



## **CONTROLLED SUBSTANCES BOARD**

**Contact: Chad Zadrazil (608) 266-2112**  
**Room 121A, 1400 East Washington Avenue, Madison**  
**December 1, 2015**

*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 October 6, 2015 (4-7)**
- 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. Patrick Mitchell – Attorney General Designee
    - h. Wendy Pietz – Dentistry Examining Board Designee
    - i. Timothy Westlake – Medical Examining Board Designee
- D. 2016 Meeting Dates – Discussion and Consideration (8)**
- E. 2015 NASCSA Annual Meeting – Discussion and Consideration (9)**
- F. Prescription Drug Monitoring Program – Discussion and Consideration**
  - 1) Operations Statistics **(10-14)**
  - 2) Pharmacy Compliance Audit Update **(15)**
  - 3) Referral Process **(16)**
  - 4) Delegate Access to Multistate Data Update **(17-18)**

- G. **10:00 A.M. PUBLIC HEARING: Clearinghouse Rule 15-083 Relating to Measurement of Controlled Substances for Purposes of Special Use Authorizations (19-28)**
  - 1) Review and Respond to Clearinghouse Report and Public Hearing Comments
- H. **Legislation and Rule Matters – Discussion and Consideration (29-128)**
  - 1) CSB 4 Relating to Date for Submission of PDMP Data (Act 199)
  - 2) CSB 4 Relating to PDMP Operations (Act 55)
  - 3) Update on Legislation and Possible or Pending Rule-Making Projects
- I. **Annual Report – Discussion and Consideration (129-130)**
- J. **Kratom (Mitragynine) Scheduling – Discussion and Consideration (131-134)**
- K. **WI ePDMP Update – Discussion and Consideration (135)**
  - 1) Grant Funding Update
  - 2) Development Update
- L. **Informational Items**
  - 1) CMS Opioid Mapping Tool – Informational Only (136-138)
  - 2) Narcan Nasal Spray Approval Article – Informational Only (139-141)
- M. Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration
- N. 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
- O. 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), and 440.205, 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.).**

- P. Credentialing Matters
- Q. Case Closures
- R. Deliberation of Items Received After Preparation of the Agenda
  - 1) Monitoring Matters
  - 2) Administrative Warnings
  - 3) Review of Administrative Warning
  - 4) Proposed Stipulations, Final Decisions and Orders
  - 5) ALJ Proposed Final Decisions and Orders
  - 6) Orders Fixing Costs/Matters Related to Costs
  - 7) Petitions for Summary Suspension
  - 8) Petitions for Re-hearings
  - 9) Complaints
  - 10) Credential Issues
  - 11) Appearances from Requests Received or Renewed
  - 12) Consulting with Legal Counsel

**RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

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

**ADJOURNMENT**

The next scheduled meeting is January 19, 2016.

**CONTROLLED SUBSTANCES BOARD  
MEETING MINUTES  
October 6, 2015**

**PRESENT:** Doug Englebert, Franklin LaDien, Gunnar Larson (*via GoToMeeting, joined the meeting at 9:31 a.m. and was excused from the meeting at 12:50 p.m.*), Jeffrey Miller, Patrick Mitchell, Wendy Pietz, Timothy Westlake

**EXCUSED:** Alan Bloom, Yvonne Bellay

**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 six (6) members was confirmed.

**ADOPTION OF AGENDA**

**MOTION:** Timothy Westlake moved, seconded by Franklin LaDien, to adopt the agenda as published. Motion carried unanimously.

**APPROVAL OF MINUTES OF AUGUST 14, 2015**

**MOTION:** Franklin LaDien moved, seconded by Jeffrey Miller, to adopt the minutes of August 14, 2015 as published. Motion carried unanimously.

**ADMINISTRATIVE MATTERS**

*Gunnar Larson joined the meeting at 9:31 a.m.*

**PUBLIC HEARING: CLEARINGHOUSE RULE 15-070 RELATING TO SUBMISSION OF DATA TO PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)**

**MOTION:** Timothy Westlake moved, seconded by Wendy Pietz, to accept all Clearinghouse comments for CR 15-070 relating to Submission of Data to the Prescription Drug Monitoring Program. Motion carried unanimously.

**MOTION:** Jeffrey Miller moved, seconded by Franklin LaDien, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule 15-070 relating to Submission of Data to the Prescription Drug Monitoring Program for submission to the Governor's Office and Legislature. Motion carried unanimously.

**MOTION:** Franklin LaDien moved, seconded by Patrick Mitchell, to authorize the Chair to draft a letter to be presented to the DSPS Secretary by Timothy Westlake, and a maximum of one other member of the Board, regarding a request for approval of a delay until April 9, 2017 for Clearinghouse Rule 15-070 relating to Submission of Data to the Prescription Drug Monitoring Program. Motion carried unanimously.

## **PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)**

### **PDMP Referral Process**

**MOTION:** Patrick Mitchell moved, seconded by Jeffrey Miller, to delegate to DSPS Staff the referral of Pharmacies that have not responded within deadlines established in communications regarding non-compliance to the Pharmacy Examining Board Screening Panel. Motion carried unanimously.

**MOTION:** Jeffrey Miller moved, seconded by Patrick Mitchell, to **rescind** the following motion from the 08/14/15 meeting: *“Franklin LaDien moved, seconded by Timothy Westlake, to address quarterly compliance issue reports with the PDMP program, DSPS Staff is delegated the authority to send a letter to gain compliance, and if compliance is not gained the dispenser will be referred to the Controlled Substances Board”*. Motion carried unanimously.

### **PDMP Dispenser Compliance Audit**

**MOTION:** Wendy Pietz moved, seconded by Franklin LaDien, to designate the Chair to approve the PDMP Compliance Audit letters provided by DSPS Staff with the following amendment and any additional changes made by the Chair: failure to submit data to the PDMP will result in referral to the Pharmacy Examining Board for investigation and possible disciplinary action. Motion carried unanimously.

**MOTION:** Timothy Westlake moved, seconded by Wendy Pietz, to address quarterly compliance issue reports with the PDMP program, DSPS Staff is delegated the authority to send a letter to gain compliance. Motion carried unanimously.

### **Minnesota PDMP Letter Regarding Interstate Data**

**MOTION:** Timothy Westlake moved, seconded by Jeffrey Miller, to authorize DSPS Staff to draft a letter to the Minnesota Board of Pharmacy regarding interstate PDMP data and include a request for access to Minnesota PDMP data for all Wisconsin delegates. In addition, the Board grants access to Minnesota delegates to Wisconsin PDMP data. Motion carried unanimously.

## **WI E-PDMP Scope**

**MOTION:** Patrick Mitchell moved, seconded by Jeffrey Miller, to delegate Timothy Westlake and, as alternates Wendy Pietz and Franklin LaDien, to the WI E-PDMP Executive Committee. Motion carried unanimously.

*Gunnar Larson was excused from the meeting at 12:50 p.m.*

## **LEGISLATION AND RULE MATTERS**

### **Adopt CR 15-007, Relating to Rescheduling Hydrocodone Combination Products**

**MOTION:** Jeffrey Miller moved, seconded by Franklin LaDien, to approve the Adoption Order for Clearinghouse Rule 15-007 relating to Rescheduling Hydrocodone Combination Products. Motion carried unanimously.

### **Adopt CR 15-008, Relating to Scheduling Tramadol**

**MOTION:** Wendy Pietz moved, seconded by Franklin LaDien, to approve the Adoption Order for Clearinghouse Rule 15-008 relating to Scheduling Tramadol. Motion carried unanimously.

### **Adopt CR 15-009, Relating to Scheduling Suvorexant**

**MOTION:** Jeffrey Miller moved, seconded by Franklin LaDien, to approve the Adoption Order for Clearinghouse Rule 15-009 relating to Scheduling Suvorexant. Motion carried unanimously.

### **Clearinghouse Report for CR 15-068, Relating to Exclusion of Naloxegol**

**MOTION:** Timothy Westlake moved, seconded by Jeffrey Miller, to reject Clearinghouse comment numbers 4 and 5(a-c), and to accept all remaining Clearinghouse comments for Clearinghouse Rule 15-068 relating to Exclusion of Naloxegol. Motion carried unanimously.

**MOTION:** Wendy Pietz moved, seconded by Franklin LaDien, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule 15-068 relating to Exclusion of Naloxegol for submission to the Governor's Office and Legislature. Motion carried unanimously.

### **Federal Exclusion of Ioflupane**

**MOTION:** Franklin LaDien moved, seconded by Jeffrey Miller, to authorize the Chair to approve the affirmative action order for the exclusion of Ioflupane pending receipt of objections dissimilarly scheduling before October 11, 2015. Motion carried unanimously.

**Draft Amending CSB 3, Relating to Special Use Authorization**

**MOTION:** Patrick Mitchell moved, seconded by Wendy Pietz, to designate the Chair to approve the preliminary rule draft of CSB 3 relating to Special Use Authorization for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

**Proposals for Amending CSB 4, Relating to Prescription Drug Monitoring Program Operation**

**MOTION:** Timothy Westlake moved, seconded by Jeffrey Miller, to designate the Chair to serve as liaison to DSPS staff for drafting CSB 4 relating to Prescription Drug Monitoring Program Operation. Motion carried unanimously.

*The Board acknowledges the appointment of Timothy Westlake as alternate Legislative Liaison.*

**ADJOURNMENT**

**MOTION:** Jeffrey Miller moved, seconded by Franklin LaDien, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:38 p.m.

