to similarly exclude naloxegol under chapter 961 effective October 19, 2015 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule amends 961.16 (2) (b), Stats. which excludes [¹²³I]ioflupane from schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois does not exclude [¹²³I]ioflupane from scheduling.

Iowa: Iowa excludes [¹²³I]ioflupane from scheduling.

Michigan: Michigan does not exclude [¹²³I]ioflupane from scheduling.

Minnesota: Minnesota does not exclude [¹²³I]ioflupane from scheduling.

Summary of factual data and analytical methodologies:

The methodology was to remove [¹²³I]ioflupane from scheduling to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule excludes a drug from scheduling and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jeffrey.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on November 15, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.40 is created to read:

CSB 2.40 Exclusion of [¹²³I]ioflupane. Section 961.16(2)(b), Stats., is amended to read:
(b) Coca leaves and any salt, compound, derivative or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [¹²³I]ioflupane is excluded from this paragraph. The following substances and any of their salts, esters, isomers and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)



P.O. Box 7857
Madison, WI 53707-7857
www.doj.state.wi.us

**BRAD D. SCHIMEL
ATTORNEY GENERAL**

NEWS RELEASE

Attorney General Brad Schimel Statement on Controlled Substances Board Decision to List Furanyl Fentanyl as Controlled Substance

July 14, 2016

Rebecca Ballweg
608-266-1221

MADISON, WI – On July 13, 2016, the Wisconsin Controlled Substances Board decided to schedule furanyl fentanyl, an analog opioid to fentanyl, as a controlled substance. Attorney General Brad Schimel issued the following statement in response to the decision:

“In order to be effective in our fight against heroin and opioids, we must respond rapidly to new drugs and trends entering the market and I applaud the Wisconsin Controlled Substances Board’s quick action to list furanyl fentanyl as a controlled substance.”

#

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.41

Relating to: Scheduling of beta-hydroxythiofentanyl and butyryl fentanyl

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to schedule beta-hydroxythiofentanyl and butyryl fentanyl as Schedule I substances.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

On May 12, 2016, the United States Food and Drug Administration published its final rule in the Federal Register placing beta-hydroxythiofentanyl and butyryl fentanyl into Schedule I of the federal Controlled Substances Act. The scheduling action was effective May 12, 2016. The Controlled Substances Board did not receive an objection to similarly treat beta-hydroxythiofentanyl and butyryl fentanyl as Schedule I controlled substances under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating beta-hydroxythiofentanyl and butyryl fentanyl as controlled substances.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat beta-hydroxythiofentanyl and butyryl fentanyl under ch. 961, Stats. by creating the following.

CSB 2.41 Scheduling of beta-hydroxythiofentanyl and butyryl fentanyl. Sections 961.14 (2) (eu) and (ey) are created to read:

961.14 (2) (eu) Beta-hydroxythiofentanyl (N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide)

(ey) Butyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide)

The Affirmative Action order, dated July 13, 2016, took effect on July 18, 2016 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.11 (1) The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227.

961.11(4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily

Rev. 3/6/2012

scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

25 hours

6. List with description of all entities that may be affected by the proposed rule:

Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

On May 12, 2016, the United States Food and Drug Administration published its final rule in the Federal Register placing beta-hydroxythiofentanyl and butyryl fentanyl into Schedule I of the federal Controlled Substances Act. The scheduling action was effective on May 12, 2016.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

Date Submitted

et seq.; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

Supplement No. 1 to Part 774— [Amended]

■ 21. In Supplement No. 1 to Part 774 (the Commerce Control List), ECCN 1C981 is removed.

Dated: May 5, 2016.

Eric L. Hirschhorn,

Under Secretary for Industry and Security.

[FR Doc. 2016–11047 Filed 5–11–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–435]

Schedules of Controlled Substances: Placement of Brivaracetam Into Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule, with request for comments.

SUMMARY: The Drug Enforcement Administration is placing the substance brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB–34714; Briviact) (including its salts) into schedule V of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act, as revised by the Improving Regulatory Transparency for New Medical Therapies Act which was signed into law on November 25, 2015.

DATES: The effective date of this rulemaking is May 12, 2016. Interested persons may file written comments on this rulemaking in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before June 13, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),” may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44. Requests for hearing and waivers of an

opportunity for a hearing or to participate in a hearing must be received on or before June 13, 2016.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA–435” on all correspondence, including any attachments.

• **Electronic comments:** The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• **Paper comments:** Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, VA 22152.

• **Hearing requests:** All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT:

Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement

Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services and Drug Enforcement Administration eight-factor analyses, to this interim final rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing, Notice of Appearance at Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a)–

(c), requests for a hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).” 21 CFR 1300.01. Requests for a hearing and notices of participation must conform to the requirements of 21 CFR 1308.44(a) or (b), as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver of an opportunity for a hearing must conform to the requirements of 21 CFR 1308.44(c) including a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of the hearing are restricted to “(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed. * * *” Requests for a hearing and waivers of participation in the hearing should be submitted to DEA using the address information provided above.

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, 21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use in

treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *” The Attorney General has delegated this scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of Health and Human Services (HHS); or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action imposes the regulatory controls and administrative, civil, and criminal sanctions of schedule V controlled substances for any person who handles or proposes to handle BRV.

The Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89) was signed into law on November 25, 2015. This law amended 21 U.S.C. 811 and states that in cases where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug, within 90 days.

The law further states that the 90-day timeframe starts the later of (1) the date DEA receives the HHS scientific and medical evaluation/scheduling recommendation or (2) the date DEA receives notice of drug approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause therefor.

Specifically, Public Law 114–89 revised section 201 of the CSA (21 U.S.C. 811) by inserting after subsection (i) a new paragraph (j), which requires that with respect to a drug referred to in subsection (f), if the Secretary recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General is required to,

within 90 days, issue an interim final rule controlling the drug in accordance with such subsections and 21 U.S.C. 812(b) using the specified procedures. For purposes of calculating the 90 days, Public Law 114–89 states that such date shall be the later of the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary in accordance with subsection (b), or the date on which the Attorney General receives notification from the Secretary that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1). Public Law 114–89 further stipulates that a rule issued by the Attorney General under paragraph (1) becomes immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause and requires that the interim final rule give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) of this section and 21 U.S.C. 812(b).

Background

Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB–34714; Briviact) is a new molecular entity with central nervous system (CNS) depressant properties. BRV is known to be a high affinity ligand for the synaptic vesicle protein, SV2A, which is found on excitatory synapses in the brain. On November 22, 2014, UCB Inc. (Sponsor) submitted three New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for the tablet, oral, and intravenous formulations of BRV. The FDA accepted the NDA filings for BRV on January 21, 2015.

On March 28, 2016 the DEA received notification that HHS/FDA approved BRV as an add-on treatment to other medications to treat partial onset seizures in patients age 16 years and older with epilepsy.

Determination to Schedule BRV

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by request of the Secretary

of the HHS.¹ On September 8, 2015, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled "Basis for the Recommendation to Place Brivaracetam in Schedule V of the Controlled Substances Act." Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of BRV as a new drug, along with the HHS' recommendation to control BRV under schedule V of the CSA.

In response, in December 2015, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that BRV met the 21 U.S.C. 812(b)(5) criteria for placement in schedule V of the CSA. Subsequently, on March 28, 2016, the DEA received notification that HHS/FDA approved three NDAs for BRV (*see* Background section).

Pursuant to the provisions of the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), and based on the HHS recommendation, NDA approvals by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (including its salts) as a controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its scheduling action. Please note that both the DEA and HHS analyses are available in their entirety under "Supporting Documents" in the public docket for this interim final rule at <http://www.regulations.gov>, under Docket Number "DEA-435." Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. *The Drug's Actual or Relative*

Potential for Abuse: BRV is a new chemical entity and has not been marketed in the United States or in any other country; information on actual abuse of BRV is not available. The HHS characterized BRV as related in its

action to lacasamide and ezogabine, which are both schedule V CNS depressant anti-epileptics (AEDs). Based on data submitted by the Sponsor in their NDAs, the HHS indicated that administration of BRV in mice, rats, and dogs resulted in CNS depressant effects, including decreased locomotor activity and reactivity, motor incoordination, and ataxia.

BRV is not self-administered in animals and, unlike schedule IV benzodiazepines and the schedule III AED perampanel, lacks pentobarbital-like (schedule II) discriminative stimulus and reinforcing effects (HHS review, 2015). In humans, BRV is most similar to the schedule V AEDs lacasamide, ezogabine, and pregabalin in producing positive subjective effects without producing sedation and withdrawal following drug discontinuation that is observed with schedule IV benzodiazepines. Based on this collective evidence, the HHS concluded that BRV has an abuse potential that is most similar to AEDs in schedule V.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* BRV selectively binds with high affinity to synaptic vesicle protein 2A (SV2A). It produces reverse inhibition caused by negative modulators of gamma aminobutyric acid (GABA) and glycine and inhibits sodium (Na⁺) channels. These sites appear to underlie pharmacological activity of BRV.

In rats, BRV at high doses partially generalizes to the schedule IV benzodiazepine chlordiazepoxide. BRV, across a wide range of doses, neither initiates nor maintains self-administration in rats trained to self-administer cocaine. Human studies have reported that healthy individuals may experience euphoria, sedation, and a drunken-like feeling following BRV administration. When treatment-emergent adverse events (TEAEs)² were pooled across several clinical BRV studies, the most common TEAEs were dizziness and sedative-related events such as fatigue, extreme drowsiness, and extreme weakness. In a human abuse potential study, the oral abuse potential, safety, tolerability, and pharmacokinetics of BRV (50 mg, 200 mg, and 1000 mg) were compared to 1.5 and 3.0 mg of the schedule IV CNS depressant alprazolam (ALP) and placebo. When surveyed, for all doses of

BRV, there was an increase of drug likability, feeling of a high, and taking the drug again in comparison to placebo. The HHS mentioned that individuals who took BRV had fewer sedative, euphoric, stimulant, dizziness, and overall negative subjective effects compared to ALP.

3. *The State of Current Scientific Knowledge Regarding Brivaracetam:*

The chemical name for brivaracetam is (2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide. Other names include BRV and UCB-34714. The Chemical Abstract Services number (CAS #) of BRV is: 357336-20-0. BRV is a racetam derivative.³ As the HHS noted, BRV does not have structural similarities to any other scheduled AED or to any major classes of abused sedative drugs with noted euphoric effects. Chemical synthesis of BRV is considered highly complex and includes several steps, reagents and specialized equipment.

BRV is readily soluble in water at up to 700 mg/mL. In an *in vitro* oral tablet dissolution evaluation, BRV oral tablets were placed in a buffer (pH 6.4) for 16 hours. Approximately 86–96% of BRV was released after 16 hours in the buffer; 14–30% of BRV was released following 1 hour and 40–66% BRV was released after 4 hours.

Following oral ingestion, BRV is rapidly and completely absorbed. In healthy young males, the half-life of BRV was determined to be approximately 9 hours. According to the HHS, the half-life of BRV is decreased to 6 hours when a repeated oral dose of 800 mg/day BRV is administered. The HHS noted that BRV binds weakly to plasma proteins and is extensively metabolized through several pathways. Clearance through the kidneys represents 5–10% of the total clearance and only 3–7% of the parent compound (BRV) was detected in the urine. The three main metabolites of BRV were detected in urine and according to the HHS, these metabolites are relatively inactive. One BRV metabolite was characterized as having a potency that was 20 times less than BRV, and this metabolite was not detected in human plasma and represented less than 3% of the dose in urine.

4. *Its History and Current Pattern of Abuse:* As noted by the HHS, information on the history and current pattern of abuse of BRV is not available since this drug is currently not marketed in any country. A review of the animal and human data indicates that BRV has an abuse potential similar to other schedule V AEDs. If BRV were to be

¹ As set forth in a memorandum of understanding entered into by the HHS, the FDA, and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of the NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

² Treatment-emergent adverse event (TEAE): An event or unexpected medical occurrence (*e.g.* adverse event) which first appears during treatment with a drug or substance. TEAEs are typically absent prior to the onset of treatment or would have been exacerbated relative to pre-treatment conditions.

³ Racetams are a class of drugs that have a pyrrolidine center.

approved for medical use, the HHS indicated that BRV would be abused for its euphoric properties and other abuse-related TEAEs that were reported in human clinical studies. Based on the available information, the HHS concluded that the history and pattern of abuse of BRV will be similar to other schedule V CNS depressants.

5. *The Scope, Duration, and Significance of Abuse:* As noted by the HHS, information on the scope, duration, and significance of abuse of BRV is not available since this drug is currently not marketed in any country. Results from animal and human studies suggest that there is abuse potential associated with BRV and if marketed in the United States, it is likely that BRV will be abused similar to other AEDs that are CNS depressants. The HHS stated that it is unlikely that epileptic individuals (the population expected to take this drug) will abuse BRV. The HHS concluded that based on abuse potential similarities between BRV and other schedule V AEDs, it is likely that the scope, duration, and significance of abuse of BRV will be similar to these compounds.

6. *What, if any, Risk There is to the Public Health:* The HHS characterized BRV's drug abuse potential to be similar to schedule V AEDs. As such, the public health risk with BRV will also be similar to other schedule V AEDs. The HHS noted that if BRV were approved for medical use, it would be abused for its rewarding properties. In healthy volunteers administered 600 mg or higher of BRV, cognitive and motor impairment and sedation were observed. It is unknown how BRV would interact in combination with other CNS depressants and if the sedative effects would be additive or even a lethal combination. In an interaction study with BRV and intravenous ethanol in healthy individuals, it was determined that BRV enhanced the effects of ethanol.

7. *Its Psychic or Physiological Dependence Liability:* BRV has limited psychological dependence and does not appear to have physical dependence. When rats were administered BRV for 30 days, no signs of physical dependence were noted in comparison to the schedule IV comparator, chlordiazepoxide. Similarly, in human clinical studies with healthy volunteers, there were no reports or adverse events that noted physical dependence or a withdrawal syndrome associated with BRV use. The low potential for physical dependence observed with BRV is consistent with other schedule V AEDs. There is limited evidence for psychological dependence with BRV.

Clinical studies have reported individuals experiencing increasing euphoria with increasing doses of BRV. Tolerance does not appear to develop with respect to BRV treatment on epileptic seizure reduction.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* BRV is not an immediate precursor of any controlled substance.

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS' recommendation, and its own eight-factor analysis, the DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of BRV. As such, the DEA hereby schedules BRV as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA outlines the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(5), finds that:

1. BRV has a low potential for abuse relative to the drugs or other substances in schedule IV. The overall abuse potential of BRV is comparable to schedule V controlled substances such as ezogabalin, pregabalin, and lacosamide;

2. With FDA's approval of the new drug applications, BRV has a currently accepted medical use in the United States as adjunctive treatment of partial onset seizures in epileptic individuals ages 16 and older; and

3. Human and animal studies demonstrate that BRV has limited psychological dependence and does not appear to have physical dependence. There was no evidence of physical dependence associated with BRV in human and animal studies since there have been no reports of withdrawal syndromes or other physical dependence effects. Based on these data, abuse of BRV may lead to limited psychological dependence similar to schedule V AEDs but less than that of drugs in schedule IV.

Based on these findings, the Acting Administrator of the DEA concludes that brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB-34714; Briviact), including its salts, warrants control in schedule V of the CSA. 21 U.S.C. 812(b)(5).

Requirements for Handling Brivaracetam

BRV is subject to the CSA's schedule V regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule V substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) BRV, or who desires to handle BRV, must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles BRV, and is not registered with the DEA, must submit an application for registration and may not continue to handle BRV, unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule V registration must surrender all quantities of currently held BRV, or may transfer all quantities of currently held BRV to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* BRV is subject to schedule III-V security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71-1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of BRV must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of BRV must take an inventory of BRV on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA must take an initial inventory of all stocks of controlled substances (including BRV) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including BRV) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports for BRV, or products containing BRV, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for BRV or products containing BRV must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Importation and Exportation.* All importation and exportation of BRV must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving BRV not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause. Therefore, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with Public Law 114–89, this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the

principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 603(a), “[w]henver an agency is required by [5 U.S.C. 553], or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretive rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis.” As noted in the above discussion regarding applicability of the Administrative Procedure Act, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, the DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the

private sector, of \$100,000,000 or more (adjusted for inflation) in any one year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Amend § 1308.15 by redesignating paragraphs (e)(1) through (e)(3) as paragraphs (e)(2) through (e)(4) and adding new paragraph (e)(1) to read as follows:

§ 1308.15 Schedule V.