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

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Chad Zadrazil and Andrea Magermans</b>		2) Date When Request Submitted: <b>11/18/15</b> Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> <li>▪ 10 work days before the meeting for Medical Board</li> <li>▪ 14 work days before the meeting for all others</li> </ul>	
3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>2016 Meetings – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 about the 2016 Board meetings, including discussion of alternative dates for the January 2016 meeting. Here are the dates of the 2016 CSB Meetings:  <div style="margin-left: 40px;">           1.19.2016            3.15.2016            5.17.2016            7.13.2016            9.20.2016            11.15.2016         </div>			

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

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3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>2015 NASCSA Annual Meeting – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 about the 2015 National Association of State Controlled Substances Authorities (NASCSA) Annual Meeting held on October 19-23, 2015.			

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

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3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page?  <b>PDMP Operations Statistics - Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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:  For the Board's consideration, attached are statistics regarding the operations of the PDMP.			

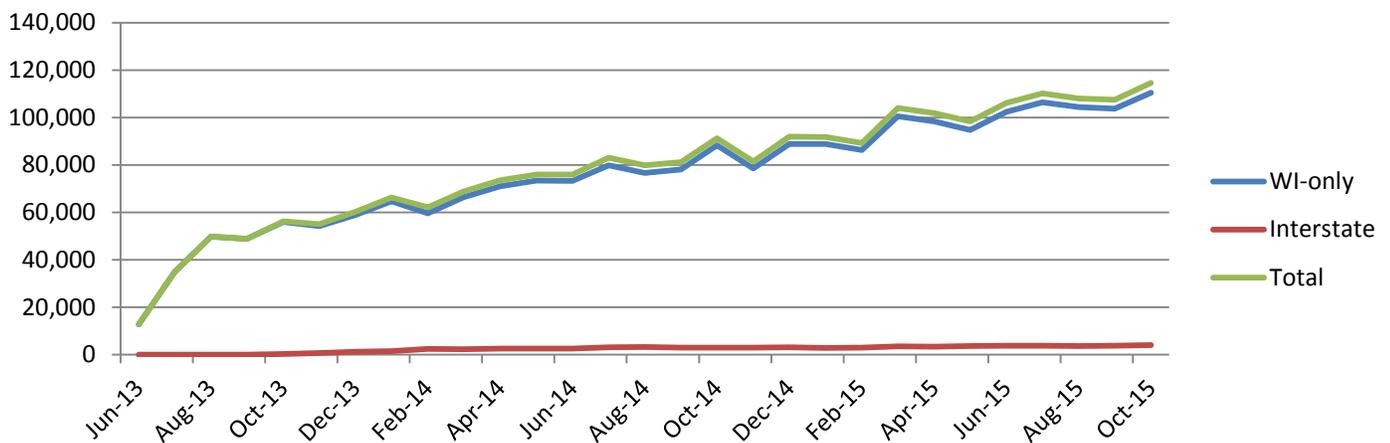


## Operational Statistics of the WI PDMP

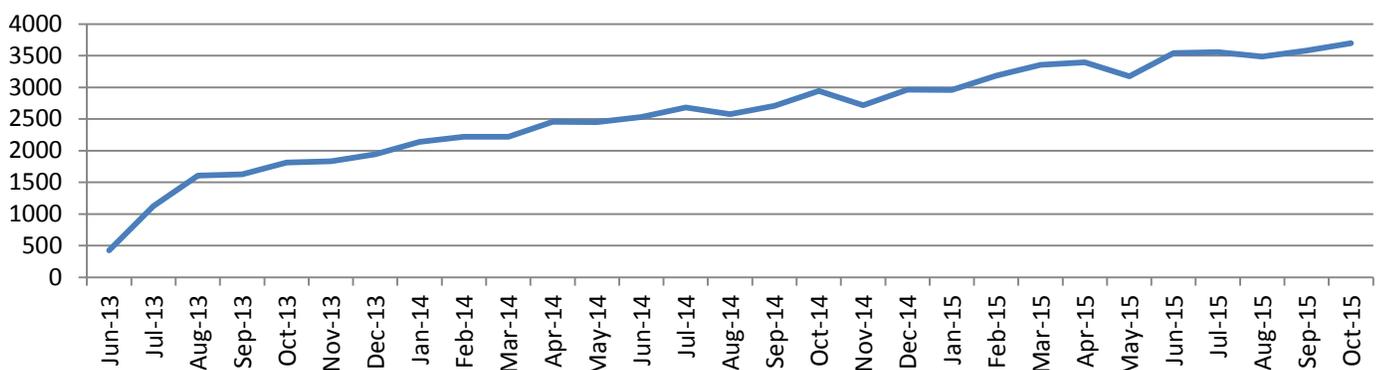
*Compiled on November 18, 2015*

- Approximately 31 million R<sub>x</sub> records in the database
- Approximately 1,800 dispensers actively submitting data
- Approximately 13,600 healthcare users have query accounts
- Healthcare users have created nearly 2.3 million recipient queries since June 1, 2013
  - In addition, healthcare users have created over 70,000 interstate queries since October 1, 2013
- Healthcare Users have initiated nearly 1,440 PDMP Alerts since July 1, 2013

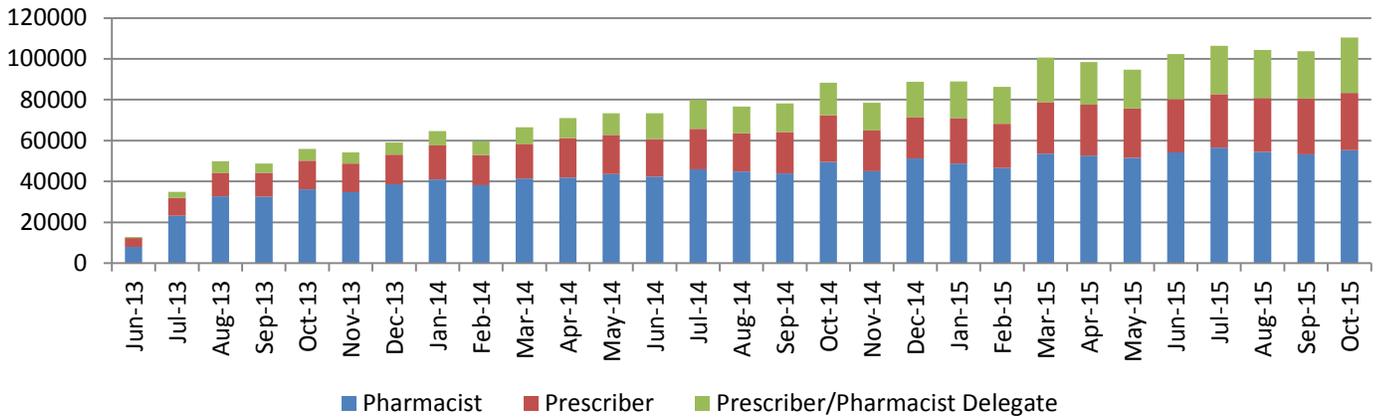
### Number of Healthcare Patient Queries Per Month



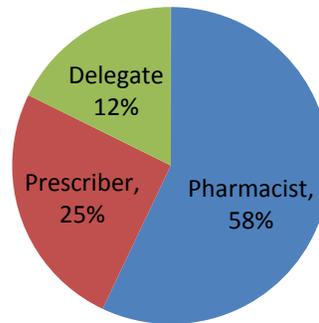
### Average Number of Healthcare Patient Queries Per Day



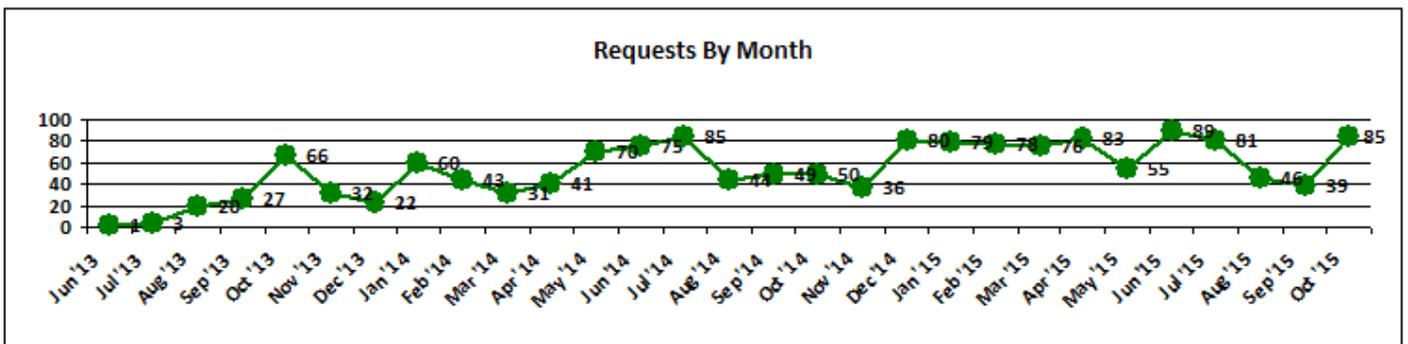
## Healthcare Patient Queries Performed by User Group



## Healthcare Patient Queries Performed by User Group



- Approximately 168 law enforcement and government users with query accounts.
- Law enforcement and government requests:



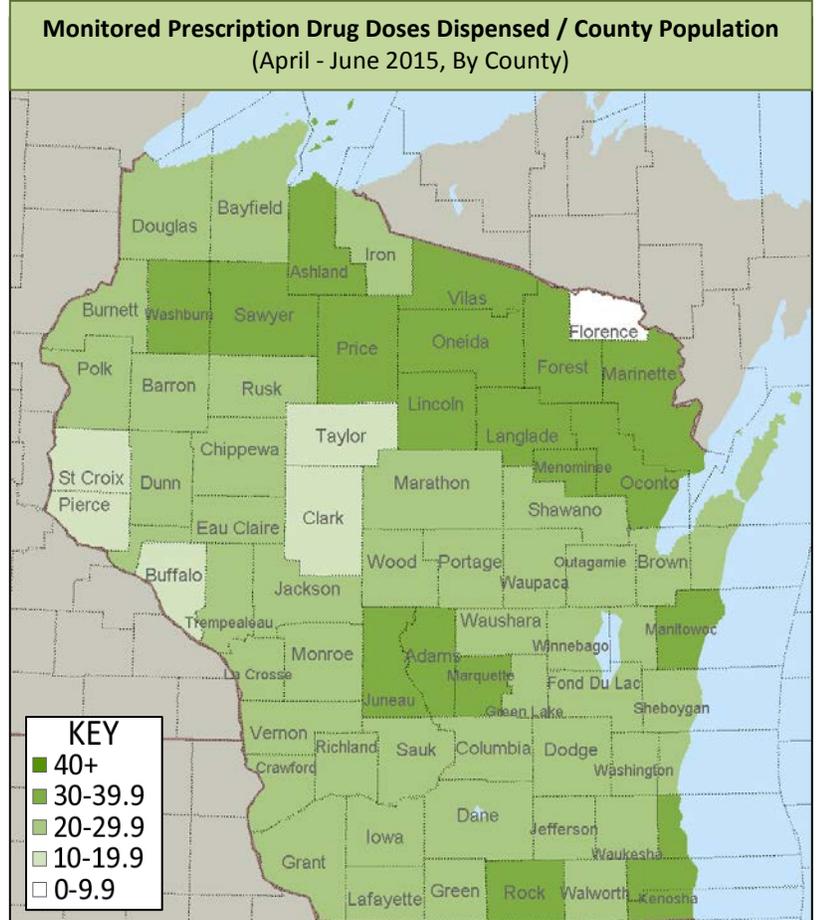


Scott Walker, Governor  
 Dave Ross, Secretary

## APRIL 1 – JUNE 30, 2015 STATISTICS SHEET #10

	April – June 2015	2015 YTD
# of Dispensers	1,693	1,788
# of Prescriptions	2,753,454	5,494,195
Quantity Dispensed	164,957,895	6,419,480,105
Estimated Days Supply	61,494,523	122,145,578

Top 15 Monitored Prescription Drug Prescriptions April - June 2015		
Drug Name	Number of Prescriptions	Percent of MPD Prescriptions
HYDROCODONE/ACETAMINOPHEN	450,225	16.91%
DEXTRAMPHETAMINE/AMPHETAMINE	215,515	8.09%
TRAMADOL HCL	200,818	7.54%
OXYCODONE HCL	199,980	7.51%
ALPRAZOLAM	180,499	6.78%
LORAZEPAM	177,657	6.67%
OXYCODONE HCL/ACETAMINOPHEN	161,583	6.07%
ZOLPIDEM TARTRATE	152,085	5.71%
CLONAZEPAM	147,021	5.52%
METHYLPHENIDATE HCL	100,267	3.77%
MORPHINE SULFATE	78,385	2.94%
DIAZEPAM	71,687	2.69%
LISDEXAMFETAMINE DIMESYLATE	60,763	2.28%
ACETAMINOPHEN WITH CODEINE	57,933	2.18%
PREGABALIN	55,308	2.08%



County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population
Adams	37.72	Dane	24.11	Iowa	25.25	Marathon	25.72	Polk	22.79	Taylor	18.93
Ashland	31.71	Dodge	28.70	Iron	21.26	Marinette	29.45	Portage	23.73	Trempealeau	26.27
Barron	25.59	Door	27.84	Jackson	28.48	Marquette	34.04	Price	28.25	Vernon	26.66
Bayfield	25.52	Douglas	27.14	Jefferson	27.08	Menominee	37.06	Racine	36.48	Vilas	36.05
Brown	26.41	Dunn	22.50	Juneau	37.06	Milwaukee	32.69	Richland	25.61	Walworth	26.93
Buffalo	15.18	Eau Claire	26.15	Kenosha	31.20	Monroe	29.53	Rock	31.21	Washburn	33.75
Burnett	28.12	Florence	6.36	Kewaunee	22.55	Oconto	30.48	Rusk	23.76	Washington	26.84
Calumet	21.32	Fond Du Lac	26.89	La Crosse	26.95	Oneida	30.71	Sauk	29.16	Waukesha	26.84
Chippewa	26.36	Forest	35.15	Lafayette	21.77	Outagamie	23.63	Sawyer	32.48	Waupaca	27.44
Clark	18.78	Grant	20.55	Langlade	35.83	Ozaukee	26.69	Shawano	26.39	Waushara	29.97
Columbia	29.96	Green	27.35	Lincoln	29.18	Pepin	18.68	Sheboygan	28.93	Winnebago	27.25
Crawford	25.72	Green Lake	28.27	Manitowoc	34.08	Pierce	13.96	St. Croix	17.51	Wood	28.50

\*The county population statistics are based on 2012 data from the Wisconsin Department of Health Services, available [here](#).



Scott Walker, Governor  
 Dave Ross, Secretary

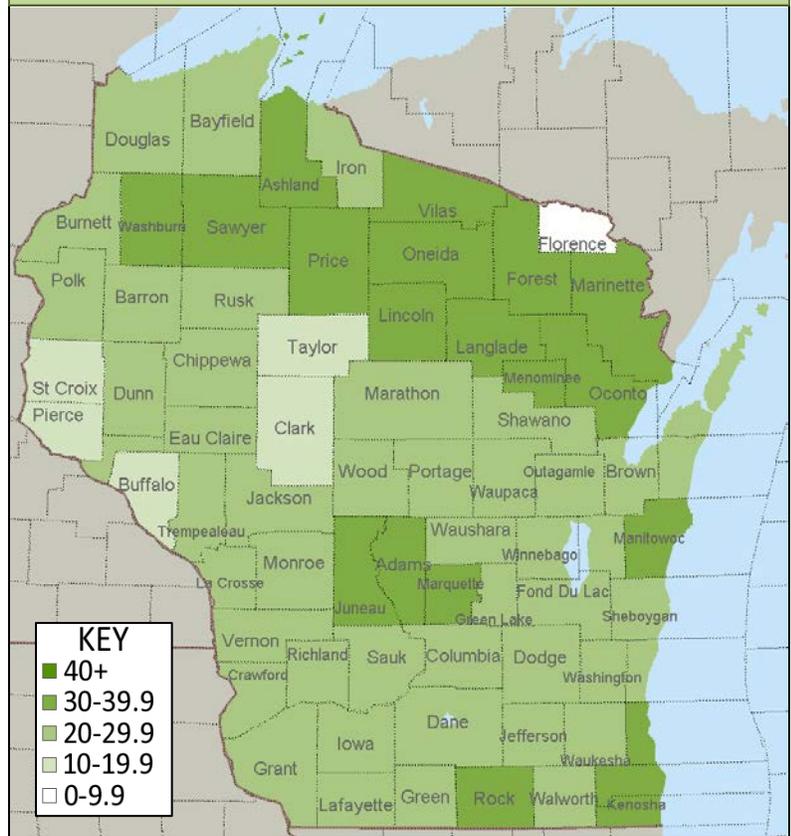
## JULY 1 – SEPTEMBER 30, 2015 STATISTICS SHEET #11

	July – September 2015	2015 YTD
<b># of Dispensers</b>	1,706	1,896
<b># of Prescriptions</b>	2,748,259	8,242,636
<b>Quantity Dispensed</b>	162,482,214	6,581,973,371
<b>Estimated Days Supply</b>	61,550,070	183,700,900

### Top 15 Monitored Prescription Drug Prescriptions July - September 2015

Drug Name	Number of Prescriptions	Percent of M/PD Prescriptions
HYDROCODONE/ACETAMINOPHEN	451,098	17.01%
DEXTROAMPHETAMINE/AMPHETAMINE	214,259	8.08%
TRAMADOL HCL	204,618	7.72%
OXYCODONE HCL	202,824	7.65%
ALPRAZOLAM	181,209	6.83%
LORAZEPAM	180,161	6.79%
OXYCODONE HCL/ACETAMINOPHEN	162,752	6.14%
ZOLPIDEM TARTRATE	151,559	5.72%
CLONAZEPAM	148,057	5.58%
METHYLPHENIDATE HCL	95,129	3.59%
MORPHINE SULFATE	78,354	2.95%
DIAZEPAM	73,263	2.76%
LISDEXAMFETAMINE DIMESYLATE	60,204	2.27%
ACETAMINOPHEN WITH CODEINE	56,542	2.13%
PREGABALIN	56,333	2.12%

### Monitored Prescription Drug Doses Dispensed / County Population (July - September 2015, By County)



County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population	County	Doses Dispensed / County Population
Adams	37.33	Dane	23.41	Iowa	25.19	Marathon	25.13	Polk	21.82	Taylor	18.16
Ashland	33.62	Dodge	28.33	Iron	21.67	Marinette	28.86	Portage	23.02	Trempealeau	25.38
Barron	24.08	Door	28.19	Jackson	27.78	Marquette	34.60	Price	29.11	Vernon	25.99
Bayfield	25.59	Douglas	26.21	Jefferson	26.42	Menominee	37.33	Racine	35.86	Vilas	35.70
Brown	26.14	Dunn	21.82	Juneau	37.36	Milwaukee	32.05	Richland	25.91	Walworth	26.91
Buffalo	16.78	Eau Claire	25.15	Kenosha	30.78	Monroe	28.57	Rock	30.43	Washburn	33.24
Burnett	29.79	Florence	6.74	Kewaunee	21.77	Oconto	30.29	Rusk	23.17	Washington	26.50
Calumet	21.05	Fond Du Lac	27.18	La Crosse	26.55	Oneida	29.77	Sauk	28.90	Waukesha	26.54
Chippewa	25.73	Forest	36.06	Lafayette	20.87	Outagamie	23.22	Sawyer	31.12	Waupaca	26.94
Clark	18.56	Grant	20.58	Langlade	34.99	Ozaukee	26.79	Shawano	26.34	Waushara	29.93
Columbia	29.06	Green	26.31	Lincoln	29.40	Pepin	18.55	Sheboygan	27.89	Winnebago	26.73
Crawford	25.17	Green Lake	27.74	Manitowoc	33.12	Pierce	13.64	St. Croix	17.46	Wood	27.75

\*The county population statistics are based on 2012 data from the Wisconsin Department of Health Services, available [here](#).