* * * * *
(e) * * *

(1) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide) (also referred to as BRV; UCB-34714; Briviact) (including its salts) 2710
* * * * *

Dated: May 6, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016-11245 Filed 5-11-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-434F]

Schedules of Controlled Substances: Temporary Placement of Butyryl Fentanyl and Beta-Hydroxythiofentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioids, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide, also known as *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide, (butyryl fentanyl) and *N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide, also known as *N*-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-*N*-phenylpropanamide, (beta-hydroxythiofentanyl), and their isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of butyryl fentanyl and beta-hydroxythiofentanyl into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, butyryl fentanyl and beta-hydroxythiofentanyl.

DATES: This final order is effective on May 12, 2016.

FOR FURTHER INFORMATION CONTACT:

Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, 21 U.S.C. 801-971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the

substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated her scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.¹ The Administrator transmitted the notice of intent to place butyryl fentanyl and beta-hydroxythiofentanyl into schedule I on a temporary basis to the Assistant Secretary by letter dated December 21, 2015. The Assistant Secretary responded to this notice by letter dated January 13, 2016, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for butyryl fentanyl or beta-hydroxythiofentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of butyryl fentanyl or beta-hydroxythiofentanyl into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary’s comments as required by 21 U.S.C. 811(h)(4). Neither butyryl fentanyl nor beta-hydroxythiofentanyl is currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for butyryl fentanyl or beta-hydroxythiofentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of butyryl fentanyl and beta-hydroxythiofentanyl in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule butyryl fentanyl and beta-hydroxythiofentanyl was published in the **Federal Register** on March 23, 2016. 81 FR 15485.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	:	AFFIRMATIVE ACTION
PROCEEDINGS BEFORE THE	:	ORDER OF THE
CONTROLLED SUBSTANCES BOARD	:	CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On May 12, 2016, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide) including its salts, isomers or salts of isomers into schedule V of the federal Controlled Substances Act. The scheduling action is effective May 12, 2016.
2. The Controlled Substances Board did not receive an objection to similarly treating brivaracetam as a schedule V under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating tramadol as a controlled substance.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rule making, designating brivaracetam as a schedule V controlled substance.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats brivaracetam under chapter 961, Stats. by creating the following:

CSB 2.43 Addition of brivaracetam to schedule V. Section 961.22(6), Stats., is created to read:

961.22(6) BRIVARACETAM. Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide), including its salts, isomers or salts of isomers.

This order shall take effect on September 26, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebert, Chair
Controlled Substances Board

■ 10. Amend § 143.23 by revising paragraph (j) and adding paragraph (k) to read as follows:

§ 143.23 Form of entry.

* * * * *

(j) Except for mail importations (see §§ 145.31 and 145.32 of this chapter), or in the case of personal written or oral declarations (see §§ 148.12, 148.13, and 148.62 of this chapter), a shipment of merchandise that qualifies for informal entry under 19 U.S.C. 1498 may be entered, including the information listed in paragraph (k) of this section, by presenting the bill of lading or a manifest listing each bill of lading when:

(1) The value of the shipment does not exceed \$100 in the case of a bona fide gift from a person in a foreign country to a person in the United States and the shipment meets the requirements in § 10.152 of this chapter (see § 10.152 of this chapter);

(2) The value of the shipment does not exceed \$200 in the case of articles (including bona fide gifts) from the Virgin Islands, Guam, and American Samoa and the shipment meets the requirements in § 10.152 of this chapter (see § 10.152 of this chapter); or

(3) The value of the shipment does not exceed \$800 and the shipment satisfies the requirements in § 10.151 of this chapter (see §§ 10.151 and 128.24(e) of this chapter).

(k) The following information is required to be filed as a part of entry made under paragraph (j) of this section:

(1) Country of origin of the merchandise;

(2) Shipper name, address and country;

(3) Ultimate consignee name and address;

(4) Specific description of the merchandise;

(5) Quantity;

(6) Shipping weight; and

(7) Value.

■ 11. Amend § 143.26 by removing the figure “\$200” and adding in its place “\$800” in two places each in paragraphs (a) and (b).

PART 145—MAIL IMPORTATIONS

■ 12. The general authority citation for part 145 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624.

* * * * *

§ 145.31 [Amended]

■ 13. Amend § 145.31 by removing the figure “\$200” and adding in its place “\$800” in the section heading and text.

R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border Protection.

Approved: August 23, 2016.

Timothy E. Skud,

Assistant Secretary of the Treasury.

[FR Doc. 2016–20581 Filed 8–25–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1305, and 1308

[Docket No. DEA–375]

Schedules of Controlled Substances: Placement of Thiafentanil Into Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: The Drug Enforcement Administration is placing the substance thiafentanil (4-(methoxycarbonyl)-4-(N-phenmethoxyacetamido)-1-[2-(thienyl)ethyl]piperidine), including its isomers, esters, ethers, salts and salts of isomers, esters and ethers as possible, into schedule II of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act, as revised by the Improving Regulatory Transparency for New Medical Therapies Act which was signed into law on November 25, 2015.

DATES: The effective date of this rule is August 26, 2016. Interested persons may file written comments on this rule in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before September 26, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),” may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity

for a hearing or to participate in a hearing must be received on or before September 26, 2016.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA–375” on all correspondence, including any attachments.

• **Electronic comments:** The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• **Paper comments:** Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

• **Hearing requests:** All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement

Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services and Drug Enforcement Administration eight-factor analyses, to this interim final rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing, Notice of Appearance at Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a)–

(c), requests for a hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01. Requests for a hearing and notices of participation must conform to the requirements of 21 CFR 1308.44(a) or (b), as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver of an opportunity for a hearing must conform to the requirements of 21 CFR 1308.44(c), including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of the hearing are restricted to "(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed . . ." Requests for a hearing and waivers of participation in the hearing should be submitted to the DEA on or before the deadline specified above, using the address information provided therein.

Background, Legal Authority, and Basis for This Scheduling Action

Thiafentanil, known chemically as 4-(methoxycarbonyl)-4-(*N*-phenylmethoxyacetamido)-1-[2-(2-thienyl)ethyl]piperidine, a potent opioid, is an analogue of fentanyl. The product Thianil (thiafentanil oxalate, a salt form of thiafentanil) was reviewed by the Food and Drug Administration (FDA) to determine whether it meets the requirements for addition to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) (21 U.S.C. 360ccc–1) as set forth by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act, 2004). The MUMS Act amended the Federal Food, Drug, and Cosmetic Act (FDCA) to allow for the legal marketing of unapproved new animal drugs intended for use in minor species. In a letter from the Department of Health and Human Services (HHS) dated June 20, 2016, the DEA received notification that HHS/FDA added Thianil (thiafentanil oxalate) to the Index under section 572 of the FDCA. In this same notification, HHS/FDA stated that on June 16, 2016, HHS/FDA granted the

request for the addition of Thianil to the Index under Minor Species Index File (MIF) 900000. Thianil is indicated for use in the immobilization of non-domestic, non-food-producing minor species hoofstock.

Thiafentanil will be marketed as thiafentanil oxalate, 4-(methoxycarbonyl)-4-(*N*-phenylmethoxyacetamido)-1-[2-(2-thienyl)ethyl]piperidinium oxalate. Thiafentanil should not be confused with thiofentanyl (*N*-phenyl-*N*-(1-(2-(thiophen-2-yl)ethyl)piperidin-4-yl)propionamide), which is currently listed as a controlled schedule I substance.

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), where the DEA receives notification from HHS that the Secretary has indexed a drug under section 572 of the FDCA, the DEA is required to issue an interim final rule controlling the drug not later than 90 days after receiving such notification from HHS. 21 U.S.C. 811(j). Accordingly, the DEA is issuing this interim final rule controlling thiafentanil.

When controlling a drug pursuant to section 811(j), the DEA must apply the scheduling criteria of subsections 811(b), (c), and (d) and section 812(b). 21 U.S.C. 811(j)(3). In accordance with these criteria, the DEA has reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document on thiafentanil pursuant to 21 U.S.C. 811(c). As explained below, based on these considerations, the DEA concludes that thiafentanil meets the criteria for placement in schedule II of the CSA.

On November 28, 2011, the HHS provided the DEA with its initial scientific and medical evaluation and scheduling recommendation regarding thiafentanil. Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of thiafentanil as a new drug, along with the HHS' recommendation to control thiafentanil and its salts under schedule II of the CSA. Subsequently, on March 23, 2016, the HHS provided the DEA with a supplement to its 2011 analysis, which indicated that the HHS/FDA planned to add Thianil (thiafentanil oxalate) to the Index for use in the immobilization of non-domestic, non-food-producing minor species hoofstock and reiterated their recommendation that thiafentanil be placed in schedule II of the CSA. By

letter dated June 20, 2016, the DEA received notification from the HHS that the FDA had granted the request on June 16, 2016, for Thianil (thiafentanil oxalate) to be added to the Index.

Pursuant to 21 U.S.C. 811(j), and based on the HHS recommendation, MUMS Act indication by the HHS/FDA, and the DEA's determination, the DEA finds that thiafentanil has a high potential for abuse, a currently accepted medical use with severe restrictions, and that abuse of thiafentanil may lead to severe psychological or physical dependence. Accordingly, the DEA is issuing this interim final rule to add thiafentanil (4-(methoxycarbonyl)-4-(*N*-phenylmethoxyacetamido)-1-[2-(2-thienyl)ethyl]piperidine) and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such, to schedule II of the CSA.

Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its scheduling action. Please note that the DEA and HHS analyses, along with the HHS supplement, are available in their entirety under "Supporting Documents" in the public docket for this interim final rule at <http://www.regulations.gov>, under Docket Number "DEA-375." Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. The Drug's Actual or Relative Potential for Abuse: Thiafentanil is a chemical substance that has not been marketed in the United States, however, it is approved and marketed in the Republic of South Africa as a salt form under the brand name Thianil (thiafentanil oxalate). There is no information available which details actual abuse of thiafentanil.

According to the HHS, thiafentanil is a synthetic analogue of fentanyl and is structurally related to other fentanyl-like opioids such as sufentanil (schedule II) and carfentanil (schedule II). It acts as a potent μ -opioid receptor agonist and produces strong morphine-like effects in animals. It is only intended for the immobilization of non-domestic, non-food-producing minor species hoofstock. Thiafentanil has been used in a manner similar to other opioid immobilizing agents such as etorphine hydrochloride (schedule II) and carfentanil (schedule II), which are approved only for veterinary use as animal immobilization agents. The abuse potential of thiafentanil has not been evaluated in humans or in animal behavioral models that are predictors of abuse by humans. Because thiafentanil

shares chemical and pharmacological similarities with schedule II fentanyl and its analogues, the abuse potential of thiafentanil is considered similar to that of schedule II opioid substances such as sufentanil and carfentanil.

Pharmacologically, as a potent μ opioid receptor agonist, thiafentanil is slightly less potent than carfentanil, which is 100 times more potent than fentanyl and 10,000 times more potent than morphine. Thiafentanil is a potent fentanyl analogue. Thus, it is reasonable to assume that there will be potentially significant diversion of thiafentanil from legitimate channels by people who have access to it, and that thiafentanil would be used without medical advice, therefore causing substantial hazards to the users or to the safety of the community if not controlled. The chemical and potent opioid-like pharmacological properties of thiafentanil predict that its risk to the public health is likely to be similar to fentanyl (schedule II) and its analogues such as carfentanil (schedule II), sufentanil (schedule II) and alpha-methylfentanyl (schedule I).

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known: According to HHS' scientific and medical review, there are no data on the effects of thiafentanil in humans. Thiafentanil's effects in humans are predicted from its effects in animals and its chemical and pharmacological similarity to other schedule II potent opioids such as fentanyl and carfentanil. The HHS eight-factor review document described a study directly comparing the immobilizing effects of thiafentanil (15 mg) and carfentanil (2 or 4 mg) in elk in which thiafentanil produced a faster immobilization effect (0.7 to 2.2 minutes) than carfentanil. In addition, the elk returned to standing 0.9 to 1.4 minutes faster under the thiafentanil condition. This study appears to support a faster immobilization and recovery time with thiafentanil relative to carfentanil. However, the authors stated that the role of the increased dose of thiafentanil is unknown.

Animal studies described by the HHS demonstrated that the effects of thiafentanil and carfentanil are completely reversed by naltrexone. As a μ -opioid receptor antagonist, naltrexone can reverse the effects of a variety of opioid drugs including thiafentanil and carfentanil. Those studies suggest that thiafentanil possesses a neuro-pharmacological mechanism of action similar to other schedule II opioid drugs with a high abuse potential.

According to HHS' review, Thianil (thiafentanil) is currently approved and

registered for use in the Republic of South Africa. Thiafentanil oxalate is suggested as a drug of choice in the capture of exotic and ungulate wildlife species.

3. The State of Current Scientific Knowledge Regarding Thiafentanil: The chemical name of free base thiafentanil is 4-(methoxycarbonyl)-4-(*N*-phenylmethoxyacetamido)-1-[2-(2-thienyl)ethyl]piperidine. It has a molecular formula of $C_{22}H_{28}N_2O_4S$ and a molecular weight of 416.52 g/mol with a Chemical Abstract Registry Number (CAS) of 101345-60-2. Thiafentanil oxalate is also known as A3080 with a CAS number of 101365-73-5 and has a molecular formula of $C_{24}H_{30}N_2O_8S$ with a molecular weight of 506.57 g/mol. Thiafentanil oxalate is a white crystalline powder with a melting point of 190–192 °C and its salt crystallizes from absolute alcohol. Thiafentanil should not be confused with thiofentanyl (*N*-phenyl-*N*-(1-(2-(thiophen-2-yl)ethyl)piperidin-4-yl)propionamide), which is currently listed as a schedule I substance.

4. Its History and Current Pattern of Abuse: According to the HHS' review, there are no reports of actual abuse and misuse of thiafentanil. This may be due to the limited use of thiafentanil as an immobilizing agent by trained veterinarians.

Current data from the National Forensic Laboratory System (NFLIS),¹ the System to Retrieve Information from Drug Evidence (STRIDE),² and the STARLiMS databases show that there is no evidence of law enforcement encounters of thiafentanil in the United States. However, thiafentanil's pharmacological and structural properties suggest that its pattern of abuse would be similar to other potent

¹ The National Forensic Laboratory System (NFLIS) is a program of the DEA, Office of Diversion Control. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 90% of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332, Dec. 12, 2011.

² The System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies. Reporting via STRIDE ceased on September 30, 2014. STRIDE was succeeded by STARLiMS.

schedule II μ -opioid receptor agonists such as fentanyl and carfentanil.

5. *The Scope, Duration, and Significance of Abuse:* An assessment of the scope, duration, and significance of thiafentanil abuse is not available since it has only been used in a limited market. However, as stated in the HHS review, the structural and pharmacological properties of thiafentanil suggest that it could lead to an abuse pattern with a scope, duration, and significance of abuse similar to that observed with other opioid drugs and opioid analogues if it were marketed in a non-controlled status or were the subject of clandestine synthesis. The HHS and DEA note that thiafentanil is not known to be or to have been the subject of abuse in the United States.

6. *What, if any, Risk There is to the Public Health:* The HHS review indicates that thiafentanil presents a significant risk to the public health and, in this vein, that thiafentanil should only be used in certain animals for very limited purposes and with extreme caution. Based on the review of the structural and pharmacological properties of thiafentanil, the HHS concluded that the abuse of thiafentanil is likely to pose a similar risk to public health as that of other potent opioid drugs such as sufentanil (schedule II), fentanyl (schedule II), carfentanil (schedule II) and clandestinely synthesized alpha-methylfentanyl (schedule I). Thus, inappropriate use of thiafentanil poses a high risk to the public health. Among other things, HHS noted that as a fentanyl derivative, and assuming that thiafentanil can be aerosolized, the use of thiafentanil presents a significant risk to the public health.

HHS described that thiafentanil's labeling indicates that it is solely intended for use by zoologic, wildlife, or exotic animal veterinarians or field biologists who have received training and are supervised by veterinarians. The sponsor recommends the use of handling protocols similar to those in place for other scheduled potent opioids such as carfentanil. HHS further indicated that thiafentanil should be handled in teams consisting of at least two individuals knowledgeable about the hazards of working with potent μ -opioid agonist substances. Personal protective equipment such as latex gloves and protective eyewear should be used and syringes must be disposed of properly. If exposure to thiafentanil occurs in a remote or distant environment, veterinary naltrexone is recommended for use as a reversal agent. The label information will further state that thiafentanil must never be

used unless an adequate amount of reversal agent (naltrexone hydrochloride) is immediately available.

HHS also describes the risk of thiafentanil intoxication upon ingestion of animals immobilized with thiafentanil. The label information states that thiafentanil is not intended for human or animal consumption or in non-food producing minor species that become eligible for consumption by humans or food-producing animals. Because thiafentanil, similar to carfentanil, etorphine hydrochloride and diprenorphine, is a potent μ -opioid receptor agonist, it will be subject to specialized handling, distribution and storage procedures similar to those applicable for carfentanil, etorphine hydrochloride and diprenorphine as set forth in 21 CFR parts 1301 and 1305. As a result, this interim final rule revises 21 CFR 1301.74(g), 1301.75(e), 1305.07 introductory text and paragraph (a), and 1305.17(d) to include "thiafentanil."

7. *Its Psychic or Physiological Dependence Liability:* HHS' review states that the structural and pharmacological properties of thiafentanil suggest that it possesses a psychic and physiological dependence liability that is similar to other schedule II related μ -opioid receptor agonist drugs such as sufentanil, fentanyl and carfentanil.

As cited by the HHS review, a double-blind abuse liability study examining intravenous fentanyl, buprenorphine, heroin, morphine, and oxycodone in methadone-maintained patients reported that fentanyl produced subjective effects similar to heroin (schedule I) on several outcome measures indicating that the two drugs produce similar subjective effects. It also demonstrates the psychic dependence liability of fentanyl, and thiafentanil is expected to produce effects similar to fentanyl and to present a similar risk of psychic and physiological dependence. There has been a major increase in abuse of opioids analgesics in the United States (HHS review document, 2011; Compton and Volkow, 2006). Thiafentanil, similar to these opioid analgesics, presents a risk of severe psychic and physiological dependence.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Thiafentanil is not considered an immediate precursor of any controlled substance.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V).

21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1. Thiafentanil has a high potential for abuse. Based on its structural and pharmacological properties, thiafentanil has an abuse potential that is comparable to other schedule II opioid drugs such as fentanyl, carfentanil, and sufentanil;

2. FDA determined that Thianil (thiafentanil oxalate) meets the requirements for addition to the Index as set forth by the MUMS Act, 2004 and accordingly added Thianil (thiafentanil oxalate) to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) under section 572 of the Federal Food, Drug, and Cosmetic Act. Thianil (thiafentanil oxalate) will be legally marketed in the United States and will have an accepted medical use with severe restrictions;³ and

3. Due to the chemical and pharmacological similarities of thiafentanil to other schedule II fentanyl derivatives, abuse of thiafentanil may lead to severe psychological or physical dependence.

Based on these findings, the Acting Administrator of the DEA concludes that thiafentanil, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existences of such isomers, esters, ethers, and salts is possible warrants control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

Requirements for Handling Thiafentanil

Thiafentanil is subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional

³ According to the HHS analysis, "[u]se of a new animal indexed drug is subject to significant restrictions. For example, use of an indexed new animal drug for minor species is limited to a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food producing animals. 21 U.S.C. § 360ccc-1(a)(1). The requester must label, distribute, and promote the new animal drug in accordance with the Index entry, and the FDA may remove a new animal drug from the Index if the conditions and limitations of use have not been followed. 21 U.S.C. 360ccc-1(d)(1)(G); (f)(1)(F). The labeling of an indexed new animal drug must prominently state that the extra-label use of the product is prohibited. 21 U.S.C. 360ccc-1(h). Such restrictions are not imposed upon approved human or animal drugs."

activities and chemical analysis with, and possession involving schedule II substances, including the following:

1. *Registration.* Any person who desires to handle thiafentanil (manufacture, distribute, reverse distribute, dispense, import, export, engage in research, or conduct instructional activities or chemical analysis with, or possess), must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Quota.* Only registered manufacturers are permitted to manufacture thiafentanil in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Upon obtaining a schedule II registration to handle thiafentanil, and if subsequently, any person who does not desire or is not able to maintain a schedule II registration must surrender all quantities of currently held thiafentanil, or may transfer all quantities of currently held thiafentanil to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

4. *Security.* Thiafentanil is subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of thiafentanil must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302. In addition, thiafentanil is subject to additional labeling requirements provided by FDA. Thiafentanil must be labeled, distributed, and promoted in accordance with the Index entry of the new animal drug and the FDA may remove a new animal drug from the Index if the conditions and limitations of use have not been followed. 21 U.S.C. 360ccc–l(d)(l)(G); (f)(l)(F). The labeling of an indexed new animal drug must prominently state that the extra-label use of the product is prohibited. 21 U.S.C. 360ccc–l(h).

6. *Inventory.* Every DEA registrant who desires to possess any quantity of thiafentanil must take an inventory of thiafentanil on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA to handle thiafentanil must take an initial inventory of all stocks of controlled substances

(including thiafentanil) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including thiafentanil) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for thiafentanil, or products containing thiafentanil, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Orders for thiafentanil.* Every DEA registrant who distributes thiafentanil is required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions and other dispensing.* All prescriptions for thiafentanil or products containing thiafentanil must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C. Moreover, given that thiafentanil is not the subject of an approved new drug application under the FDCA, and that it is only allowed under the MUMS Act amendments to the FDCA to be marketed for extremely limited use in minor species, DEA would not consider any dispensing of thiafentanil for human use to be for a legitimate medical purpose within the meaning of the CSA. Likewise, DEA would not consider any dispensing of thiafentanil for animal use beyond the scope of the drug's labeling authorized under the MUMS Act amendments to the FDCA to be for a legitimate medical purpose within the meaning of the CSA.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of thiafentanil may only be for the legitimate purposes consistent with the drug's labeling authorized under the MUMS Act, or for research activities authorized by the FDCA and CSA.

11. *Importation and Exportation.* All importation and exportation of thiafentanil must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving thiafentanil not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a new drug is (1) approved or indexed by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause. Therefore, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with Public Law 114–89, this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 603(a), “[w]hen an agency is required by [5 U.S.C. 553], or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretive rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis.” As noted in the above discussion regarding applicability of the Administrative Procedure Act, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 et seq., the DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small

Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1305

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR parts 1301, 1305 and 1308 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965.

■ 2. In § 1301.74, revise paragraph (g) to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

* * * * *

(g) Before the initial distribution of thiafentanil, carfentanil, etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

* * * * *

■ 3. In § 1301.75, revise paragraph (e) to read as follows:

§ 1301.75 Physical security controls for practitioners.

* * * * *

(e) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

■ 4. The authority citation for 21 CFR part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

■ 5. In § 1305.07, revise the introductory text and paragraph (a) to read as follows:

§ 1305.07 Special procedure for filling certain orders.

A supplier of thiafentanil, carfentanil, etorphine hydrochloride, or diprenorphine, if he or she determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research, and is authorized by the Administrator to handle these substances, may fill the order in accordance with the procedures set forth in § 1305.17 except that:

(a) A DEA Form 222 or an electronic order for thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances in reasonable quantities.

* * * * *

■ 6. In § 1305.17, revise paragraph (d) to read as follows:

§ 1305.17 Preservation of DEA Forms 222.

* * * * *

(d) The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms 222 and records required to be maintained by the registrant.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 7. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 8. In § 1308.12, add paragraph (c)(29) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(29) Thiafentanil 9729

* * * * *

Dated: August 18, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016-20463 Filed 8-25-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 232

[Docket ID: DOD-2013-OS-0133]

RIN 0790-ZA11

Military Lending Act Limitations on Terms of Consumer Credit Extended to Service Members and Dependents

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Interpretive rule.

SUMMARY: The Department of Defense (Department) is interpreting its regulation implementing the Military Lending Act (the MLA). The MLA as implemented by the Department, limits the military annual percentage rate (MAPR) that a creditor may charge to a maximum of 36 percent, requires certain disclosures, and provides other substantive consumer protections on “consumer credit” extended to Service members and their families. On July 22, 2015, the Department amended its regulation primarily for the purpose of extending the protections of the MLA to a broader range of closed-end and open-end credit products (the July 2015 Final Rule). This interpretive rule provides guidance on certain questions the Department has received regarding compliance with the July 2015 Final Rule.

DATES: *Effective Date:* August 26, 2016.

FOR FURTHER INFORMATION CONTACT: Marcus Beauregard, 571-372-5357.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

In July, 2015, the Department of Defense (Department) issued a final rule¹ (the July 2015 Final Rule) amending its regulation implementing the Military Lending Act (MLA)² primarily for the purpose of extending the protections of the MLA to a broader range of closed-end and open-end credit products, rather than the limited credit products that had been defined as “consumer credit.”³ Moreover, among

other amendments, the July 2015 Final Rule modified provisions relating to the optional mechanism a creditor may use when assessing whether a consumer is a “covered borrower,” modified the disclosures that a creditor must provide to a covered borrower, and implemented the enforcement provisions of the MLA.

Subsequently, the Department received requests to clarify its interpretation of points raised in the July 2015 Final Rule. The Department is issuing this interpretive rule to inform the public of its views. The Department has chosen to provide this guidance in the form of a question and answer document to assist industry in complying with the July 2015 Final Rule. This interpretive rule does not substantively change the regulation implementing the MLA, but rather merely states the Department’s preexisting interpretations of an existing regulation. Therefore, under 5 U.S.C. 553(b)(A), this rulemaking is exempt from the notice and comment requirements of the Administrative Procedure Act, and, pursuant to 5 U.S.C. 553(d)(2), this rule is effective immediately upon publication in the **Federal Register**.

II. Interpretations of the Department

The following questions and answers represent official interpretations of the Department on issues related to 32 CFR part 232. For ease of reference, the following terms are used throughout this document: MLA refers to the Military Lending Act (codified at 10 U.S.C. 987); MAPR refers to the military annual percentage rate, as defined in 32 CFR 232.3(p); TILA refers to the Truth in Lending Act (codified at 15 U.S.C. 1601 *et seq.*); Regulation Z refers to the regulation, and interpretations thereof, issued by the Consumer Financial Protection Bureau (or the Board of Governors of the Federal Reserve System, as applicable) to implement TILA, as defined in 32 CFR 232.3(s); DMDC refers to the Defense Manpower Data Center.

1. What types of overdraft products are within the scope of 32 CFR 232.3(f) defining “consumer credit”?

Answer: The MLA regulation generally directs creditors to look to provisions of TILA and its implementing regulation, Regulation Z, in determining whether a product or service is considered “consumer credit” for purposes of the MLA.⁴ Also, the

supplementary information to the July 2015 Final Rule discusses coverage of overdraft products.

The MLA regulation defines “consumer credit” as credit offered or extended to a covered borrower primarily for personal, family or household purposes that is either subject to a finance charge or payable by a written agreement in more than four installments, with some exceptions. The exceptions include: Residential mortgage transactions; purchase money credit for a vehicle or personal property that is secured by the purchased vehicle or personal property; certain transactions exempt from Regulation Z (not including transactions exempt under 12 CFR 1026.29); and credit extended to non-covered borrowers consistent with 32 CFR 232.5(b). Although coverage by the MLA and the MLA regulation is not completely identical to that of TILA and Regulation Z, the July 2015 Final Rule amends the definition of consumer credit under the MLA to be more consistent with how credit is defined under TILA. The supplementary information to the July 2015 Final Rule states:

As proposed, the Department is amending its regulation so that, in general, consumer credit covered under the MLA would be defined consistently with credit that for decades has been subject to TILA, namely: Credit offered or extended to a covered borrower primarily for personal, family, or household purposes, and that is (i) subject to a finance charge or (ii) payable by a written agreement in more than four installments.⁵

The MLA regulation also defines “closed-end credit” and “open-end credit” with express references to the definitions of the same terms in Regulation Z.

The supplementary information to the July 2015 Final Rule illustrates how to apply these standards specifically with respect to overdraft products and services.⁶ It states that consistent with Regulation Z, an overdraft line of credit with a finance charge is a covered consumer credit product when: It is offered to a covered borrower; the credit extended by the creditor is primarily for personal, family, or household purposes; it is used to pay an item that overdraws an asset account and results in a fee or charge to the covered borrower; and, the extension of credit

connection with certain credit features offered in conjunction with prepaid card accounts). It is the Department’s intention that this part should wherever possible be interpreted consistently with Regulation Z as it evolves in order to harmonize the two regulations and thereby minimize compliance burden.

⁵ 80 FR 43563 (footnotes omitted).

⁶ 80 FR 43579-43580.

¹ 80 FR 435560.

² 10 U.S.C. 987.

³ 32 CFR 232.3(b) as implemented in a final rule published at 72 FR 50580 (Aug. 31, 2007).

⁴ The Department notes that the Consumer Financial Protection Bureau may from time to time revise Regulation Z. *See, e.g.*, 79 FR 77102 (Dec. 23, 2014) (proposing to revise the definition of finance charge with respect to charges imposed in

Phenol (less than 1.5 percent)
 Poloxamer iodine complex
 Povidone-iodine (5 to 10 percent)
 Secondary amylicresols
 Sodium oxychlorosene
 Tribromsalan
 Triclocarban
 Triclosan
 Triple Dye
 Undecoylium chloride iodine complex

* * * * *
 (d) * * *

(41) September 6, 2017, for products subject to paragraph (a)(27)(iii) or (iv) of this section.

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-21337 Filed 9-2-16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-433]

Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical

analysis, or possess), or propose to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

DATES: *Effective date:* September 6, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purposes of this action. 21 U.S.C. 801-971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *." The Attorney General has

delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated by the former Deputy Administrator of the DEA on his own motion and is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

Background

On January 10, 2014, the DEA published a notice of intent to temporarily place quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) into schedule I pursuant to the temporary scheduling provisions of the CSA. 79 FR 1776. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA. 79 FR 7577. That final order was effective on the date of publication, and was based on findings by the DEA that the temporary scheduling of these four synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

¹ As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

Section 201(h)(2) of the CSA requires that the temporary control of these substances expires two years from the effective date of the scheduling order, or on or before February 9, 2016. 21 U.S.C. 811(h)(2). However, the CSA also provides that the temporary scheduling may be extended for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1). *Id.*

Accordingly, on February 5, 2016, the DEA extended the temporary scheduling of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA by one year, until February 9, 2017. 81 FR 6175. Also, on February 5, 2016, DEA published a notice of proposed rulemaking (NPRM) to permanently control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA. 81 FR 6190.

DEA and HHS Eight Factor Analyses

On January 19, 2016, the HHS provided the DEA with four scientific and medical evaluation documents prepared by the FDA entitled “Basis for the recommendation to place 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester or quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” “Basis for the recommendation to place quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5F-PB-22) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” “Basis for the recommendation to place *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” and “Basis for the recommendation to place *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA).” After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA and concluded that these substances warrant control in schedule I of the CSA. Both the DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA-433/DEA-2016-0002) at <http://www.regulations.gov> under “Supporting Documents.”

Determination To Schedule PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

After a review of the available data, including the scientific and medical evaluations and the scheduling recommendations from the HHS, the DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into Schedule I,” proposing to control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA. 81 FR 6190. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before March 7, 2016. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before March 7, 2016.

Comments Received

The DEA received three comments on the proposed rule to control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA.

1. *Request for Alternate Manufacturing/Packaging of Opiate Pills:* One commenter stated that alternate manufacturing and packaging of opiate pills would reduce access to these drugs. The comment was addressed to the FDA.

- *DEA Response:* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are synthetic cannabinoid substances. Opiate pills are not addressed or affected by this rulemaking.

2. *Support for rulemaking:* One commenter gave support for the rulemaking stating that the rule was a step in the right direction.

- *DEA Response:* The DEA appreciates the comment in support of this rulemaking.

3. *Mixed Support and Dissent:* One commenter supported in part and dissented in part, suggesting that research into potential medical uses of these substances be conducted prior to scheduling.

- *DEA Response:* On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA. 79 FR 7577. That final order was based on findings by the DEA that the temporary scheduling of these four synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Adverse effects following ingestion of these substances have included:

Seizures, neurotoxicity, and death for PB-22; respiratory failure, organ failure, and death for 5F-PB-22; diaphoresis, nausea, confusion, tachycardia, and death for AB-FUBINACA; and anxiety, delirium, psychosis, aggression, and seizures for ADB-PINACA. There is no currently accepted medical use for these four substances in treatment in the United States, and the substances fulfill all requirements for placement into schedule I of the CSA.