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

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Chad Zadrazil and Andrea Magermans</b>		2) Date When Request Submitted:  Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> <li>▪ 10 work days before the meeting for Medical Board</li> <li>▪ 14 work days before the meeting for all others</li> </ul>	
3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>10/6/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>PDMP Compliance Audit Update – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 ongoing PDMP compliance audit of pharmacies.			

**State of Wisconsin  
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3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>PDMP Referral Process – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 the board may utilize to refer licensees to a regulatory board for PDMP-related investigations.			

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

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Chad Zadrazil and Andrea Magermans</b>		2) Date When Request Submitted: <b>11/18/15</b> Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> <li>▪ 10 work days before the meeting for Medical Board</li> <li>▪ 14 work days before the meeting for all others</li> </ul>	
3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>PDMP Delegate Access to Multistate Data – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 ability of delegates of WI PDMP users to access data stored by PDMPs in other states.			



November 19, 2015

Cody Wiberg  
2829 University Ave. SE, #530  
Minneapolis, MN 55414-3251

Dear Mr. Wiberg:

Thanks for reaching out to us regarding delegate access to interstate PDMP data via the PMP InterConnect. I presented your letter to the Controlled Substances Board at its October 6 meeting. Since July, the Controlled Substances Board oversees the operations of the PDMP, and not the Pharmacy Examining Board.

At the meeting, the Board moved to grant access to data contained in the WI PDMP to all delegates of MN PMP users. We have since granted access to delegates of MN PMP users in the PMP InterConnect console.

The Board further moved to request that all delegates of WI PDMP users, including licensed and unlicensed delegates, be granted access to data contained in the MN PMP. However, this will only solve part of the issue, as the WI PDMP currently does not grant any delegates access to PMP InterConnect multistate queries. The Pharmacy Examining Board previously did not grant delegates access to the functionality, because states with which the WI PDMP initially exchanged data prohibited unlicensed delegates of WI PDMP users to access data contained in their states' PDMP databases. The WI PDMP does not differentiate between licensed and unlicensed delegates, and, therefore, no delegates of WI PDMP users could obtain interstate data.

In the short term, we will work with our vendor to determine the cost feasibility of granting delegate users' access to PMP InterConnect multistate queries. In the long term, we will grant delegates of WI PDMP users' access to PMP InterConnect multistate queries during the first quarter of 2017, if not sooner.

At this time, delegates of MN PMP users have access to data contained in the WI PDMP database. Going forward, I will be in touch as we learn more about the possibility of enabling delegates of WI PDMP users' access to PMP InterConnect multistate queries.

Sincerely,

Chad Zadrazil  
Managing Director  
Prescription Drug Monitoring Program  
Controlled Substances Board

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

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Sharon Henes Administrative Rules Coordinator</b>		2) Date When Request Submitted:  19 November 2015  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:  1 December 2015	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Public Hearing on Clearinghouse Rule CR 15-083 relating to measurement of controlled substances for purposes of special use authorizations</b>  <b>Review and respond to Clearinghouse Report and Public Hearing comments</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled?  <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:  <b>Hold Public Hearing at 10:00 a.m.</b>  <b>Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.</b>			
11) Authorization  <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center; width: 45%;"> <p style="font-size: 1.2em; font-style: italic;"><b>Sharon Henes</b></p> <hr/> <p>Signature of person making this request</p> </div> <div style="text-align: center; width: 45%;"> <p style="font-size: 1.2em; font-style: italic;"><b>19 November 2015</b></p> <hr/> <p>Date</p> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center; width: 45%;"> <p>Supervisor (if required)</p> <hr/> </div> <div style="text-align: center; width: 45%;"> <p>Date</p> <hr/> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center; width: 45%;"> <p>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</p> <hr/> </div> <div style="text-align: center; width: 45%;"> <p>Date</p> <hr/> </div> </div>			
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.			

STATE OF WISCONSIN  
CONTROLLED SUBSTANCES BOARD

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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 amend CSB 3.04 (6) (a) and (b) and 3.07 (1) (c), relating to measurements of controlled substances for purposes of special use authorizations.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

**Statutes interpreted:** s. 961.335, Stats.

**Statutory authority:** s. 961.335(8), Stats.

**Explanation of agency authority:**

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. s. 961.335(8), Stats.

**Related statute or rule:** CSB 3

**Plain language analysis:**

This rule indicates the controlled substances are to be measured in total weight in grams for solid controlled substances and in volume and concentration for liquid controlled substances for purposes of inventory list, records and application purposes.

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

Federal regulations require any person who possess, manufactures, distributes or dispenses any controlled substances to register with the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control.

**Comparison with rules in adjacent states:**

**Illinois:** Illinois controlled substance license (other) does not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

**Iowa:** Iowa registration for independent activities does not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

**Michigan:** Michigan licenses for controlled substances do not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

**Minnesota:** Minnesota controlled substance registration does not indicate a requirement for total weight or volume of the controlled substances for purposes of inventory list, records or application process.

**Summary of factual data and analytical methodologies:**

The current rule indicates weight in grams regardless of the state of the liquid. A more accurate reflection of how the substances are measured includes volume for liquid controlled substances. Therefore, the Board is updating the rule to take into consideration the state of the controlled substance and the method for which each state of matter is measured.

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

**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 Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

**Agency contact person:**

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 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 Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to Sharon.Henes@wisconsin.gov. Comments must be received at or before the public hearing to be held on December 1, 2015 to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. CSB 3.04 (6) (a) and (b) are amended to read:

CSB 3.04 (6) (a) An inventory listing the total weight in grams if solid, or volume and concentration if liquid of each controlled substance in the lab or intended for purchase for the lab.

CSB 3.04 (6) (b) Whenever the lab purchases or otherwise adds to its inventory a new controlled substance or an additional amount of a controlled substance that was not previously authorized in a permit, an amended SUA application that includes the total weight in grams if solid, or volume and concentration if liquid for each such new or additional substance.

SECTION 2. CSB 3.07 (1) (c) is amended to read:

CSB 3.07 (1) (c) The total weight in grams if solid, or volume and concentration if liquid of each controlled substance on hand.

SECTION 3. 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.

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(END OF TEXT OF RULE)

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

Original    Updated    Corrected

---

2. Administrative Rule Chapter, Title and Number

CSB 3

---

3. Subject

Measurements of controlled substances for purposes of special use authorizations

---

4. Fund Sources Affected

GPR    FED    PRO    PRS    SEG    SEG-S

5. Chapter 20, Stats. Appropriations Affected

20.165(1)(g)

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6. Fiscal Effect of Implementing the Rule

No Fiscal Effect    Increase Existing Revenues    Increase Costs  
 Indeterminate    Decrease Existing Revenues    Could Absorb Within Agency's Budget  
 Decrease Cost

---

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy    Specific Businesses/Sectors  
 Local Government Units    Public Utility Rate Payers  
 Small Businesses (if checked, complete Attachment A)

---

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes    No

---

9. Policy Problem Addressed by the Rule

Currently the rule indicates controlled substances are to be measured in total weight in grams. This rule would amend the rule to have controlled substances be measured in total weight in grams for solid controlled substances and in volume and concentration for liquid controlled substances for purposes of inventory list, records and application purposes. These are more accurate measurements based upon the state of the matter.

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10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

This rule was posted for economic comments for 14 days and none were received.

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11. Identify the local governmental units that participated in the development of this EIA.

None

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12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

This rule does not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

---

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit is to more accurately measure the controlled substance.

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14. Long Range Implications of Implementing the Rule

The long range implication is to have accurate measurements of the controlled substance.

---

15. Compare With Approaches Being Used by Federal Government

None.

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16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Our surrounding states do not have requirements for the controlled substance to be listed by total weight or volume for purposes of inventory list, records or application process.

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**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

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17. Contact Name

Sharon Henes

18. Contact Phone Number

(608) 261-2377

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This document can be made available in alternate formats to individuals with disabilities upon request.

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

**ATTACHMENT A**

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
  - Less Stringent Schedules or Deadlines for Compliance or Reporting
  - Consolidation or Simplification of Reporting Requirements
  - Establishment of performance standards in lieu of Design or Operational Standards
  - Exemption of Small Businesses from some or all requirements
  - Other, describe:
- 

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

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5. Describe the Rule's Enforcement Provisions

---

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes    No
-



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Scott Grosz**  
*Clearinghouse Director*

**Margit S. Kelley**  
*Clearinghouse Assistant Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Jessica Karls-Ruplinger**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE **15-083**

AN ORDER to amend CSB 3.04 (6) (a) and (b) and 3.07 (1) (c), relating to measurement of controlled substances for purposes of special use authorizations.

Submitted by **CONTROLLED SUBSTANCES BOARD**

10-29-2015 RECEIVED BY LEGISLATIVE COUNCIL.

11-17-2015 REPORT SENT TO AGENCY.

SG:MM

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]  
Comment Attached            YES             NO
2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]  
Comment Attached            YES             NO
3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]  
Comment Attached            YES             NO
4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]  
Comment Attached            YES             NO
5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]  
Comment Attached            YES             NO
6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]  
Comment Attached            YES             NO
7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]  
Comment Attached            YES             NO



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

---

---

Scott Grosz  
*Clearinghouse Director*

Terry C. Anderson  
*Legislative Council Director*

Margit Kelley  
*Clearinghouse Assistant Director*

Jessica Karls-Ruplinger  
*Legislative Council Deputy Director*

### CLEARINGHOUSE RULE 15-083

#### Comments

**[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]**

#### 2. Form, Style and Placement in Administrative Code

In SECTION 1 of the proposed rule, it is not necessary to repeat the citation to s. CSB 3.04 (6) when showing the treatment of par. (b). See the example following s. 1.04 (2) (a) 4., Manual.

#### 5. Clarity, Grammar, Punctuation and Use of Plain Language

In the material added throughout the proposed rule, should a comma follow “liquid”?

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

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Sharon Henes</b> <b>Administrative Rules Coordinator</b>		2) Date When Request Submitted:  <b>19 November 2015</b> Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections:  <b>Controlled Substances Board</b>			
4) Meeting Date:  <b>1 December 2015</b>	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Legislation and Rule Matters – Discussion and Consideration</b> <b>1. CSB 4 Relating to Date for Submission of PDMP Data (Act 199)</b> <b>2. CSB 4 Relating to PDMP Operations</b> <b>3. Update on Pending Legislation and Pending and Possible Rulemaking Projects</b> <b>4. § 961.36 Report to the Legislature</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled?  <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i><b>Sharon Henes</b></i>		<i><b>19 November 2015</b></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.			



November 19, 2015

Mr. Doug Englebert  
Chair, Controlled Substances Board  
P.O. Box 2969  
Madison, WI 53701

Dear Chairperson Englebert:

I am writing in response to your letter dated October 15, 2015 requesting a one-year extension in the effective date of rules promulgated pursuant to 2013 Wisconsin Act 199. As you know, Act 199 requires the Controlled Substances Board to promulgate rules to identify and record the name of the person picking up a schedule II or III controlled substance as data required to be submitted to the Prescription Drug Monitoring Program. The statute requires the Board to promulgate the rules to become effective on April 9, 2016, or, with my approval, to delay the effective date of the rules.

After reviewing the evidence in your request and consulting with affected stakeholders, I have decided to approve your request for a one-year extension. Therefore, the rules currently being promulgated by the Board pursuant to 2013 Wisconsin Act 199 may have an effective date no later than April 9, 2017.

Sincerely,



Dave Ross  
Secretary

STATE OF WISCONSIN  
CONTROLLED SUBSTANCES BOARD

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IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD  
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 15-070)

---

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 4.04 (2) (p) relating to submission of data to the prescription drug monitoring program.

Analysis prepared by the Department of Safety and Professional Services.

---

ANALYSIS

**Statutes interpreted:** s. 961.385(2)(b), Stats.

**Statutory authority:** s. 961.385, Stats.

**Explanation of agency authority:** “The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs.” s. 961.385, Stats.

**Related statute or rule:** ch. CSB 4, Admin. Code

**Plain language analysis:**

This rule implements 2013 Act 199 requiring the name of the person, either from on the id presented or known by the pharmacist, to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

**Summary of, and comparison with, existing or proposed federal regulation:** None

**Comparison with rules in adjacent states:**

**Illinois:** Illinois does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

**Iowa:** Iowa does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

**Michigan:** Michigan does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

**Minnesota:** Minnesota does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

**Summary of factual data and analytical methodologies:**

The methodology was to insert this requirement into the enumeration of required data to be submitted to the prescription drug monitoring program.

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

This rule was posted for economic comments for 14 days and none were received. Any economic impact resulting from the requirement to submit the name to PDMP is a result of the statutory requirement created by 2013 Act 199.

**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 Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

**Agency contact person:**

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

-----  
TEXT OF RULE

SECTION 1. CSB 4.04 (p) is created to read:

CSB 4.04 (p) The name recorded under s. 450.11(1b)(bm), Stats.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on April 9, 2017.

-----  
(END OF TEXT OF RULE)  
-----

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated \_\_\_\_\_

Agency \_\_\_\_\_

Chair  
Controlled Substances Board

## Chapter CSB 4

### PRESCRIPTION DRUG MONITORING PROGRAM

CSB 4.01	Authority and scope.	CSB 4.08	Exemptions from compiling and submitting dispensing data.
CSB 4.02	Definitions.	CSB 4.09	Direct access to PDMP information.
CSB 4.03	Drugs that have a substantial potential for abuse.	CSB 4.10	Requests for review.
CSB 4.04	Compilation of dispensing data.	CSB 4.11	Methods of obtaining PDMP information.
CSB 4.05	Electronic submission of dispensing data.	CSB 4.12	Use of PDMP information by the board and department.
CSB 4.06	Frequency of submissions.	CSB 4.13	Confidentiality of PDMP information.
CSB 4.07	Correction of dispensing data.	CSB 4.14	Exchange of PDMP information.

**Note:** Chapter Phar 18 was renumbered chapter CSB 4 under s. 13.92 (4) (b) 1., Stats., Register September 2015 No. 717.

**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 information relating to the prescribing and dispensing of prescription drugs.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.

**CSB 4.02 Definitions.** As used in this chapter:

(1) “Access” means to have the ability to view PDMP information through an account established with the board.

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

(3) “Animal” has the meaning given in s. 89.02 (1m), Stats.

(3m) “ASAP” means the American Society for Automation in Pharmacy.

**Note:** Contact: American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160; Blue Bell, PA 19422; phone: (610) 825-7783; fax: (610) 825-7641; webpage: <http://asapnet.org/index.html>.

(4) “Board” has the meaning given in s. 450.01 (2), Stats.

(5) “Controlled substance” means a drug, substance, analog, or precursor described in any of the following:

(a) Schedule I, II, III, IV, or V in the federal controlled substances act, 21 USC 812 (b) (1) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(b) Schedule I, II, III, IV, or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

(6) “Department” means the department of safety and professional services.

(7) “Dispense” has the meaning given in s. 450.01 (7), Stats.

(8) “Dispenser” means all of the following:

(a) A pharmacy.

**Note:** A site of remote dispensing authorized under s. 450.062, Stats., and s. Phar 7.095 is under the supervision of a pharmacy.

(b) A practitioner who dispenses a monitored prescription drug.

(9) “Dispenser delegate” means any of the following:

(a) A managing pharmacist of a pharmacy.

(b) An agent or employee of a practitioner who has been delegated the task of satisfying the data compilation and submission requirements of ss. CSB 4.04 and 4.05.

(10) “Dispensing data” means data compiled pursuant to s. CSB 4.04.

(11) “Drug” has the meaning given in s. 450.01 (10), Stats.

(11g) “Hospital” has the meaning given in s. 50.33 (2), Stats.

(11r) “Managing pharmacist” has the meaning given in s. Phar 1.02 (6).

(12) (a) “Monitored prescription drug” means all of the following:

1. A controlled substance included in s. 961.385 (1), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. CSB 4.03.

(b) “Monitored prescription drug” does not mean a controlled substance that by law may be dispensed without a prescription order.

(13) “Patient” has the meaning given in s. 450.01 (14), Stats.

(14) “Person authorized by the patient” means person authorized by the patient in s. 146.81 (5), Stats., and includes persons with delegated authority under s. 48.979, Stats.

(14e) “PDMP” means the Wisconsin prescription drug monitoring program.

(15) “PDMP information” means any of the following:

(a) The data compiled and stored by the board from dispensing data submitted to it by dispensers.

(b) The information created by the board to satisfy the requirements in s. CSB 4.12.

(15g) “Pharmacist” has the meaning given in s. 961.385 (1) (aL), Stats.

(15r) “Pharmacist delegate” means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing PDMP information.

(16) “Pharmacy” means any place of practice licensed by the board under ss. 450.06 or 450.065, 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.

(18) “Practitioner delegate” means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing PDMP information.

(19) “Prescription” has the meaning given in s. 450.01 (19), Stats.

(20) “Prescription order” has the meaning given in s. 961.385 (1) (b), Stats.

(21) “Program” means the prescription drug monitoring program established under this chapter.

(23) “Zero report” means a report that indicates that a dispenser has not dispensed a monitored prescription drug since the previous submission of dispensing data or a zero report.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: cr. (3m), (13e), am. (16), (17), r. (22) Register February 2014 No. 698, eff. 3-1-14; (13e) renum. to (14e) under s. 13.92 (4) (b) 1., Stats., Register February 2014 No. 698; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14-003: am. (8) (a), renum. (9) to (9) (intro.) and am., cr. (9) (a), (b), (11g), (11r), am. (15) (intro.), cr. (15g), (15r), am. (17) Register August 2014 No. 704, eff. 9-1-14; correction in (3), (9) (b), (10), (12) (a) 1., 2., (15) (b), (15g), (17), (20) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.

**CSB 4.03 Drugs that have a substantial potential for abuse.** Pursuant to s. 961.385 (1) (ag), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

(1) A controlled substance identified in schedule II, III, IV or V in the federal controlled substances act, 21 USC 812 (b) (2) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(2) A controlled substance identified in schedule IV or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

**(3) Tramadol.**

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: am. (intro.) Register February 2014 No. 698, eff. 3-1-14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; **correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

**CSB 4.04 Compilation of dispensing data. (1)** As used in this section:

(a) "DEA registration number" means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration.