After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA be controlled in schedule I of the CSA. In response, the DEA reviewed the scientific and medical evaluations of HHS and all other relevant data on PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA and concurs with the HHS evaluations and findings. The current scientific, medical and other evidence on PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA warrant control of these substances in schedule I of the CSA.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluations and accompanying recommendations of the HHS, and the DEA’s consideration of its own eight-factor analyses, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. As such, the DEA is scheduling PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analyses and recommendations of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-

pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9 -THC) and JWH-018;

(2) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) under medical supervision.

Based on these findings, the Administrator of the DEA concludes that quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) including their salts, isomers and salts of isomers, including optical, positional and geometric isomers, whenever the existence of such salts, isomers, salts of isomers, optical isomers, positional isomers, and geometric isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

Upon the effective date of this final rule, any person who handles PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA continues² to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research and conduct of instructional activities or chemical

analysis, and possession of schedule I controlled substances, including those listed below. These controls will continue on a permanent basis:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, or who desires to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312 as of September 6, 2016. Any person who currently handles PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA and is not registered with the DEA must submit an application for registration and may not continue to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA as of September 6, 2016 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of Stocks.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA continue to be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.93 as of September 6, 2016.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must continue to comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302 as of September 6, 2016.

5. *Quota.* Only registered manufacturers are permitted to manufacture PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of September 6, 2016.

6. *Inventory.* Every DEA registrant whose registration currently authorizes handling of these substances and who possesses any quantity of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on the effective date of this final rule is required to continue to maintain an inventory of all stocks of PB-22, 5F-PB-22, AB-FUBINACA, and/

or ADB-PINACA on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA on or after the effective date of the final rule is required to take an initial inventory of all stocks of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317 as of September 6, 2016. Manufacturers and distributors must submit reports regarding PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of September 6, 2016.

8. *Order Forms.* Every DEA registrant who distributes PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305, as of September 6, 2016.

9. *Importation and Exportation.* All importation and exportation of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of September 6, 2016.

10. *Liability.* Any activity involving PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA not authorized by, or in violation of, the CSA or its implementing regulations continues to be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a

² PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 81 FR 6175, Feb. 5, 2016.

hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 7577. On February 5, 2016, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 81 FR 6175. Accordingly, all entities that currently handle or plan to handle these synthetic cannabinoids are

estimated to have already established and implemented the systems and processes required to handle PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on businesses that currently handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA for lawful purposes. This estimate applies to entities large and small. Accordingly, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action will not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: “an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Amend § 1308.11 as follows:

- a. Add paragraphs (d)(51) through (54);
- b. Remove paragraphs (h)(4) through (7);
- c. Redesignate paragraphs (h)(8) through (22) as paragraphs (h)(4) through (18); and
- d. Redesignate paragraphs (h)(26) and (27) as paragraphs (h)(19) and (20).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *	
(d) * * *	
(51) quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	(7222)
(52) quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	(7225)
(53) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	(7012)
(54) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	(7035)
* * * * *	

Dated: August 30, 2016.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-21345 Filed 9-2-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2016-0241]

RIN 1625-AA00

Safety Zone; Swim Around Charleston; Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016-21231 Filed 9-6-16; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-440]

Schedules of Controlled Substances: Temporary Placement of U-47700 Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule the synthetic opioid, 3,4-dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide (also known as U-47700), into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of this synthetic opioid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I controlled substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, exportation, research, and conduct of, instructional activities of this synthetic opioid.

DATES: September 7, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION: Any final order will be published in the **Federal Register** and may not be effective prior to October 7, 2016.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled

Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into

schedule I of the CSA.¹ The Administrator transmitted notice of his intent to place U-47700 in schedule I on a temporary basis to the Assistant Secretary by letter dated April 18, 2016. The Assistant Secretary responded to this notice by letter dated April 28, 2016, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for U-47700. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of U-47700 into schedule I of the CSA. U-47700 is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for U-47700 under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of U-47700 in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

U-47700

The substance U-47700 was first described in 1978 in the patent literature. Publications in the scientific literature in the early 1980's found that U-47700 behaved similarly to morphine in animal models. No approved medical

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

use has been identified for this synthetic opioid, nor has it been approved by the FDA for human consumption. The recent identification of U-47700 in drug evidence and the identification of this substance in association with fatal overdose events indicate that this substance is being abused for its morphine-like properties. In addition, U-47700 is available for purchase over the Internet and is marketed as a “research chemical.” Labels which state “not for human consumption” or “for research purposes only” have been encountered and are likely used in an effort to circumvent statutory restrictions on controlled substance analogues. 21 U.S.C. 813.

Available data and information for U-47700, summarized below, indicate that this synthetic opioid has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA’s three-factor analysis is available in its entirety under the public docket of this action as a supporting document at www.regulations.gov under Docket Number DEA-440.

Factor 4. History and Current Pattern of Abuse

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories across the country. The first laboratory submissions of U-47700 were recorded in the first quarter of 2016; 10 records were reported from January–March 2016 according to NFLIS (query date: 06/20/2016).

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposit in STARLiMS; data from STARLiMS were queried on April 12, 2016. STARLiMS registered one report containing U-47700 in 2016 from Montana. Through information collected from law enforcement reports and personal communications,^{2,3} the DEA is aware of the identification of U-47700 from toxicology reports and submitted evidence to forensic laboratories in

several states, including New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Texas, and Wisconsin. These identifications occurred in 2015 and 2016.

Evidence suggests that the pattern of abuse of synthetic opioids, including U-47700, parallels that of heroin and prescription opioid analgesics. Seizures of U-47700 have been encountered in powder form and in counterfeit tablets that mimic pharmaceutical opioids. U-47700 has also been encountered in glassine bags and envelopes and knotted corners of plastic bags, which demonstrates the abuse of this substance as a replacement for heroin or other opioids, either knowingly or unknowingly. U-47700 has been encountered as a single substance as well as in combination with other substances, including heroin, fentanyl, and furanyl fentanyl.

Factor 5. Scope, Duration and Significance of Abuse

The DEA is currently aware of at least 15 confirmed fatalities associated with U-47700. The information on these deaths occurring in 2015 and 2016 was collected from personal communications and toxicology and medical examiner reports and was reported from New Hampshire (1), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). The population likely to abuse U-47700 appears to overlap with the populations abusing prescription opioid analgesics and heroin, as evidenced by drug use history documented in U-47700 fatal overdose cases. This is further supported by U-47700 being sold on the illicit market in glassine bags, some of which are marked with stamped logos, imitating the sale of heroin. Because abusers of U-47700 are likely to obtain this substance through non-regulated sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (*i.e.* use an illicit drug for the first time) U-47700 abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.*, fentanyl, morphine, etc.).

STARLiMS contains a report in which U-47700 was identified in drug exhibits submitted in 2016 from Montana. A query of NFLIS returned 10 records of U-47700 being identified in exhibits submitted to Federal, State and local forensic laboratories in the first quarter of 2016. The DEA is not aware of any laboratory analyses of drug evidence identifying U-47700 prior to 2015, indicating that this synthetic opioid

only recently became available as a replacement for other opioids that are commonly abused (*i.e.* oxycodone, heroin, fentanyl). U-47700 is available over the Internet and is marketed as a “research chemical” which allows this substance to be easily obtainable.

Factor 6. What, if Any, Risk There Is to the Public Health

U-47700 exhibits pharmacological profiles similar to that of morphine and other mu-opioid receptor agonists. Due to limited scientific data, the potency and toxicity of U-47700 are not known; however, the toxic effects of U-47700 in humans are demonstrated by overdose fatalities associated with this substance. Abusers of U-47700 may not know the origin, identity, or purity of these substances, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone.

Based on the documented case reports of overdose fatalities, the abuse of U-47700 leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

U-47700 has been associated with fatalities. At least 15 confirmed overdose deaths involving U-47700 occurred in 2015 and 2016 in New Hampshire (1), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). This indicates that U-47700 poses an imminent hazard to the public safety.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard To Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of U-47700 poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for U-47700 in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and

² Email from North Carolina Department of Health and Human Services, to DEA (April 13, 2016 09:54 a.m. EST) (on file with DEA).

³ Email from Erie County, Central Police Services, to DEA (March 22, 2016 10:12 a.m. EST) (on file with DEA).

information for U-47700 indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 18, 2016, notified the Assistant Secretary of the DEA's intention to temporarily place this substance in schedule I.

Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule U-47700 in schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling this substance will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular scheduling process. 21 U.S.C. 811(h) (1) and (2). It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. U-47700 will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed

to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553

of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(21).

The addition reads as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(21) 3,4-Dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: U-47700). (9547)

* * * * *

Dated: August 31, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016-21477 Filed 9-6-16; 8:45 am]

BILLING CODE 4410-09-P

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil & Andrea Magermans		2) Date When Request Submitted: 9/12/2016 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? U-47700 Scheduling – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of U-47700 scheduling status: - Rep. Kleefisch Release - Article			



JOEL KLEEFISCH

STATE REPRESENTATIVE • 38TH ASSEMBLY DISTRICT

FOR IMMEDIATE RELEASE
August 31, 2016

FOR MORE INFORMATION:
(608) 266-8551

Kleefisch/Law Enforcement Team Up To Stop Legal “Heroin”

MADISON – Wisconsin is at the center of a frightening new trend. U-47700, synthetic heroin, which is not currently illegal to sell or possess, is growing in popularity and accounts for two Racine County deaths according to Sheriff Christopher Schmaling. “Synthetic heroin does nothing more than fuel the opioid epidemic,” said Schmaling.

The chemical compound mirrors heroin but is different enough that it skirts the restrictions for controlled substances in Wisconsin. State Representative Joel Kleefisch (R) Oconomowoc, Chairman of the Assembly Criminal Justice Committee is taking quick action to make this deadly drug illegal. “Not only can U-47700 be legally purchased on the internet, or on the street, it can be taken as a pill, cooked and injected, or snorted. We must make sure we get ahead of this trend by at very least making it illegal to traffic,” said Kleefisch.

The state’s Department of Justice and law enforcement support Kleefisch’s efforts to take a two-pronged approach. Kleefisch will write legislation to make U-47700 illegal to sell or possess and encourage efforts for the state’s Controlled Substances Board to add it to the list of banned substances through administrative rule.

“This drug is as deadly, if not more deadly, than heroin,” said Sheriff Schmaling, “We’re 100 percent behind Kleefisch getting this done as soon as possible. People who buy it don’t understand the potency of what they’re buying”.

Kleefisch is heading a coalition to combat heroin. Its members are considering all aspects of the growing epidemic from over-prescription at the pharmacy to street sales to effective treatments for addiction.

For more information or answers to your questions please contact Joel Kleefisch at (888) 534-0038 or Racine County Sheriff Christopher Schmaling at (262) 636-3822.

###

U-47700 kills two in Racine County

- ANDREW DAWSON andrew.dawson@journaltimes.com
- Aug 15, 2016
- [9](#)

RACINE COUNTY — A quick internet search, a simple online order and soon enough U-47700 could be at your doorstep.

U-47700 is a currently legal, synthetic opiate that is hitting the streets of the U.S. and reportedly caused two deaths in Racine County in June and July, according to Racine County Medical Examiner Michael Payne.

After those deaths and 50 throughout the nation, local and state law enforcement are working to add the drug to the state's controlled substance list, making it illegal.

Both Racine County deaths are being investigated by the Metro Drug Unit, Special Investigations Unit and Gang Task Force, according to Racine District Attorney Rich Chiapete.

“As with all of these controlled substances, we will aggressively address this issue,” Chiapete said.

U-47700 recently emerged in the United States. It is a synthetic opioid that is legal in the U.S. though is just as dangerous as other opiates, according to Payne.

Payne said the deaths in Racine County occurred on the east and west ends of the county. Both cases involved men, although he could not name the individuals because there are open investigations into their cases. Though final autopsy reports have not come in, the deaths are confirmed to be caused by U-47700, Payne said.

One is confirmed in an adjacent county as well, according to Payne.

“This is just as dangerous, if not more dangerous than any other synthetic opiate that is illegal.” Payne said.

Many synthetic opioids are scheduled under state and federal statutes, which means they are categorized as controlled substances. What makes U-47700 legal is its chemical makeup. It is almost identical to regulated synthetics and mimics the effects of those synthetic opioids, but this exact formula was never scheduled.

“Synthetic opioid substances like U-47700 are very concerning because they are so potent, addictive and dangerous,” said Robert Bell, the Drug Enforcement Administration's Milwaukee assistant special agent in charge. “Abusing these types of powerful opioid substances could be very damaging — the results could be deadly.”

With the drug now entering the U.S., there is worry that this drug, created originally in the 1970s, will cause problems sooner rather than later, leaving many to call for action.

"U-47700 will kill you," Payne said. "It's something to be considered at this point a health hazard to people who elect to try this or use this."

'Russian roulette'

Bell said that because U-47700 was not approved by the FDA, and because its effects mimic those of other dangerous synthetic opiates, the risk of taking the drug is high.

"Experimenting with them is like playing Russian roulette," Bell said. "You don't know what you're getting and the first time could be the last time."

Chris Eberlein, medical adviser for the southwest region of the Department of Health Services, said the drug has the same effects as most opiates and is often mixed into a "drug cocktail."

Once in the body, the central nervous system fails, breathing becomes harder, the body goes into respiratory arrest, then cardiac arrest and, in many cases, death.

"The cartels or whomever make them overseas will produce them in a lab to make something much more potent," Eberlein said.

Payne said he worries that because people can obtain U-47700 on the internet legally, that they will mistake it as a safe substance. However, he said that is not the case at all.

Racine County Sheriff Christopher Schmaling said that U-47700 needs to be scheduled because of the present dangers it creates.

"I'm very concerned with the two deaths that have occurred in the county," Schmaling said. "Like any other street drug, addicts are unaware of its potency, thus causing accidental overdoses."

Scheduling to be determined

Though U-47700 is not currently listed as a controlled substance, the Wisconsin DEA and the Controlled Substances board for the Wisconsin Department of Safety and Professional Services are looking to schedule the drug in the future.

Payne said that drug trends are seen at the grassroots levels before they reach the national or even state levels.

"We're going to see this before it reaches the federal level," he said. "We knew we had a heroin problem before the state did."

The DEA is investigating the drug and working with legislators to potentially schedule in the future.

"I think I can safely say steps are being taken to control it under the Federal Controlled Substances Act," Bell said. "A lot of info needs to be gathered before that happens. The DEA is looking at the substance and evaluating with an eye toward scheduling it."

Though it is not scheduled, prosecution is still possible for distributing the substance.

"We're more concerned with if we identify people who are distributing the substance and putting users and others at risk," Bell said. "Prosecution could be brought forward under the Federal Analogue Act."

The state Controlled Substances Board will meet Sept. 20 to discuss scheduling U-47700. Though the state usually goes with what is federally scheduled, the board has the power to schedule drugs in the state.

"We're going to put it on the next Controlled Substances Board's agenda for potential scheduling," said Jeff Weigand, assistant deputy secretary at the Department of Department of Safety and Professional Services.

Assembly Speaker Robin Vos, R-Rochester, said it is important to get drugs like this scheduled.

"While the Legislature has passed more than a dozen laws to help combat the problem, tragedies like these make it clear more needs to be done," Vos said. "It's essential that law enforcement has the necessary tools to fight the spread of these new drugs, which includes exploring the placement of this compound on the controlled substance list."

With the two deaths confirmed in the county, and three confirmed in southeastern Wisconsin in the past six weeks, Payne hopes the drug is scheduled sooner rather than later.

"I don't need another name up on my board," Payne said.



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

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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Statewide Naloxone Standing Order – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the new standing order for naloxone.			

STATEWIDE NALOXONE STANDING ORDER STATUS

Start Date (active team work): June 23,2016

Team: Lisa Bullard-Cawthorne, Kerry Zaleski, Crystal Gibson, Jennifer Tranmer; Dr. Jon Meiman

www.dhs.wisconsin.gov/opioids/standing-order.htm

	ACCOMPLISHMENTS	FUTURE WORK/ OUTSTANDING ISSUES
Statewide Naloxone Standing Order		
	<p>Finalized, signed by Dr. Jon Meiman and on Webpage on August 26, 2016. Revised and signed again by Jon Meiman on August 31, 2016</p> <p>As of September 7, 34 pharmacies signed up plus 2 chains (96 pharmacies) will be shortly. Hometown Pharmacy of Fitchburg (Chair of Pharmacy Examining Board) was first to sign up on August 26.</p> <p><i>Input received by Dr. Randy Brown and Aleksandra Zgierska—UW Family Medicine, Doug Engelbert (Pharmacist @ DHS), Pharmacy Society of WI-PSW folks (Anna Dopp, Sarah Sorum, Kari Trapskin, Tia), Thad Schumacher (Pharmacy Examining Board--PEB), Ian Hamilton (Community Pharmacy), Jenny Ullsvik (DHS-OLC)</i></p>	<p>Determination of process for chain pharmacies.</p>
Pharmacist & Pharmacy Technician Education		
	<p>Training recommendations for one hour training requirement listed in Standing order</p> <p>Plans underway for partnership with PSW on expanded training; notification when ready (October 2016).</p>	<p>PSW will be augmenting national training on naloxone, with how to use standing order video (CE credits provided)</p>
Pharmacist/Pharmacy Technician tools		
	<p>Tools developed, finalized and located on website on August 26. Revisions are being made (format/visual) and will be posted by 9/12.</p> <ul style="list-style-type: none"> • Naloxone kit assembly • Red Flag reminder • Screening checklist for patient 	<p>Suggestions made for slight revisions (9/6); will finish and repost on (9/8)</p>

<p><i>Input received by Sarah Sorum (PSW), Doug Engelbert (DHS), Thad Schumacher (PEB), Ian Hamilton (Community Pharmacy), Scott Stokes (ARCW)</i></p>	
<p>Patient Education</p>	
<p>Materials developed, finalized and placed on website on August 26, 2016 Revisions are being made (format/visual) and will be posted by 9/12.</p> <ul style="list-style-type: none"> • Opioid Safety & Overdose Education brochure • Overdose response/administering naloxone handout • Patient Resource Guide (medication disposal, SUD treatment referral, naloxone resource) <p><i>National Research on order of steps to take when responding to an overdose and using naloxone. Settled on recommendations of WA state (Prescribe to Prevent) and NY state DOH Technical Workgroup and agreed upon by local expert Dr. Randy Brown and Dr. Jon Meiman:</i></p> <ul style="list-style-type: none"> • <i>Call 911; Give rescue breaths; Administer naloxone....</i> <p><i>Local input received by ARCW (Scott Stokes), PSW (Sarah Sorum), PEB (Thad Schumacher), Randy Brown, Skye Tikkanen (SC/Connections Counseling), HIV/Hep C staff (Sheila, Lauren), Community Pharmacy (Ian Hamilton), DMHSAS staff (Christy Niemuth), Parent Addiction Network (Ellen Taylor Powell), United We CAN (Lori Cross Schotten), Public Health Madison & Dane County & NM DPH (Melissa Heinz).</i></p>	<p>Suggestions made for slight revisions (9/6); will finish and repost on (9/8)</p>
<p>Data Tracking</p>	
<p>Pharmacy participation information (on REDCap). Once pharmacy has agreed to meet requirements, they provide contact information, then they will be taken to link to signed standing order.</p> <p>Dispensing data is entered directly into REDCap every quarter:</p> <ul style="list-style-type: none"> • Quarterly reports on dispensing is a requirement of the contract: total doses dispensed, naloxone dispensed by standing order, total refill doses, naloxone by type • Excel spreadsheet set up for pharmacy chains to provide data and send to mailbox. 	<p>Contact info collected on REDCap. List will be used to send reminders about data reporting and annual renewals needed. A list will be compiled of participating pharmacies.</p>

	<p><i>Input received from Pharmacists – Sarah Sorum (PSW), Doug Engelbert (DHS), Thad Schumacher (PEB) & Ian Hamilton (Pharm Tech at Community Pharmacy).</i></p> <ul style="list-style-type: none"> • Met with PDMP to find out what data would be possible to collect, if approved, to include naloxone • Brandeis University PDMP School of Excellence contacted to find out examples of data reporting and use of data for surveillance. (Liz Feder) 	<p>Conversations with PDMP to see what information we can provide to assist in introducing legislation on adding naloxone to PDMP</p> <ul style="list-style-type: none"> • Research about what other states are doing • Liz work with WI Leg. Counsel
<p>Naloxone reimbursement</p>		
	<ul style="list-style-type: none"> • Kimberly Smithers (Medicaid) contacted us on 8/26 to let us know that they will reimburse for Standing Order of physician signing standing order if MA certified. DR. JON MEIMAN IS MA CERTIFIED! • Liz Feder met with WEA Trust (Tim Bartholomew) to discuss barriers to reimbursement of naloxone – would potentially cover patients of record (prescribed opioids or SUD treatment) 	<ul style="list-style-type: none"> • Liz to continue discussions with WEA Trust • Attend WQHC meeting (9/13) to ask about naloxone reimbursement issues among private insurers. • Lisa to contact Angie at CDC to contact Change Labs for knowledge about other states. • Work with NSCL staff for WI group to gather info on other states. • Liz to contact Fred Brason (Lazarus Program) to find out about their funding sources
<p>Promotion of Standing Order: Pharmacists</p>		
	<ul style="list-style-type: none"> • Video finalized and aired (on big screen) at Opioid Panel discussion at PSW Annual meeting and located on Standing order webpage on 8/26 • Joint memo (DHS, PSW, PEB) handed out at PSW meeting • PSW Annual Meeting: <ul style="list-style-type: none"> ○ Tom Engels raised issue of naloxone at legislative breakfast (August 26 – 7:00 am) ○ Governor launched, with Jon Meiman signing (8/26 - 2:00 pm). Showed general public video, ○ Jon Meiman sat on Panel to give overview of standing order and show Pharmacist video (August 27 – 9:30 am) 	<p>Memo to go on PSW website</p> <p>Filming of launch to go on website.</p> <p>Compile Governor’s office, PSW and WMS news releases and comments about launch</p> <p><i>Presentation at Pharmacy Examining Board in September.</i></p>
<p>Promotion of Standing Order: General Public</p>		
	<ul style="list-style-type: none"> • General public video aired at launch and posted on website on 8/26 <p><i>Developed by the Secretary’s Office</i></p>	

Promotion of Standing Order: Medical Providers	
<ul style="list-style-type: none"> • Media release sent out from WMS and on Wheeler report • Conversations took place with Mark Grapentine at PSW Annual Meeting (Public Affairs WMS) and discussed future collaboration. <ul style="list-style-type: none"> ○ Suggested we have meeting with WMS & MEB (Tim Westlake) 	Set up meeting with WMS & MEB.
Website	
<ul style="list-style-type: none"> • All components posted on August 26 at 1:00 pm • Shared Mailbox for queries set up on (9/7/16) 	

Outstanding Questions/Issues:

- Cost containment of Naloxone
- Reimbursement for naloxone and reimbursement for time spent educating patients
- Minimum age for picking up naloxone
- Pharmacy plan for crisis overdose at or near pharmacy – not different for other drugs pharmacies have and does not seem to be a concern for most pharmacists



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SCOTT WALKER
OFFICE OF THE GOVERNOR

GOVERNOR WALKER ANNOUNCES EXPANDED ACCESS TO NALOXONE

POTENTIALLY LIFE-SAVING DRUGS CAN REVERSE EFFECTS OF OPIOID OVERDOSE, INCLUDING PRESCRIPTION OPIOIDS AND HEROIN

Friday, August 26, 2016 - Press Release

Wisconsin Dells – Governor Scott Walker today joined state health officials at the Pharmacy Society of Wisconsin annual meeting to announce the signing of a statewide naloxone standing order, which allows pharmacists to dispense the medication that reverses the effects of an opioid overdose without requiring individual prescriptions.

Governor Walker signed Wisconsin Act 115 in December of 2015, to allow practitioners to prescribe an opioid antagonist to pharmacies under a standing order. This is the latest of the state’s efforts to combat opioid use, abuse, and overdose, which includes the HOPE (Heroin Opiate Prevention and Education) legislation package.

“In Wisconsin, and nationwide, we’re seeing lives lost and families shattered by opioid overdoses, whether from heroin or prescription painkillers, in our urban centers and rural areas,” said Governor Walker. “This standing order allows pharmacies the ability to make this life-saving drug more accessible for friends, family and loved ones of those at risk of overdose, and potentially open the door for treatment and recovery.”

Naloxone is a nonaddictive medication that blocks the effects of opioids on the brain and restores breathing. Administering naloxone to someone experiencing an overdose can provide the extra time needed for emergency responders to arrive on the scene.

“Naloxone is safe and effective. Newer ways to administer the drug make it easier to give naloxone in a life-and-death situation,” said Dr. Jon Meiman, Chief Medical Officer for the Bureau of Environmental and Occupational Health in DHS’ Division of Public Health, who signed the standing order. “Allowing pharmacists to provide naloxone without a prescription can help reduce the number of deaths due to an opioid overdose. “

Opioid overdose deaths have steadily increased over the past 15 years in Wisconsin. In 2014, there were 392 deaths due to prescription drugs in Wisconsin and 266 due to heroin. Since 2009, opioid overdoses have exceeded car crashes as the leading cause of injury deaths in Wisconsin.

To learn more, visit the DHS website [here](#).

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Scott Walker - 45th Wisconsin Governor



Governor Walker, DHS, and PSW Debut Statewide Standing Order for Naloxone

FOR IMMEDIATE RELEASE

August 26, 2016

Contact: Danielle M. Laurent, MPH

Director of Public Affairs

dlaurent@pswi.org

WISCONSIN DELLS – At the Pharmacy Society of Wisconsin’s Annual Meeting Friday, Governor Scott Walker announced a statewide standing order that will allow pharmacists across the state to dispense naloxone to those deemed at risk for an opioid overdose.

In response to the heroin and prescription opioid addiction epidemic in Wisconsin, which resulted in at least 850 deaths in 2014, the state of Wisconsin enacted more than 15 new laws aimed at combatting opioid-related deaths. One of these laws allows pharmacists to order and dispense naloxone without a prescription, so long as the pharmacist has a standing order from a physician. Administration of naloxone, an opioid antagonist, can prevent drug overdose deaths when given in a timely manner.

Dr. Jonathan Meiman, Chief Medical Officer at the Department of Health Services, has signed the statewide standing order for naloxone prescriptions to be ordered and filled by pharmacists, allowing all pharmacists who meet certain training and other qualifying criteria across the state to dispense naloxone to those deemed to have a medical need for the antidote.

Governor Walker praised the signing of the standing order as a positive step toward combatting preventable deaths from opioid abuse with the help of pharmacists:

“In Wisconsin, and nationwide, we’re seeing lives lost and families shattered by opioid overdoses, whether from heroin or prescription painkillers, in our urban centers and rural areas,” said Governor Scott Walker. “This standing order allows our pharmacy partners at the Pharmacy Society of Wisconsin and the Pharmacy Examining Board to make opioid antagonist drugs, like naloxone, more accessible for friends, family and loved ones of those at risk of overdose, and will open the door for treatment and recovery.”

###

About the Pharmacy Society of Wisconsin

The Pharmacy Society of Wisconsin has championed the cause of helping pharmacists deliver the best care for their patients. Today, with more than 3500 members statewide, PSW is the professional organization that pharmacists, pharmacy technicians and student pharmacists join to further their careers, advance the standing of pharmacists, and improve the care of patients in Wisconsin. PSW invites all pharmacy professionals in the state who share the organization’s vision to be part of its voice. Please visit us online at www.pswi.org for more details.



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Top Stories

Order allows pharmacists to provide naloxone without prescription

August 29, 2016

Wisconsin pharmacists can offer an antidote that counteracts the effects of a heroin or painkiller overdose without a prescription if their pharmacies sign onto a statewide standing order approved by the Department of Health Services Friday.

The order is the result of [legislation](#) enacted last December as part of Marinette Republican Rep. John Nygren's Heroin, Opioid Prevention and Education Agenda. Under the law, pharmacists who have a standing order from a doctor can dispense naloxone to those at risk for an opioid overdose or to people who can help those at risk.



Gov. Scott Walker speaks about the standing order at the Pharmacy Society of Wisconsin's annual meeting in Wisconsin Dells on August 26, 2016.

Dr. Jon Meiman, chief medical officer at DHS, signed the standing order at the Pharmacy Society of Wisconsin's annual meeting.

"Our ultimate goal is prevention," Gov. Scott Walker said at the meeting. "They can't very well recover if they're not

alive.”

Naloxone, also known by the brandname Narcan, blocks the effects of opioids on the brain and restores breathing to overdose victims, according to a statement from Walker’s office. It can also provide more time to allow emergency responders to arrive at the scene.

Last year, there were 658 deaths due to heroin and prescription drugs, according to Walker’s office. Opioid overdoses have been the leading cause of injury death since 2009 in Wisconsin.

Under the order, managing pharmacists at pharmacies that want to offer naloxone without a prescription can sign the order. Pharmacists have to complete an hour of training recommended by the Department of Health Services and PSW before they can dispense the medication.

“All these materials have been developed with pharmacists and addiction medical efforts throughout the state,” Meiman at DHS said at a panel Saturday. “We think that they’re going to help put naloxone in the hands of people who need it the most.”

Dr. Donn Dexter, chief medical officer at the Wisconsin Medical Society, lauded the decision in a statement.

“By making naloxone more readily available to individuals at-risk for heroin overdose or those close to them, today’s action has the potential to save countless lives,” Dexter said. “It’s another step in the right direction as we all work to address this public health crisis.”

Read [more](#).



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

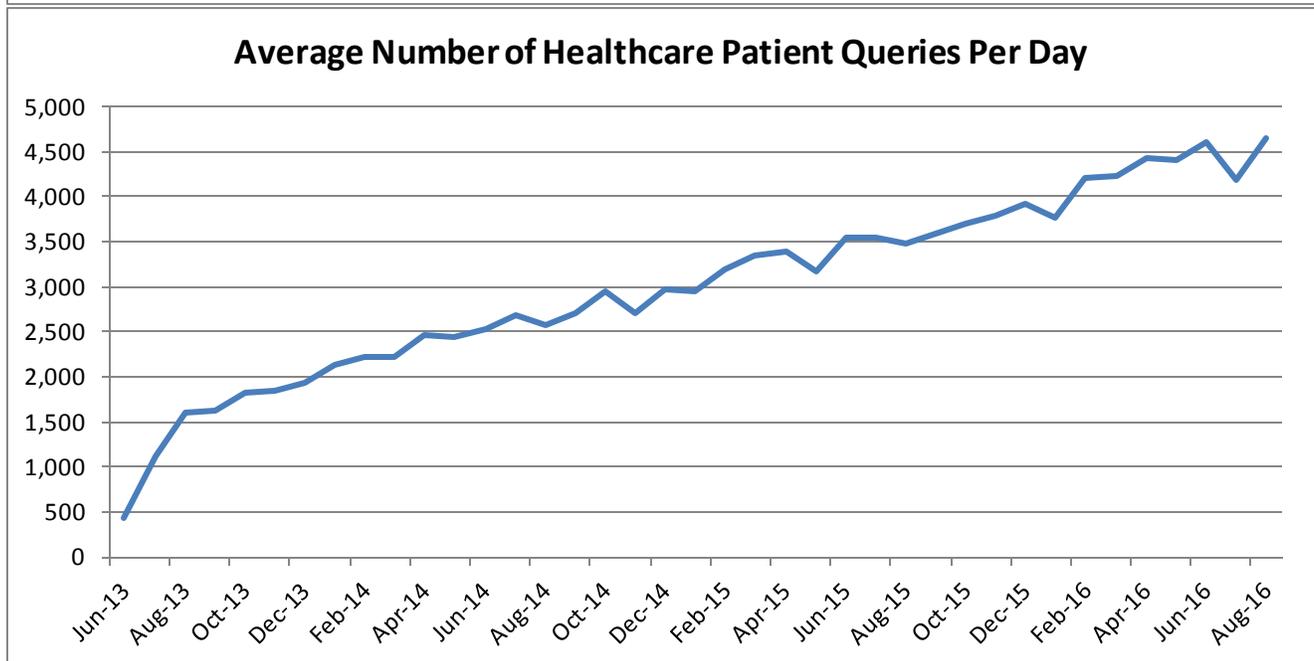
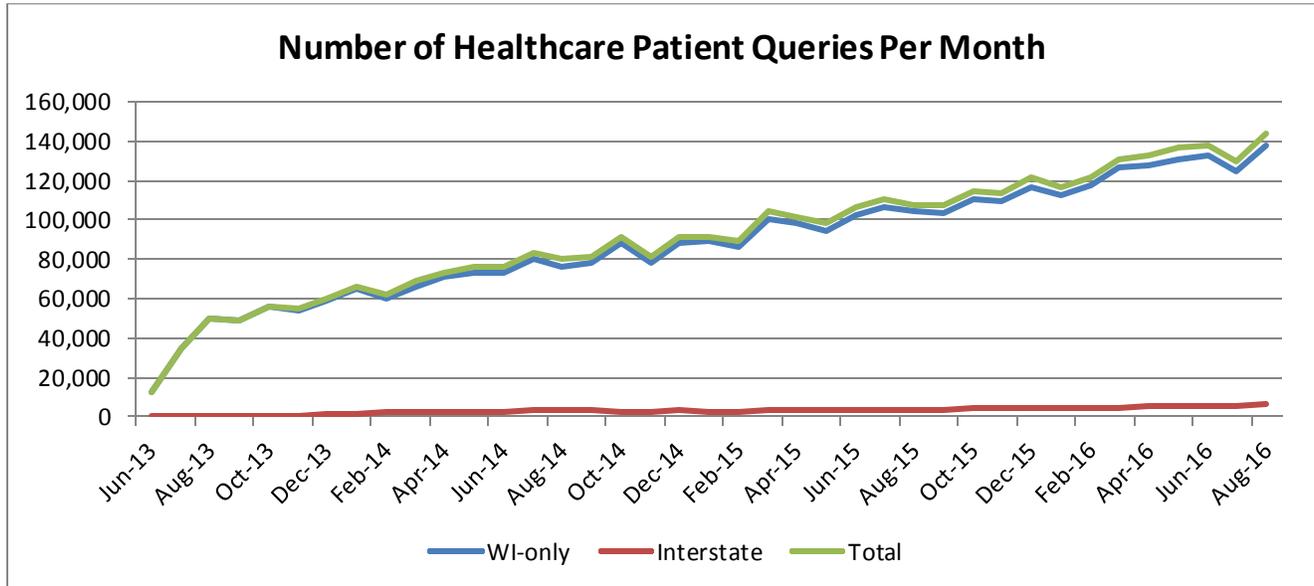
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1) Name and Title of Person Submitting the Request: Chad Zadrazil & Andrea Magermans		2) Date When Request Submitted: 9/12/2016 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Statistics – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the operations of the PDMP.			