(b) "Dispenser identifier" means the DEA registration number or when the DEA registration number is not available, the NPI number.

(c) "NDC number" means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

(d) "NPI number" means national provider identifier number, the registration number issued to a dispenser or practitioner by the national provider identifier registry.

(e) "Practitioner identifier" means the DEA registration number or when the DEA registration number is not available, the NPI number.

**(2)** Subject to s. CSB 4.08, a dispenser shall compile dispensing data that contains all of the following information each time the dispenser dispenses a monitored prescription drug:

- (a) The dispenser's full name.
- (b) The dispenser identifier, if available.
- (c) The date dispensed.
- (d) The prescription number.
- (e) The NDC number or the name and strength of the monitored prescription drug.
- (f) The quantity dispensed.
- (g) The estimated number of days of drug therapy.
- (ge) The classification code for payment type.
- (gm) The number of refills authorized by the prescriber.
- (gs) The refill number of the prescription.
- (h) The practitioner's full name.
- (i) The practitioner identifier, if available.
- (j) The date prescribed.
- (L) The patient's full name or if the patient is an animal, the animal's name and the owner's last name.
- (m) The patient's address, or if the patient is an animal, patient's owner's address, including street address, city, state, and ZIP code.
- (n) The patient's date of birth, or if the patient is an animal, patient's owner's date of birth.
- (o) The patient's gender.

**(4)** A dispenser and dispenser delegate, if applicable, who fail to compile dispensing data as required by sub. (2) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1) (b), (e), (3) (b), (d), (i), (k) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (title), renum. (2) to (2) (intro.) and am., cr. (2) (ge), (gm), (gs), renum. (3) (a) to (g) and (h) to (j) to (2) (a) to (g) and (h) to (j), r. (3) (k), renum. (3) (L) to (o) to (2) (L) to (o) and am. (L) to (n), am. (4) Register August 2014 No. 704, eff. 9-1-14; correction in (2) (intro.) made under s. 35.17, Stats., and in (4) made under s. 13.92 (4) (b) 7., Stats., Register August 2014 No. 704; **correction in (2) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

**CSB 4.05 Electronic submission of dispensing data. (1)** Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data through an account with the board.

**Note:** The application to create an account may be completed online at [www.dps.wi.gov](http://www.dps.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.

**(2)** The dispensing data shall be submitted to the board in compliance with the data standards in the version and release of ASAP implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board.

**Note:** The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at [www.dps.wi.gov](http://www.dps.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.

**(3)** If a dispenser is not able to create an account or submit dispensing data as required by subs. (1) and (2), the board may grant a waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser agrees to begin filing dispensing data on a paper form identified by the board for each monitored prescription drug dispensed.

(b) The dispenser files with the board a written application for a waiver on a form provided by the board.

**Note:** The application for a waiver may be obtained online at [www.dps.wi.gov](http://www.dps.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.

**(4)** A dispenser and dispenser delegate, if applicable, who fail to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver under sub. (3) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (2) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (1), (4) Register August 2014 No. 704, eff. 9-1-14; **correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

**CSB 4.06 Frequency of submissions. (1)** A dispenser shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

**(2)** If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board for each 7-day period during 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 a monitored prescription drug as required by sub. (1), 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 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.

**Note:** The application for an emergency waiver may be obtained online at [www.dps.wi.gov](http://www.dps.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.

**(4)** Unless otherwise specified by the board, an emergency waiver granted under sub. (3) shall only be effective for 7 days.

**(5)** A dispenser and dispenser delegate, if applicable, who 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, who submit false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1), (2), (3) (intro.), r. (4) to (6), (9), renum. (7) to (4) and am., renum. (8) to (5) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (2), (5) Register August 2014 No. 704, eff. 9-1-14.

**CSB 4.07 Correction of dispensing data.** If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall submit correct information within 7 days.

**Note:** The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

**History:** CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. Register August 2014 No. 704, eff. 9–1–14.

**CSB 4.08 Exemptions from compiling and submitting dispensing data. (1)** The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that the dispenser does not dispense monitored prescription drugs.

(b) The dispenser files with the board a written request for exemption on a form provided by the board.

**Note:** The application for an exemption may be obtained online at [www.dsp.wi.gov](http://www.dsp.wi.gov) or at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

**(2)** A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is administered directly to a patient.

**(3)** A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is a substance listed in the schedule in s. 961.22, Stats., and is not a narcotic drug, as defined in s. 961.01 (15), Stats., and is dispensed pursuant to a prescription order for a number of doses that is intended to last the patient 7 days or less.

**History:** CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1) (a), cr. (3) Register August 2014 No. 704, eff. 9–1–14.

**CSB 4.09 Direct access to PDMP information. (1)** Pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access PDMP information 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.

**(2)** To obtain access to PDMP information, pharmacists, pharmacist delegates, practitioners, and practitioner delegates shall do one of the following:

(a) Create an account with the board on a form provided by the board.

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with whom the board exchanges PDMP information 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 PDMP information 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 PDMP information or that is connected to and lawfully obtains data from the state–designated entity under ch. 153, Stats.

**Note:** The application to create an account may be completed online at [www.dsp.wi.gov](http://www.dsp.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.

**(3)** The board may deny, suspend, revoke or otherwise restrict or limit a pharmacist's, pharmacist delegate's, practitioner's, or practitioner delegate's direct access to PDMP information for any of the following reasons:

(a) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate uses PDMP information 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 pharmacist, pharmacist delegate, practitioner, or practitioner delegate is no longer licensed in this state or another state and recognized by this state as a person authorized to prescribe or dispense monitored prescription drugs.

(c) The board, or other licensing board, or regulatory agency takes adverse action against the pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(e) The federal department of justice, drug enforcement administration takes adverse action against the pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(f) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate 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 PDMP information.

**History:** CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1), renum. (2) to (2) (intro.) and am., cr. (2) (a) to (d), am. (3) Register August 2014 No. 704, eff. 9–1–14; **corrections in (1), (2) (b), (3) (a) Register September 2015 No. 717.**

**CSB 4.10 Requests for review. (1)** A pharmacist, pharmacist delegate, practitioner, or practitioner delegate may request that the board review any of the following:

(a) The denial of a waiver requested pursuant to s. CSB 4.05 (3).

(b) The denial of an emergency waiver requested pursuant to s. CSB 4.06 (3).

(c) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's account pursuant to s. CSB 4.09 (3).

**(2)** To request a review, the pharmacist, pharmacist delegate, practitioner, or practitioner delegate 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 dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

(b) The citation to the specific statute or rule on which the request is based.

**(3)** The board shall conduct the review at its next regularly scheduled meeting and notify the pharmacist, pharmacist delegate, practitioner, or practitioner delegate of the time and place of the review.

**(4)** No discovery is permitted.

**(5)** The board shall preside over the review. The review shall be recorded by audio tape unless otherwise specified by the board.

**(6)** The board shall provide the pharmacist, pharmacist delegate, practitioner, or practitioner delegate 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, pharmacist delegate, practitioner, or practitioner delegate 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.

**History:** CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14–003: am. (1) (intro.), (2) (intro.), (b), (3), (6), (7) Register August 2014 No. 704,

eff. 9-1-14; correction in (1) (a) to (c) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.

**CSB 4.11 Methods of obtaining PDMP information.**

**(1)** The board shall disclose PDMP information 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.

(b) Makes a request for the PDMP information on a form provided by the board.

**(2)** The board shall disclose PDMP information about a patient to a person authorized by the patient if the person authorized by the patient 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.

(b) Provides proof sufficient to the board of the authorization or delegation from the patient.

(c) Makes a request for the PDMP information on a form provided by the board.

**(5)** The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

**(6)** The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

**(7)** The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 21., Stats.

(c) Makes a request for the PDMP information through its account with the board.

**(8)** The board shall disclose the minimum amount of PDMP information necessary 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.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.

(c) Makes a request for the PDMP information through its account with the board.

**(9)** The board may disclose de-identified PDMP information which does not and cannot be reasonably used to identify any patient upon written request.

**(10)** The board shall disclose the minimum amount of PDMP information 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 if the designated staff does all of the following:

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

(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 the law enforcement agency is entitled to the information under s. 146.82 (2) (a) 11., Stats.

(c) Makes a request for PDMP information through its account with the board.

**Note:** The application to create an account and form to request PDMP information may be completed online at [www.dsp.wi.gov](http://www.dsp.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.

**History:** CR 12-009; cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: r. (3), (4), am. (6) (intro.), renum. (9) (intro.) to (9) and am., r. (9) (a) to (c) Register August 2014 No. 704, eff. 9-1-14; correction in (5) (intro.), (6) (intro.), (7) (intro.), (8) (intro.), (10) (intro.) Register September 2015 No. 717.

**CSB 4.12 Use of PDMP information by the board and department.** **(1)** The board shall develop and maintain a PDMP database to store PDMP information.

**(2)** The PDMP database shall store PDMP information in an encrypted format.

**(3)** The board shall maintain a log of persons to whom the board grants access to PDMP information.

**(4)** The board shall maintain a log of information submitted by each dispenser.

**(4g)** The board shall maintain a log of information accessed by each pharmacist, pharmacist delegate, practitioner, and practitioner delegate.

**(4r)** The board shall maintain a log of information disclosed, including the name of the person to whom the information was disclosed.

**(5)** The board shall maintain a log of requests for PDMP information.

**(6)** Board and department 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 necessary for all of the following purposes:

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

(b) The collection of dispensing data as part of the assigned duties and responsibilities under s. 961.385, Stats., and this chapter.

(c) Evaluating and responding to legitimate requests for PDMP information.

(d) Other legally authorized purposes.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (4), cr. (4g), (4r) Register August 2014 No. 704, eff. 9-1-14; **correction in (6) (b) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

**CSB 4.13 Confidentiality of PDMP information.**

**(1)** The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

**(2)** A person who discloses PDMP information 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 the licensing 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.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; **correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717.**

**CSB 4.14 Exchange of PDMP information. (1)**

The board may exchange PDMP information 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:

(a) The prescription monitoring program is compatible with the program.

(b) The relevant agency operating the prescription monitoring program agrees to exchange similar information with the program.

**(2)** In determining the compatibility of a prescription monitoring program to the program, the board may consider any of the following:

(a) The safeguards for privacy of patient records and the prescription monitoring program's success in protecting patient privacy.

(b) The persons authorized to access the information stored by the prescription monitoring program.

(c) The schedules of controlled substances monitored by the prescription monitoring program.

(d) The information required by the agency to be submitted regarding the dispensing of a prescription drug.

(e) The costs and benefits to the board of sharing information.

**(3)** The board may assess a prescription monitoring program's continued compatibility with the program at any time.

**History:** CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1) (intro.) Register August 2014 No. 704, eff. 9-1-14.

## CSB 4 Items

2015 Act 55 requires rules defining what constitutes suspicious or critically dangerous conduct or practices for purposes of disclosure to relevant state boards and agencies, relevant agencies of other states and relevant law enforcement agencies under circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient. **Material is attached for consideration what constitutes suspicious or critically dangerous conduct or practices. Please come prepared to discuss.**

### Clean-up Changes

Repeal CSB 4.02 (4), (llr), and (15g): Definitions are not used.

Repeal CSB 4.03 (3): Tramadol is now a scheduled drug.

Amend CSB 4.08 (1)(into), 4.10(1)(c), and 4.10 (2)(a): Missed in previous rule clean-ups

CSB 4.08 (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew ~~his or her~~ its license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

CSB 4.10 (1) (c) The denial, suspension, revocation or other restriction or limitation imposed on the ~~dispenser's pharmacist's, dispenser pharmacist~~ pharmacist's, dispenser pharmacist delegate, practitioner's, or practitioner delegate's account pursuant to s. CSB 18.09 (3).

CSB 4.10 (2) (a) The ~~dispenser's pharmacist's, dispenser pharmacist~~ pharmacist's, dispenser pharmacist delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

Prescription Drug Monitoring Program Center of Excellence at Brandeis

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## Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers

October 2014

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### Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers

The prescription drug abuse epidemic is driven in part by a minority of prescribers who over-prescribe or mis-prescribe controlled substances, especially opioids and benzodiazepines. In this report we will refer to prescribers who deviate from accepted standards of practice or whose prescribing is unusual or uncharacteristic for their specialty as *at-risk* prescribers. Identifying and intervening where appropriate with at-risk prescribers is a key strategy in efforts to control prescription drug misuse and diversion. The CDC has recently recommended focusing efforts on prescribers not following accepted medical practice.<sup>1</sup>

#### The Role of PDMPs in Identifying Possible At-Risk Prescribers

Because they collect comprehensive dispensing data, PDMPs are uniquely positioned to help identify prescribers at risk of over-prescribing or prescribing inappropriately. The top prescribers in a state as ranked by frequency of prescribing or dosage units prescribed often account for a high proportion of the total amount of dispensed controlled substances. For example, in the first three quarters of 2012 the top 8% of prescribers in Oregon accounted for 79% of all prescriptions for Schedule II - IV drugs.<sup>2</sup> In Florida in 2012, the top 10% of prescribers (top decile) were responsible for over 60% of opioid prescriptions.<sup>3</sup> While high frequency or dosage are not themselves indicators of inappropriate prescribing, it is one reason to consider further analysis and review by the PDMP or a licensing board. PDMP data analyses can readily identify the top 10% or 20% of prescribers for all controlled substances or for particular classes or combinations of drugs that are most involved in misuse or diversion.

Other criteria identifiable in PDMP data for possible problematic prescribing include having a high proportion of possible doctor shoppers in a practice, patients coming from long distances, and a high proportion of dispensed prescriptions paid for in cash.<sup>4</sup> When combined with data on prescriber license activity and specialty, analyses can also identify those prescribers who exceed the norm for their licensed profession, specialty, and standards of practice. Having identified possible at-risk prescribers with the help of the PDMP, professional licensing agencies and boards tasked with maintaining medical standards can intervene as appropriate, taking into

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<sup>1</sup> The CDC writes that efforts to reduce the epidemic should include focus on “prescribers who clearly deviate from accepted medical practice in terms of prescription painkiller dosage, numbers of prescriptions for controlled substances, and proportion of doctor shoppers among their patients.” CDC, Policy Impact: Prescription Painkiller Overdoses, at <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/>.

<sup>2</sup> See Prescription Drug Dispensing in Oregon, October 1, 2011 – March 31, 2012, Figure 1, p. 30, [http://www.orpdmp.com/orpdmpfiles/PDF\\_Files/Reports/Statewide\\_10.01.11\\_to\\_03.31.12.pdf](http://www.orpdmp.com/orpdmpfiles/PDF_Files/Reports/Statewide_10.01.11_to_03.31.12.pdf).

<sup>3</sup> Data from the Prescription Behavior Surveillance System (PBSS) as presented by Dr. Len Paulozzi at the 2013 Harold Rogers PDMP National Meeting, see <http://www.pdmpassist.org/pdf/PPTs/National2013/26-8-A%20Paulozzi.pdf> slide 21.

<sup>4</sup> For a description of PDMP measures indicative of possible at-risk prescribing, see Definitions of Prescription Behavior Surveillance System (PBSS) Measures, Section 5: Pill Mill Measures, pp. 4-7, <http://www.pdmpexcellence.org/sites/all/pdfs/Definitions%20of%20PBSS%20Measures%20112113.docx>

## Interventions with Possible At-Risk Providers

account all the evidence that bears on a case.<sup>5</sup> PDMPs may also be able to refer to law enforcement those prescribers potentially involved in illegal activities, including diversion of controlled substances.

PDMP data analyses can be used to track changes in prescribing by those who have been subjects of agencies' actions, thereby helping to assess the effectiveness of interventions.<sup>6</sup> Below are descriptions of initiatives undertaken or planned in Arizona, Tennessee, Kentucky, Texas, New Jersey, Massachusetts and New York. These can serve as models for other states to emulate or modify in their efforts to reduce prescription drug abuse and diversion. Some programs, for instance the Arizona report card, are directed at all prescribers who exceed norms for prescribing in a particular geographical area, while others such as Kentucky's are geared toward specific prescribers who are confirmed to be contravening good medical practice.<sup>7</sup> In Texas and New Jersey, data on both prescribers and dispensers are reviewed.

### State Initiatives for Possible At-Risk Prescribers

Arizona: Prescriber report cards. In a pilot program planned for state-wide adoption, the Arizona PDMP conducts analyses to identify 'outlier prescribers', defined as those one standard deviation above the average for their specialty and county in prescribing commonly abused controlled substances, whether in numbers of prescriptions or total dosage units. Outlier prescribers are sent "report cards" that summarize in graphical format the prescriber's prescribing as compared to local averages for the past year (see Appendix A for a sample report card). Report cards were sent to over 1,000 prescribers in Yavapai, Pinal, Graham and Greenlee counties. Outcomes thus far are promising. In Pinal county after one year, the percentage of prescribers meeting the outlier criterion for total dosage units fell from 19.2 percent to 14.2 percent, a 26% decline, while the number of prescriptions for all controlled substances fell by over 5%.<sup>8</sup> These findings suggest that report cards alert prescribers that they are prescribing well above practice norms, leading them to re-examine their prescribing policies.

The report cards may also serve to increase prescriber awareness and participation in the Arizona PDMP. In the four pilot program counties, 39% of prescribers were enrolled in the PDMP as of June 2014, compared to 26% for the state, and enrollment in the PDMP for these counties increased 111% from June 2012 to June 2014, compared to an increase of 72% for the state. In Pinal County, prescriber use of the PDMP increased 14% after the first year of the pilot.<sup>8</sup> Research studies and surveys of prescribers indicate that they change their prescribing

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<sup>5</sup> It is important in what follows to distinguish between *possible* at-risk prescribers and those actually confirmed to be prescribing outside standards of practice.

<sup>6</sup> The CDC has recently called for increased use of PDMP data for surveillance of possible excessive prescribing and for evaluation of initiatives to change prescriber behavior, see [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s\\_cid=mm6326a2\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w).

<sup>7</sup> In general, PDMP data are only indicators, not proof, that a prescriber is engaging in medically unwarranted prescribing.

<sup>8</sup> Data courtesy of the Arizona PDMP.

## Interventions with Possible At-Risk Providers

behavior in response to viewing PDMP data, which may account for some of the decline in prescribing observed following the report cards.<sup>9</sup>

It should be noted that the report card initiative is only one facet of the pilot program carried out in these counties, so changes in prescribing and PDMP participation may be the result of factors in addition to the report cards themselves, such as prescriber trainings, community education, and media coverage of the problem. As part of its [Prescription Drug Reduction Initiative](#), Arizona is seeking to expand the program, including prescriber report cards, to the entire state.