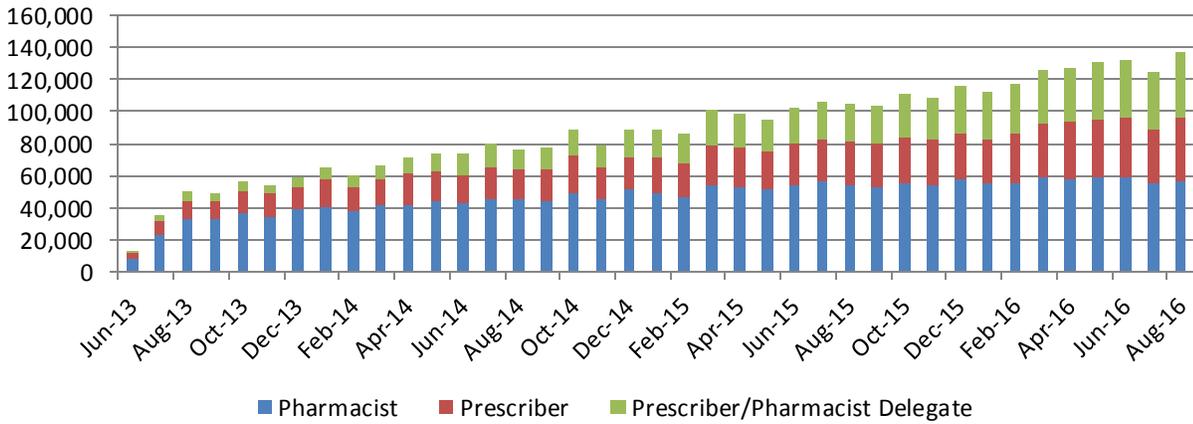


Operational Statistics of the WI PDMP

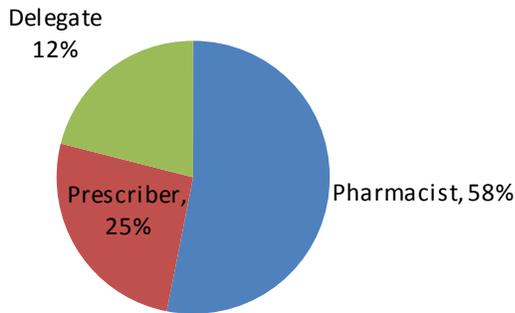
Compiled on September 9, 2016



Healthcare Patient Queries Performed by User Group

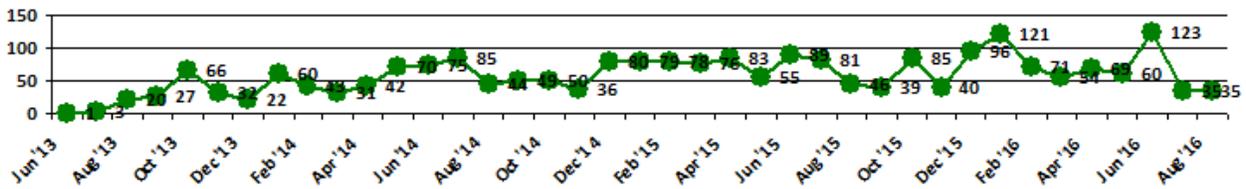


Healthcare Patient Queries Performed by User Group



- Law enforcement and government requests:

Requests By Month

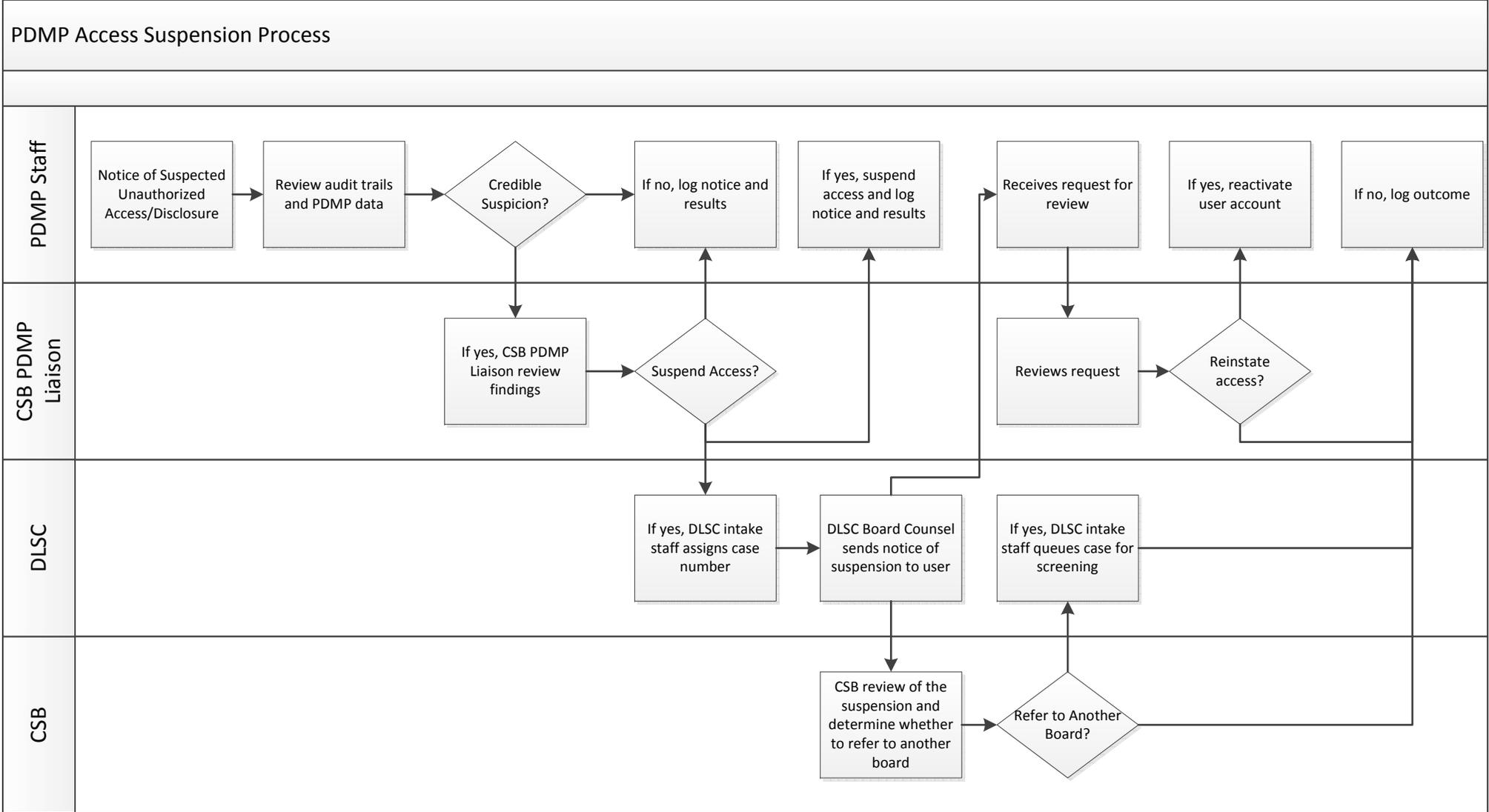


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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Suspension Process – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the process to review suspected misuse of the PDMP and streamline the suspension and review process.			

Draft PDMP Suspension Process
For 9/20/16



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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Identification of pharmacy or facility under CSB 4.09 – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the Board’s implementation of CSB 4.09 (2) (c) through (d), Wis. Admin for integration of PDMP records into electronic health records.			

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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? ePDMP Development – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the development status of the Enhanced Prescription Drug Monitoring Program (ePDMP).			

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4) Meeting Date: 9/20/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Quarterly Report – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the quarterly PDMP report requirements of 961.385 (5) and (6): - PDMP User Satisfaction Survey			

shall be determined by the controlled substances board but shall not exceed \$5.

(6) Persons who possess a valid permit issued under this section are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

(7) The controlled substances board may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative or other proceeding to identify or to identify to the board the individuals who are the subjects of research for which the authorization was obtained.

(8) The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records other than those that may be withheld under sub. (7), submissions of protocols, filing of applications and suspension or revocation of permits.

Cross-reference: See also ch. CSB 3, Wis. adm. code.

(9) The controlled substances board may suspend or revoke a permit upon a finding that there is a violation of the rules of the board.

History: 1971 c. 219; 1975 c. 110, 199; 1977 c. 26; 1995 a. 448 s. 233; Stats. 1995 s. 961.335; 2013 a. 198; 2015 a. 298.

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

(1) The direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a).

(2) The transfer by the ultimate user, or by another person that lawfully possesses the controlled substance or controlled substance analog, of a controlled substance or controlled substance analog to a drug disposal program that has been authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a), and that accepts the controlled substance or controlled substance analog.

History: 2013 a. 198.

961.34 Controlled substances therapeutic research.

(1) Upon the request of any practitioner, the controlled substances board shall aid the practitioner in applying for and processing an investigational drug permit for marijuana under 21 USC 355 (i). If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies can distribute the marijuana to patients upon written prescription. Only pharmacies located within hospitals are eligible to receive the marijuana for distribution. The controlled substances board shall also approve which practitioners can write prescriptions for the marijuana.

(2) (a) Upon the request of any physician, the controlled substances board shall aid the physician in applying for and processing an investigational drug permit under 21 USC 355 (i) for cannabidiol as treatment for a seizure disorder. If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients.

(b) If cannabidiol is removed from the list of controlled substances, or if cannabidiol is determined not to be a controlled substance, under schedule I of 21 USC 812 (c), the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients as treatment for a seizure disorder.

History: 1981 c. 193; 1983 a. 189 s. 329 (18); 1985 a. 146 s. 8; 1995 a. 448 ss. 16 to 19; Stats. 1995 s. 961.34; 2013 a. 267.

Reefer Madness: Lighting Up in the Dairyland. Bailey. Wis. Law. Nov. 2014.

961.36 Controlled substances board duties relating to diversion control and prevention, compliance with controlled substances law and advice and assistance.

(1) The controlled substances board shall regularly prepare and make available to state regulatory, licensing and law enforcement agencies descriptive and analytic reports on the potential for diversion and actual patterns and trends of distribution, diversion and abuse within the state of certain controlled substances the board selects that are listed in s. 961.16, 961.18, 961.20 or 961.22.

(1m) At the request of the department of safety and professional services or a board, examining board or affiliated credentialing board in the department of safety and professional services, the controlled substances board shall provide advice and assistance in matters related to the controlled substances law to the department or to the board, examining board or affiliated credentialing board in the department making the request for advice or assistance.

(2) The controlled substances board shall enter into written agreements with local, state and federal agencies to improve the identification of sources of diversion and to improve enforcement of and compliance with this chapter and other laws and regulations pertaining to unlawful conduct involving controlled substances. An agreement must specify the roles and responsibilities of each agency that has information or authority to identify, prevent or control drug diversion and drug abuse. The board shall convene periodic meetings to coordinate a state diversion prevention and control program. The board shall assist and promote cooperation and exchange of information among agencies and with other states and the federal government.

(3) The controlled substances board shall evaluate the outcome of its program under this section and shall annually submit a report to the chief clerk of each house of the legislature, for distribution to the legislature under s. 13.172 (3), on its findings with respect to its effect on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances.

History: 1981 c. 200; 1987 a. 186; 1995 a. 305 ss. 2, 3; 1995 a. 448 s. 234; Stats. 1995 s. 961.36; 1997 a. 35 s. 339; 2011 a. 32.

961.37 Law enforcement duty. (1) A law enforcement officer shall report as provided in sub. (2) if the law enforcement officer, while acting in an official capacity, does any of the following:

(a) Encounters a situation in which the law enforcement officer reasonably suspects that a violation of this chapter involving a monitored prescription drug, as defined in s. 961.385 (1) (ag), is occurring or has occurred.

(b) Encounters an individual who the law enforcement officer believes is undergoing or has immediately prior experienced an opioid-related drug overdose, as defined in s. 256.40 (1) (d), or a deceased individual who the law enforcement officer believes died as a result of using a narcotic drug.

(c) Receives a report of a stolen controlled-substance prescription.

(2) A law enforcement officer under sub. (1) shall report to the law enforcement agency that employs him or her all of the following:

(a) The name and date of birth of all of the following, if applicable:

1. The individual who is suspected of violating this chapter.
2. The individual who experienced an opioid-related drug overdose.
3. The individual who died as a result of using a narcotic drug.
4. The individual who filed the report of a stolen controlled-substance prescription.

5. The individual for whom a prescription drug related to an event under subd. 1., 2., 3., or 4. was prescribed.

ers, pharmacists, and others to whom the board may make disclosures under par. (c).

(2m) (a) The rules promulgated under sub. (2) may not require that a record submitted to the board before 2 years after April 9, 2014, contain the name recorded under s. 450.11 (1b) (bm).

(b) After consultation with representatives of licensed pharmacists and pharmacies, and subject to the approval of the secretary of safety and professional services, the board may delay the requirement that a record submitted to the board contain the name recorded under s. 450.11 (1b) (bm) for an additional period beyond the date specified in par. (a).

(3) (a) A pharmacy, pharmacist, or practitioner is immune from civil or criminal liability or professional discipline arising from the pharmacy's, pharmacist's, or practitioner's compliance in good faith with this section or with rules promulgated under this section.

(b) Nothing in this section may be construed to require a pharmacy or pharmacist to obtain, before dispensing a monitored prescription drug to a patient, information about the patient that has been collected pursuant to the program established under sub. (2).

NOTE: Par. (b) is shown as amended eff. 4–1–17 by 2015 Wis. Act 266. Prior to 4–1–17 it reads:

(b) Nothing in this section may be construed to require a pharmacy, pharmacist, or practitioner to obtain, before prescribing or dispensing a monitored prescription drug to a patient, information about the patient that has been collected pursuant to the program established under sub. (2).

(4) Records generated under the program under this section are not subject to inspection or copying under s. 19.35.

(5) (a) Beginning with the 3rd calendar quarter of 2016, no later than 30 days after the end of each calendar quarter, the board shall conduct a review of the program under this section to evaluate the actual outcomes of the program compared with projected outcomes, as determined by the board. The board's review shall include an evaluation of all of the following:

1. The satisfaction with the program of pharmacists, pharmacies, practitioners, and other users of the program.

2. The program's impact on referrals of pharmacists, pharmacies, and practitioners to licensing or regulatory boards for discipline and to law enforcement agencies for investigation and possible prosecution.

(b) This subsection does not apply after October 30, 2020.

(6) Beginning with the 3rd calendar quarter of 2016, no later than 30 days after the end of each calendar quarter, the board shall provide a report to the department of safety and professional services that includes all of the following:

(a) The results of the board's review under sub. (5). This paragraph does not apply after October 30, 2020.

(b) An assessment of the trends and changes in the use of monitored prescription drugs in this state.

(c) The number of practitioners, by profession, and pharmacies submitting records to the board under the program in the previous quarter.

(d) A description of the number, frequency, and nature of submissions by law enforcement agencies under s. 961.37 (3) (a) in the previous quarter.

(e) A description of the number, frequency, and nature of requests made in the previous quarter for disclosure of records generated under the program.

(f) The number of individuals receiving prescription orders from 5 or more practitioners or having monitored prescription drugs dispensed by 5 or more pharmacies within the same 90-day period at any time over the course of the program.

(g) The number of individuals receiving daily morphine milligram equivalents of 1 to 19 milligrams, 20 to 49 milligrams, 50 to 99 milligrams, and 100 or more milligrams in the previous quarter.

(h) The number of individuals to whom both opioids and benzodiazepines were dispensed within the same 90-day period at any time over the course of the program.

(7s) (a) The board may contract with an analytics firm to augment the program under this section with an analytics platform that provides data integration, advanced analytics, and alert management capabilities to detect problematic behaviors of practitioners, pharmacies, pharmacists, and patients.

(b) If the board augments the program under this section as specified in par. (a), the goals of that augmentation shall include all of the following:

1. Allowing the board, with the assistance of the analytics firm, to identify past patterns of abuse, addiction, or criminal activity.

2. Proactively improving painkiller prescribing, informing clinical practice, and protecting patients at risk.

3. Measuring program outcomes at an individual level to minimize the abuse of monitored prescription drugs in this state.

(c) For purposes of this subsection, the board may disclose records generated under the program to an analytics firm with which the board contracts.

History: 2009 a. 362; 2011 a. 260 s. 81; 2013 a. 3, 20, 124, 199; 2015 a. 55; 2015 a. 55 ss. 4477, 4737f to 4731k; Stats. 2015 s. 961.385; 2015 a. 195, 266, 267, 268.

Cross-reference: See also ch. CSB 4, Wis. adm. code.

961.39 Limitations on optometrists. An optometrist who is allowed under s. 449.18 (1) to use therapeutic pharmaceutical agents and under s. 449.18 (6) (am) 2. b. to dispense a contact lens that delivers a therapeutic pharmaceutical agent:

(1) May not prescribe, dispense, or administer a controlled substance included in schedule I or II.

(2) May prescribe, dispense, or administer only those controlled substances included in schedules III, IV, and V that are permitted for prescription or administration under the rules promulgated under s. 449.18 (6) (cm).

(2m) Notwithstanding sub. (1), may prescribe, dispense, or administer any of the following, if permitted for prescription or administration under the rules promulgated under s. 449.18 (6) (cm):

(a) Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with a four-fold or greater quantity of an isoquinoline alkaloid of opium.

(b) Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Shall include with each prescription order all of the following:

(a) A statement that he or she is allowed under s. 449.18 (1) to use therapeutic pharmaceutical agents.

(b) The indicated use of the controlled substance included in schedule III, IV, or V so prescribed or the indicated use of the controlled substance under sub. (2m) (a) or (b) so prescribed.

(4) May not dispense other than as provided under s. 449.18 (6) (am) 2.

History: 1989 a. 31; 1995 a. 448 s. 241; Stats. 1995 s. 961.39; 2005 a. 297; 2009 a. 168; 2015 a. 34.

961.395 Limitation on advanced practice nurses.

(1) An advanced practice nurse who is certified under s. 441.16 may prescribe controlled substances only as permitted by the rules promulgated under s. 441.16 (3).

(2) An advanced practice nurse certified under s. 441.16 shall include with each prescription order the advanced practice nurse prescriber certification number issued to him or her by the board of nursing.

(3) An advanced practice nurse certified under s. 441.16 may dispense a controlled substance only by prescribing or administering the controlled substance or as otherwise permitted by the rules promulgated under s. 441.16 (3).

History: 1995 a. 448.

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

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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Abuse Deterrent Opioids Article – Information Only	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Information only.			



Abuse-Deterrent Opioids: What You Need to Know

Lauri R. Graham; Laurie Scudder, DNP, NP; Douglas Throckmorton, MD | August 25, 2016

Editor's Note:

Addressing the ongoing opioid epidemic in the United States is a complicated task, necessitating a variety of approaches, including education of clinicians and patients, guidance for clinicians on pain management, development of alternative strategies for treating pain, and new regulations (such as prescription drug monitoring programs) to monitor for and detect misuse and abuse of opioids. Critical to the success of these prevention efforts is the development of pain drugs with abuse-deterrent properties. Medscape spoke with Douglas Throckmorton, MD, deputy director for regulatory programs at the Center for Drug Evaluation and Research at the US Food and Drug Administration (FDA), about these up-and-coming formulations designed to reduce the risk for misuse and abuse of opioids.

Opioid Abuse-Deterrent Formulations

Medscape: Can you define abuse-deterrent properties? What makes these products less likely to be abused?

Dr Throckmorton: The term "abuse-deterrent" is often misunderstood to mean "abuse-proof." Abuse-deterrent properties are defined as those properties expected to meaningfully *deter* abuse, even if they do not fully prevent it. Abuse-deterrent properties make certain types of abuse, such as crushing in order to snort or dissolving in order to inject, more difficult or less rewarding. This does not mean that the product is impossible to abuse or that these properties will necessarily prevent addiction, overdose, or death.

Of note, currently marketed abuse-deterrent formulation technologies do not effectively deter one of the most common forms of opioid abuse—which is simply swallowing a number of intact tablets or capsules. Abuse-deterrent opioids do not reduce the risk for opioid addiction, and they carry the same warnings about the risk for addiction as conventional opioids.

Medscape: Can you discuss the data examining the effect that abuse-deterrent opioids could have on misuse and abuse of these products in the community?

Dr Throckmorton: This is an area the agency has been working on for a number of years, and we are prioritizing the need for data and study methods that will help evaluate the impact of abuse-deterrent opioids on misuse and abuse in the community. To collect this important information, FDA is requiring all of the companies that have brand-name opioids with labeling describing abuse-deterrent properties to conduct postmarket studies to determine the impact of abuse-deterrent formulation technologies in the real world. Each company is given a timeline to which they must adhere. These types of studies take several years to conduct and analyze. Data collected will include the amount of prescribing for each product; adverse events related to the use, abuse, and misuse of the products; and epidemiologic data on the rates of abuse and misuse and their consequences (addiction, overdose, and death).

The studies should allow the FDA to assess the impact, if any, attributable to the abuse-deterrent properties in the community. Having that information is critical and will allow us to determine the next steps in this area. It's important to understand that the science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving.

Medscape: How many products with these properties have been approved? How do they differ, and are there clinical scenarios that are particularly appropriate for each?



Douglas Throckmorton, MD, deputy director for regulatory programs, Center for Drug Evaluation and Research, US Food and Drug Administration

Dr Throckmorton: To date, the FDA has approved seven extended-release/long-acting (ER/LA) opioids with labeling describing abuse-deterrent properties (Table) that remain consistent with the FDA's 2015 final guidance for industry, [Abuse-Deterrent Opioids—Evaluation and Labeling](#).

Table. Abuse-Deterrent Products

Product	Formulation	Approval Date
OxyContin®	Oxycodone—crush/extraction resistant	April 2013
Targiniq™ ER	Oxycodone hydrochloride and naloxone	July 2014
Embeda®	Morphine sulfate and naltrexone	October 2014
Hysingla™ ER	Hydrocodone—crush/extraction resistant	November 2014
Morphabond™	Morphine sulfate—crush/extraction resistant	October 2015
Xtampza™ ER	Oxycodone—crush/extraction resistant	April 2016
Troxyca® ER	Oxycodone hydrochloride and naltrexone hydrochloride	August 2016

ER = extended-release

Prescribers should carefully review the labeling of these products for more detailed information on the routes of abuse that each product is expected to deter and the studies that support those conclusions.

Are Abuse-Deterrent Drugs Less Addictive?

Medscape: In a national survey^[1] of internists, family physicians, and general practitioners, nearly one half stated that they believed abuse-deterrent formulations were less addictive than their counterparts. What are the FDA's efforts to provide correct information to clinicians?

Dr Throckmorton: We are working with health professional organizations and medical education providers to help educate prescribers about the value and limitations of current abuse-deterrent technologies. As I noted, abuse-deterrent properties do not signify that a product is abuse-proof; there is currently no technology that completely prevents abuse. Furthermore, addiction to opioid medications, with or without abuse-deterrent properties, can occur even when taken at recommended doses, so it's important that both prescribers and their patients understand these risks before taking any type of opioid medication, abuse-deterrent or not.

Abuse-deterrent properties do not signify that a product is abuse-proof; there is currently no technology that completely prevents abuse.

Medscape: Earlier this year, the FDA released draft recommendations for the evaluation of generic versions of abuse-deterrent opioid drug products. Generic versions should have the same abuse-deterrent properties as their brand-name counterparts. Why is this an important element in the overall strategy to combat the problem of opioid abuse?

Dr Throckmorton: Generic drugs play an important role in the United States, especially for patients in pain. Each year, 100 million Americans experience significant pain, and 9-12 million have significant chronic pain.^[2] In general, generic drugs are important to help keep healthcare costs down. And for the millions of Americans with significant pain and the health systems that serve them, generics are crucial to delivering appropriate and affordable patient care. Many of these people have such serious and painful illnesses as cancer or sickle cell disease, and many have significant residual pain that is not effectively managed by other medications.

We hope that the availability of less costly generic products with abuse-deterrent properties has the potential to accelerate prescribers' shift away from the older products that do not have abuse-deterrent properties. The FDA looks forward to the day, hopefully soon, when most opioids in the United States are marketed in abuse-deterrent forms. To facilitate an open dialogue

on this important issue, and to obtain clinical and scientific input from outside experts, the FDA plans to hold a [public meeting](#) in November to discuss issues related to the development and evaluation of abuse-deterrent technologies, particularly for generic drugs.

Education Is the Cornerstone

Medscape: What are the key points that clinicians should be aware of in educating their patients about opioids?

Dr Throckmorton: The FDA's work to improve the safe use of opioids is taking place within a larger policy framework aimed at addressing opioid abuse while ensuring appropriate access to pain treatment. The FDA has undertaken several efforts that can be helpful to clinicians. The [Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy \(ER/LA REMS\)](#) is a program required by the FDA for all companies who make these products. The goal of the ER/LA REMS is to reduce serious adverse outcomes of inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.

As part of the REMS, all ER/LA opioid analgesic companies must provide:

- Education for prescribers of these medications through accredited continuing education activities supported by independent educational grants from ER/LA opioid analgesic companies; and
- Information that prescribers can use when counseling patients about the risks and benefits associated with ER/LA opioid analgesic use.

It is critically important for clinicians to understand that all currently approved abuse-deterrent opioid products are still capable of being abused.

The FDA developed core messages to be communicated to prescribers in the [Blueprint for Prescriber Education](#). The content is directed to prescribers of ER/LA opioid analgesics but also may be relevant for other healthcare professionals (eg, pharmacists). The ER/LA Opioid Analgesics REMS Program Companies provides a [list](#) of REMS-compliant continuing education activities.

Furthermore, it is critically important for clinicians to understand that all currently approved abuse-deterrent opioid products are still capable of being abused. Their abuse-deterrent properties are expected to deter, but do not wholly prevent, abuse. Because opioid medications must in the end be able to deliver the opioid to the patient, there will probably always be potential for abuse of these products.

Clinicians should counsel their patients on the following:

- Keep medicines in a secure location, out of the reach and sight of children and pets. Put medicines away after every use. Accidental exposure to medicine in the home is a major source of unintentional poisonings in the United States.
- If medicines are no longer needed, it's important to dispose of them properly. Disposing of all unused opioid analgesics reduces access to these medications by family members and household guests seeking opioids for abuse.
- We recommend returning most prescription medications through a local or US Drug Enforcement Administration (DEA)-sponsored take-back program or DEA-authorized collector. For a small number of drugs, we recommend immediate removal from the home by flushing them down the toilet or sink.

A Work in Progress

Medscape: Besides supporting the development of abuse-deterrent products, can you briefly describe the other strategies that the FDA is exploring to address the opioid epidemic that may be helpful to clinicians?

Dr Throckmorton: In February of this year, Commissioner Robert Califf (then the FDA's Deputy Commissioner for Medical Products and Tobacco) announced the [FDA Opioids Action Plan](#). The plan focuses on policies aimed at reversing the opioid

epidemic, while still providing patients in pain access to effective pain relief.

The FDA actions include:

- Convening an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Consulting with the [Pediatric Advisory Committee](#) (meeting scheduled for this September) about a framework for pediatric opioid labeling before any new labeling is approved;
- Updating the REMS requirements for ER/LA opioid analgesics after considering the advisory committee's recommendations from a [meeting](#) held in May 2016 and reviewing existing requirements;
- Improve access to naloxone (by facilitating the development of an over-the-counter version of naloxone, which is currently only available by prescription, making naloxone more accessible to treat opioid overdose), and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative, nonaddictive treatments for pain. For example, the FDA is conducting research on pain measurements for such conditions as chronic low back pain, osteoarthritis, diabetic neuropathy, postherpetic neuralgia, and fibromyalgia. The FDA is also working to support the development of nonopioid options for these patients.

Consistent with the plan, in March 2016, the FDA announced that it was requiring changes to the labeling on [immediate-release opioids](#), including additional warnings and safety information that are expected to incorporate elements similar to the ER/LA opioid analgesics labeling that is currently approved.

Furthermore, among other steps, the FDA has contracted with the National Academy of Medicine to provide us with advice on how we should incorporate current evidence about the public health impact of opioid use (for patients who are prescribed opioids, as well as for nonpatients) into regulatory activities concerning opioids. We look forward to the recommendations from the academy, with a report expected in 2017, and other experts to further inform our policies in this area.

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1. Hwang CS, Turner LW, Kruszewski SP, Kolodny A, Alexander GC. Primary care physicians' knowledge and attitudes regarding prescription opioid abuse and diversion. *Clin J Pain*. 2016;32:279-284. [Abstract](#)
2. American Academy of Pain Medicine. AAPM facts and figures on pain. http://www.painmed.org/patientcenter/facts_on_pain.aspx#incidence Accessed August 4, 2016.

Public Information from the FDA and Medscape

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Department of Safety & Professional Services**

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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? CARA 2016 Article – Information Only	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Information only.			

Comprehensive Addiction and Recovery Act (CARA)

UPDATE: On July 22, 2016, President Obama signed into law the Comprehensive Addiction and Recovery Act ([P.L. 114-198](#)). This is the first major federal addiction legislation in 40 years, and the most comprehensive effort undertaken to address the opioid epidemic, encompassing all six pillars necessary for such a coordinated response – prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. While it authorizes over \$181 million each year in new funding to fight the opioid epidemic, monies must be appropriated every year, through the regular [appropriations process](#), in order for it to be distributed in accordance with the law.

The Comprehensive Addiction and Recovery Act (CARA) S.524/H.R.953

The Comprehensive Addiction and Recovery Act (CARA) establishes a comprehensive, coordinated, balanced strategy through enhanced grant programs that would expand prevention and education efforts while also promoting treatment and recovery.

The bill passed the U.S. Senate on March 10, 2016, by a vote of 94-1. The bill passed the U.S. House of Representatives on May 13, 2016, by a vote of 400-5.

Brief Summary of Provisions of CARA

- Expand prevention and educational efforts—particularly aimed at teens, parents and other caretakers, and aging populations—to prevent the abuse of methamphetamines, opioids and heroin, and to promote treatment and recovery.
- Expand the availability of naloxone to law enforcement agencies and other first responders to help in the reversal of overdoses to save lives.
- Expand resources to identify and treat incarcerated individuals suffering from addiction disorders promptly by collaborating with criminal justice stakeholders and by providing evidence-based treatment.
- Expand disposal sites for unwanted prescription medications to keep them out of the hands of our children and adolescents.
- Launch an evidence-based opioid and heroin treatment and intervention program to expand best practices throughout the country.
- Launch a medication assisted treatment and intervention demonstration program.
- Strengthen prescription drug monitoring programs to help states monitor and track prescription drug diversion and to help at-risk individuals access services.

Section-by-Section Summary of Provisions of CARA

Title I: Prevention and Education

Sec. 101 – Development of Best Practices for Prescribing of Prescription Opioids: This section requires the establishment of an inter-agency task force, composed of representatives from HHS, VA, DEA, CDC, and other federal agencies, as well as addiction treatment organizations and other stakeholder communities to develop best practices for pain management and pain medication prescribing. It also requires the Task Force to submit a report to Congress outlining a dissemination strategy and other recommendations.

Sec. 102 – Awareness Campaigns: This section requires HHS and the Attorney General to advance the education and awareness of the public of the risk of abuse of prescription opioid drugs if they are not taken properly. It also establishes a national drug awareness campaign led by the Office of National Drug Control Policy (ONDCP) to bring attention to the association between prescription opioid abuse and heroin use, as well as focus on the dangers of fentanyl.

Sec. 103 – Community-Based Coalition Enhancement Grants to Address Local Drug Crises: This section authorizes HHS, in consultation with the Director of ONDCP, to make grants to entities suffering from drug crises (experiencing above average rates of prescription drug, heroin, or methamphetamines abuse for extended periods or sudden spikes) to implement community-wide prevention strategies.

Title II: Law Enforcement and Treatment

Sec. 201 – Treatment Alternative to Incarceration Programs: This section authorizes HHS, in coordination with the Attorney General, to make grants to states, local governments, Indian tribes, or nonprofits to develop, implement, or expand treatment alternatives to incarceration under specific circumstances (including with the consent of prosecuting and defense attorneys, corrections officials, and other appropriate stakeholders) for individuals who meet certain criteria. It requires periodic updates on the progress of individuals placed in alternative settings.

Sec. 202 – First Responder Training for the Use of Drugs and Devices that Rapidly Reverse the Effects of Opioids: This section authorizes HHS, in coordination with the Attorney General, to make grants to state, local, and tribal law enforcement agencies for training in the use of naloxone and for the purchase of naloxone.

Sec. 203 – Prescription Drug Take Back Expansion: This section authorizes the Attorney General, in coordination with the Administrator of the Drug Enforcement Administration (DEA), the Secretary of HHS, and the Director of ONDCP, to coordinate with State, local, or tribal law enforcement agencies, as well as pharmacies and others, to develop or expand disposal sites for unwanted prescription medications.

Sec. 204 – Heroin and Methamphetamine Task Forces: This section authorizes the Attorney General to make grants to State law enforcement agencies to locate or investigate illicit activities related to the distribution of heroin or fentanyl, or the unlawful distribution of prescription opioids.

Title III: Treatment and Recovery

Sec. 301 – Evidence-Based Prescription Opioid and Heroin Treatment and Interventions Demonstration: This section authorizes the Director of the Center for Substance Abuse Treatment to award grants to State substance abuse agencies, units of local government, Indian tribes or tribal organizations, or nonprofit organizations in geographic areas that have a high rate of—or have had rapid increases in—heroin or other opioids to expand activities (including those making available medication assisted treatment) in the relevant areas.

Sec. 302 – Criminal Justice Medication Assisted Treatment and Interventions Demonstration: This section authorizes HHS, in coordination with the Attorney General, to make grants to eligible entities for the administration of medication assisted treatment programs through criminal justice agencies.

Sec. 303– National Youth Recovery Initiative: This section authorizes the Secretary of Health and Human Services, in coordination with the Secretary of Education, to make grants to eligible entities (including high schools, institutions of higher learning, nonprofit organizations, and others) to provide support for recovery from substance use disorders to individuals in high school or enrolled in institutions of higher learning.

Sec. 304 – Building Communities of Recovery: This section authorizes HHS to award grants to certain independent nonprofit organizations for the development and expansion of recovery services.

Title IV: Addressing Collateral Consequences

Sec. 401 – Correctional Education Demonstration Grant Programs: This section authorizes the Attorney General to award grants to states, local governments, nonprofit organizations, or Indian tribes to design, implement, and expand educational opportunities for offenders in jails, prisons, and juvenile detention facilities. Grants under this section may be used to pay for basic education, secondary level education, high school equivalency examination preparation, career technical education, and English as a second language education. They may also be used for instructor hiring and teaching and the screening and assessment of individuals to determine educational and other needs, risk, and aptitude.

Sec. 402 – National Task Force on Recovery and Collateral Consequences: This section creates a task force made up of representatives from the health care, housing, employment, substance use disorder, law enforcement, and legal communities to identify the collateral consequences faced by individuals with state or federal drug convictions and to recommend ways of reducing and, where possible, eliminating them.

Title V: Addiction and Recovery Services for Women, Families, and Veterans

Sec. 501 – Improving Treatment for Pregnant and Postpartum Women: This section authorizes the creation of grants for the purpose of expanding a State's services for women offenders who are pregnant and women offenders with dependent children who are suffering from substance use disorder.

Sec. 502 – Report on Grants for Family-Based Substance Abuse Treatment: This section directs the Attorney General to submit to Congress an annual report that describes the number of grants awarded under section 2921(1) of the Omnibus Crime Control Bill that are used for family-based substance abuse treatment programs that serve as alternatives to incarceration for custodial parents to receive treatment and services as a family.

Sec. 503 – Veterans' Treatment Courts: This section amends the Omnibus Crime Control and Safe Streets Act of 1968 to allow for veterans who were discharged or released from service under dishonorable conditions, if the reason for that discharge was attributable to a substance use disorder.

Title VI: Incentivizing State Comprehensive Initiatives to Address Prescription Opioid and Heroin Abuse

Sec. 601 – State Demonstration Grants for Comprehensive Opioid Abuse Response: This section authorizes the Attorney General, in coordination with the Secretary of Health and Human Services and the Director of the Office of National Drug Control Policy, to award planning and implementation grants to eligible state, units of local government, territories, or Indian Tribes, or combination thereof, to prepare a comprehensive plan for, and implement, an integrated opioid abuse response initiative. The comprehensive response must include specific

improvements to state prescription drug monitoring programs, as well as prevention/education efforts, expanded treatment programs, and plans for reversing opioid overdoses.

Title VII: Miscellaneous

Sec. 701 – GAO Report on IMD Exclusion: This section requires GAO to publish a report, within 365 days, on the impact that the Medicaid Institutions for Mental Disease exclusion has on access to treatment for individuals with substance abuse disorders.

Sec. 702 – Funding: This section authorizes \$62 million for each FY 2016 through FY 2020 in funding for the Attorney General and HHS to carry out the provisions of the bill.

Sec. 703 – Conforming Amendments: This section amends the Omnibus Crime Control and Safe Streets Act to include the heading “Comprehensive Addiction and Recovery”.

Sec. 704 – Grant Accountability: This section requires all grants awarded under the provisions of the bill to be subject to audits and other accountability measures.

Sec. 705 – Programs to Prevent Prescription Drug Abuse under the Medicare Program: This section authorizes amendments to the Social Security Act to ensure the prevention of prescription drug abuse within Medicare among at-risk individuals.

Title VIII: Transnational Drug Trafficking Act

Sec. 801 – Short Title: This section names the Title of the bill as the “Transnational Drug Trafficking Act of 2015”.

Sec. 802 – Possession, Manufacture, or Distribution for Purposes of Unlawful Importations: This section makes it illegal to manufacture or distribute a Schedule I or Schedule II controlled substance with the knowledge that this will be imported into the U.S.

Sec. 803 – Trafficking in Counterfeit Goods or Services: This section adds trafficking in a drug to the U.S. while knowingly using a counterfeit mark with the drug as a crime to be punished by fine or imprisonment.

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

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BUSINESS INSIDER

At least 8 Cincinnati residents overdosed on heroin laced with elephant tranquilizer



STEVE BITTENBENDER, REUTERS
16H

(Reuters) - At least eight people in the Cincinnati area who died of heroin drug overdoses since mid-July had traces of a drug used to tranquilize elephants in their bodies, a coroner said Tuesday.



At least five other overdose deaths since mid-July are suspected to be connected to

heroin laced with carfentanil, Hamilton County Coroner Lakshmi Sammarco told a news conference.

The coroner's office is awaiting the test results on those cases, she said.

Authorities expect that tally to rise as they test blood and urine samples from older cases, Sammarco added.

Drug users might not know they are taking the drug. Dealers may be adding it to heroin to boost their supply or the effects, authorities said.

Carfentanil is roughly 10,000 times more potent than morphine, according to the National Center for Biotechnology Information.

Throughout Ohio, the number of overdose deaths rose from 2,531 in 2014 to 3,050 last year, and the number of fentanyl-related overdose fatalities surged from just 84 in 2013 to 1,155 in 2015.

The Ohio deaths come as authorities in several parts of the United States are grappling with opioid and heroin crises. For example, in Scott County, Indiana, a rural county 75 miles southwest of Cincinnati, a state of emergency was declared last year after the number of HIV cases skyrocketed due to the use of intravenous pain killers.

Sammarco, the county coroner, said the strength of the powerful sedative renders "conventional treatment methods for overdoses not as effective."

WCPO/Screenshot

Last week, officials in Kentucky, one state to the south of Ohio, issued a public health advisory urging hospitals to stock up on antidotes to drug overdoses after law enforcement agencies reported illicit drugs mixed with other, legal substances were coming into the state.

According to a press release, officials in Kentucky said they anticipated heroin and other drugs were being laced with fentanyl, an addictive and powerful opioid, and being distributed within the state.

Hiram Polk, the Kentucky Department for Public Health Commissioner, likened the drug scourge to a tornado and said it was "tied to a number of overdoses, hospitalizations and deaths across the county and needs public attention now."

Sammarco said some of the batches her offices has tested included traces of carfentanil and fentanyl.

(Reporting by Steve Bittenbender in Louisville, Kentucky; Editing by Eric M. Johnson)

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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA News Release

FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from combined use

Action to better inform prescribers and protect patients as part of Agency's Opioids Action Plan

For Immediate Release

August 31, 2016

Release

After an extensive review of the latest scientific evidence, the U.S. Food and Drug Administration announced today that it is requiring class-wide changes to drug labeling, including patient information, to help inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and a class of central nervous system (CNS) depressant drugs called benzodiazepines.

Among the changes, the FDA is requiring boxed warnings – the FDA's strongest warning – and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines – nearly 400 products in total – with information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma and death. Today's actions are one of a number of steps the FDA is taking as part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic, while still providing patients in pain access to effective and appropriate pain management.

“It is nothing short of a public health crisis when you see a substantial increase of avoidable overdose and death related to two widely used drug classes being taken together,” said FDA Commissioner Robert Califf, M.D. “We implore health care professionals to heed these new warnings and more carefully and thoroughly evaluate, on a patient-by-patient basis, whether the benefits of using opioids and benzodiazepines – or CNS depressants more generally – together outweigh these serious risks.”

Given the importance of reaching health care professionals and the public with information about the risks of using these products together, today the FDA also issued a Drug Safety Communication. Through the Drug Safety Communication and by requiring patient Medication Guides, the agency also provides information for anyone who is

taking, or who knows someone taking, either of these types of medications and encourages them to better understand the risks of taking them together; and, when it is medically necessary, for health care providers to be careful to prescribe them as directed, without increasing the dose or dosing frequency for either drug.

Opioid analgesics are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among other drugs, under both brand and generic names. Certain other opioid medications are also approved to treat cough. Opioid analgesic misuse and abuse have increased significantly in the United States over the past two decades, and represent major public health concerns due to the risk of coma and fatal respiratory depression associated with opioid analgesic overdose. Benzodiazepines are drugs typically prescribed for the treatment of neurological and/or psychological conditions, including anxiety, insomnia and seizure disorders. Both classes of drugs depress the central nervous system (“CNS depressants”); however, each has unique pharmacology, safety risks, and labeling information related to its use. Therefore, the FDA is requiring opioid analgesics, prescription opioid cough products, and benzodiazepines to have slightly different labeling. Additionally, due to the unique medical needs and benefit/risk considerations for patients undergoing medication-assisted therapy treatment (MAT) to treat opioid addiction and dependence, the FDA is continuing to examine available evidence regarding the use of benzodiazepines and opioids used as part of MAT.

The FDA’s data review showed that physicians have been increasingly prescribing them together, and this has been associated with adverse outcomes. Among the data reviewed by the FDA, the agency concluded that from 2004 to 2011, the rate of emergency department visits involving non-medical use of both drug classes increased significantly, with overdose deaths (from taking prescribed or greater than prescribed doses) involving both drug classes nearly tripling during that period. Additionally, the number of patients who were prescribed both an opioid analgesic and benzodiazepine increased by 41 percent between 2002 and 2014, which translates to an increase of more than 2.5 million opioid analgesic patients receiving benzodiazepines.

Clinical guidelines from the U.S. Centers for Disease Control and Prevention (CDC) and existing labeling warnings regarding combined use caution prescribers about co-prescribing opioids and benzodiazepines to avoid potential serious health outcomes. The actions of the FDA today are consistent with the CDC.

In February 2016, the FDA received a citizen petition from numerous local and state public health officials and other stakeholders asking the agency to make certain changes to the existing labeling for benzodiazepines and opioid analgesics. The FDA had already initiated a review of the scientific information on concomitant use of these two drug classes when the agency received the petition, and was encouraged that these public health officials shared the agency’s concerns. Today, the FDA also responded to the citizen petition.

Working with the health care community and federal and state partners to help reduce opioid misuse and abuse and improve appropriate opioid prescribing, while ensuring that patients in pain continue to have appropriate access to opioid analgesics, is a top priority for the FDA and part of HHS’ targeted approach focused on prevention, treatment, and intervention. The agency is committed to continuing to monitor these products and take further actions as needed.

The FDA, an Agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The Agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

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4) Meeting Date: 9/20/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Federal Action on Kratom – Information Only	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
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HEADQUARTERS NEWS

August 30, 2016
Contact: DEA Public Affairs
(202) 307-7977

DEA Announces Intent to Schedule Kratom
SE Asian drug is imminent hazard to public safety

AUG 30 (WASHINGTON) - The Drug Enforcement Administration (DEA) today announced its intention to place the active materials in the kratom plant into Schedule I of the Controlled Substances Act in order to avoid an imminent hazard to public safety. Mitragynine and 7-hydroxymitragynine are found in kratom, which is a tropical tree indigenous to Thailand, Malaysia, Myanmar, and other areas of Southeast Asia. The announcement was made in the U.S. Federal Register and can be found by following this [link](#).

[Kratom](#) is abused for its ability to produce opioid-like effects and is often marketed as a legal alternative to controlled substances. Law enforcement nationwide has seized more kratom in the first half of 2016 than any previous year and easily accounts for millions of dosages intended for the recreational market, according to DEA findings. In addition, kratom has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of accepted safety for use under medical supervision. These three factors constitute a Schedule I controlled substance according to the [Controlled Substances Act](#) passed by Congress in 1970.

Kratom has been seized by law enforcement in various forms, including powder, plant, capsules, tablets, liquids, gum/resin, and drug patch. Because the identity, purity levels, and quantity of these substances are uncertain and inconsistent, they pose significant adverse health risks to users.

From February 2014 to July 2016, over 55,000 kilograms of kratom material were encountered by law enforcement at various ports of entry within the United States. Additionally, another 57,000+ kilograms of kratom material offered for import into the United States between 2014 and 2016 are awaiting an FDA admissibility decision. Together, this material is enough to produce over 12 million doses of kratom. The FDA has also warned the public not to use any products labeled as containing kratom due to concerns about toxicity and potential health impacts. In addition, FDA has issued and updated two import alerts related to kratom products. Kratom has been on DEA's list of drugs and chemicals of concern for several years.

The American Association of Poison Control Centers identified two exposures to kratom from 2000 and 2005. Between 2010 and 2015, U.S. poison centers received 660 calls related to kratom exposure. The Center for Disease Control (CDC) found that kratom abuse leads to agitation, irritability, tachycardia, nausea, drowsiness, and hypertension. Health risks found in kratom abusers include hepatotoxicity, psychosis, seizure, weight loss, insomnia, tachycardia, vomiting, poor concentration, hallucinations, and death. DEA is aware of 15 kratom-related deaths between 2014 and 2016.

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