Tennessee: Letters to top prescribers and reports to licensing boards. In 2013, the Tennessee legislature adopted a requirement that, using the PDMP, the Tennessee Department of Health (TDH) identify and notify at least annually the top fifty prescribers in the past calendar year.<sup>10</sup> The notification letters include information about the practitioner's level of prescribing and ask the prescribers or their medical supervisors to justify the amounts prescribed as medically necessary, on pain of disciplinary action for non-compliance. Letters are not sent if the prescriber is a subject of an active investigation. TDH then determines, in consultation with medical experts on appropriate prescribing, whether the prescriber's explanation is justified, taking into account factors such as medical specialty and ages of patients. If the explanation leaves concerns about over-prescribing unaddressed, the prescriber or medical supervisor is given 15 days to produce additional supporting evidence that the level of prescribing is medically warranted. If concerns about excess prescribing still remain, TDH may contact the relevant licensing board for its review of the case, which may trigger an investigation should inappropriate prescribing seem likely. As of this report no data were available on numbers of prescribers contacted thus far or other outcomes of the letter initiative.<sup>11</sup>

In addition to the letter initiative, the Tennessee PDMP currently provides data to licensing board investigators on the most frequent prescribers, both for numbers of prescriptions and total dosage units of certain controlled substances. The PDMP is in the process of incorporating refinements to these criteria, such as data on how a provider's prescribing compares to norms for a particular specialty (e.g., general medicine or orthopedics) and how practices vary in the types and dosages of prescribed controlled substances. The PDMP has added staff with analytical and epidemiological expertise to develop these measures using PDMP data. As of this report, no data were available yet with respect to outcomes related to this initiative.

Kentucky: Reports to investigators on possible at-risk prescribers. As part of recent efforts in Kentucky to more effectively address prescription drug abuse, Kentucky's PDMP—the Kentucky All Schedule Prescription Electronic Reporting system (KASPER)—sends PDMP reports on prescribers to investigators at the Drug Enforcement and Professional Practices

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<sup>9</sup> See the [COE Briefing on PDMP Effectiveness](#) for studies and surveys on the impact of viewing PDMP data on prescribing.

<sup>10</sup> The relevant text of the legislation can be found at <http://state.tn.us/sos/acts/108/pub/pc0396.pdf>, pages 2-3.

<sup>11</sup> See <http://www.psychsearch.net/tn-withholds-doctors-names/> and <http://www.timesfreepress.com/news/2012/apr/18/tenncare-blocks-top-drug-prescribers/?news> for news stories about an initiative by Iowa Senator Charles Grassley to identify the top ten prescribers billing to Medicaid in states. Some of those identified in Tennessee using TennCare (Medicaid) data have been barred from billing Medicaid because their prescribing was judged medically unwarranted.

## Interventions with Possible At-Risk Providers

Branch (DEPPB) of the Office of the Inspector General. Investigators then evaluate the reports to see if further inquiry into potentially inappropriate or illegal prescribing is warranted. Prescribers selected by KASPER for review and possible referral to DEPPB are identified using criteria recommended by the Governor's KASPER Advisory Council. Prior reviews included the top two percent of prescribers issuing prescriptions for oxycodone, hydrocodone, oxymorphone, methadone, alprazolam, and drug "cocktails" (e.g., hydrocodone, alprazolam, carisoprodol). Once the DEPPB receives a report from KASPER, investigators, who are registered pharmacists as well as certified peace officers in Kentucky, review the provider's prescribing history. The review includes types of controlled substances prescribed, prescribing unusually large quantities and/or medically questionable combinations, issuing new prescriptions before all refills are exhausted, and having patients who travel long distances. Investigators also take into account the practitioner's specialty, and, in consultation with licensure boards, any record of disciplinary action or known problems with the practitioner. If the review indicates a substantial likelihood of problematic prescribing, the information is forwarded to the appropriate board for further investigation. If criminal activity is suspected, cases are sent to law enforcement investigators.

From July 2012 (the start of this initiative) to November 2013, DEPPB had received 95 cases for review, and completed reviews of 76. Of these, 46 (60 %) were determined to meet criteria for referral to the Kentucky Board of Medical Licensure (KBML) or law enforcement. KBML took action in 23 (50 %) of the cases referred to it.<sup>12</sup> Actions thus far have resulted in retirements, agreed orders setting out sanctions and terms to be imposed upon the prescriber, and controlled substance license revocations. Thus, some problematic prescribers have modified their practices or have been removed from the system. The KASPER Advisory Council is now considering criteria for reviews of dentists prescribing large quantities of benzodiazepines, hydrocodone and oxycodone, high volume prescribing of Schedule II stimulants, and pharmacies dispensing high volumes of hydrocodone, oxycodone and Schedule II stimulants.

Texas: Reports to licensing boards and law enforcement. The Texas PDMP conducts frequent analyses of its database to detect possible problematic prescribing and dispensing that can be brought to the attention of appropriate authorities. Automated algorithms generate reports on providers meeting pre-defined criteria suggestive of at-risk practice, such as being among the most frequent prescribers or dispensers of widely abused controlled substances. Prescription data are reviewed to help rule out legitimate reasons for what seems to be problematic prescribing or dispensing, as well as to scan for indicators warranting further data analyses. When a provider is identified as reportable to law enforcement, staff decides whether to refer the case to investigators within the Department of Public Safety (home to the PDMP) or to another law enforcement agency—federal, state, county, or local. Investigators receive a complete prescription history report; in some cases, copies of prescriptions are included. Cases on medical providers not deemed appropriate for law enforcement investigation are referred to

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<sup>12</sup> Data from DEPPB provided courtesy of KASPER.

## Interventions with Possible At-Risk Providers

licensing boards. Care is taken to coordinate with other agencies in order not to compromise investigations already underway (de-confliction) and to supply PDMP data relevant to those investigations. The Texas PDMP has produced an average of 20-25 prescription drug cases a month for law enforcement investigation, making it among the most active PDMPs for this type of intervention.<sup>13</sup>

New Jersey: Proactive reporting on risky prescribing and dispensing. The New Jersey PDMP conducts quarterly analyses to look for concerning patterns of prescribing and dispensing, such as identifying the state's top prescribers and pharmacies for controlled substances commonly encountered in cases of illegal prescribing. Database searches are conducted using drug therapeutic codes, dosage types (e.g., 30 mg Roxicodone) and payment type. If suspicious departures from normal prescribing practice are detected, the appropriate law enforcement agency or licensing board, depending on the level and type of activity, is contacted. Recent analyses related to possible diversion have focused on top prescribers of oxycodone where payments for prescriptions are made in cash. The PDMP also runs ad hoc analyses to further explore patterns identified in quarterly reviews or to investigate developments reported to the PDMP by other agencies. For example, law enforcement agencies may report that promethazine with codeine syrup is turning up on the street, so analyses are run for promethazine.<sup>13</sup>

Massachusetts: Outreach to prescribers with high proportions of possible doctor shoppers. In an initiative aimed at increasing awareness and utilization of its PDMP, Massachusetts analyzed its data to identify "high risk" prescribers, defined as those with relatively high proportions of possible doctor shoppers in their practices (i.e., patients meeting thresholds for numbers of prescribers and pharmacies in a six month period). Those high risk prescribers not enrolled in the PDMP were notified via letter about their status and encouraged to enroll. The initiative resulted in 150 notifications in 2012, and as of 2013 over 40% of the notified prescribers had enrolled in the PDMP. In a separate study of the top 50 high risk prescribers, those enrolled in the PDMP (n=12) had a 26 percent decline from 2010 to 2011 in the number of patients meeting criteria for doctor shopping, compared to a 7.5 percent decline for those not enrolled in the PDMP (n=38).<sup>14</sup> In a future initiative, Massachusetts plans to engage identified high risk prescribers via academic detailing – one-on-one provider education aimed at improving opioid prescribing.

New York: Identifying and contacting at-risk prescribers. In an initiative under consideration, New York PDMP data will be analyzed to identify at-risk prescribers, defined as those who frequently prescribe opioids in combination with benzodiazepines and/or prescribe high volume and high doses of opioids. These prescribers will receive a mailing from the New York State

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<sup>13</sup> The text in this section has been adapted from the COE guidance document on unsolicited reporting at [http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis\\_COE\\_Guidance\\_on\\_Unsolicited\\_Reporting\\_final.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_COE_Guidance_on_Unsolicited_Reporting_final.pdf).

<sup>14</sup> These findings should be interpreted with caution since there may be bias in favor of more proactive scrutiny and modification of prescribing practices for those voluntarily enrolling in the PDMP. The initiative and study are described in a presentation by Leonard Young for the 2013 National Rx Abuse Summit; see <http://www.slideshare.net/OPUNITE/new-focuses-forpdmpseffortfinal>, slides 58-9.

## Interventions with Possible At-Risk Providers

Department of Health indicating concern about potentially harmful prescribing practices. The mailing will also provide corresponding educational materials focused on risks and benefits of long-term opioid use and risks of combining opioids with other central nervous system depressants. Outcomes of the intervention will be measured by comparing pre-intervention prescribing history to post-intervention prescribing using PDMP data.

### Conclusion

The initiatives summarized above illustrate some options states may wish to pursue in addressing a primary source of controlled substances implicated in the prescription drug abuse epidemic: practitioners who prescribe, intentionally or not, in excess of or otherwise inconsistent with good medical practice. PDMPs are critical tools in this effort, in their capacity to (1) identify prescribers who may be intentionally or unintentionally prescribing outside the standards of practice; and (2) track prescribing behavior longitudinally for assessing the effectiveness of interventions aimed at prescribing reform. As these initiatives continue, more data will become available to permit their evaluation and enhancement.

It should be noted that the initiatives described above are by no means exhaustive of those underway in states with active PDMPs. Future updates to this briefing will cover additional interventions and provide new information on their outcomes as measured by PDMP data, data on licensing board and law enforcement actions, and health indicators affected by controlled substance prescribing.

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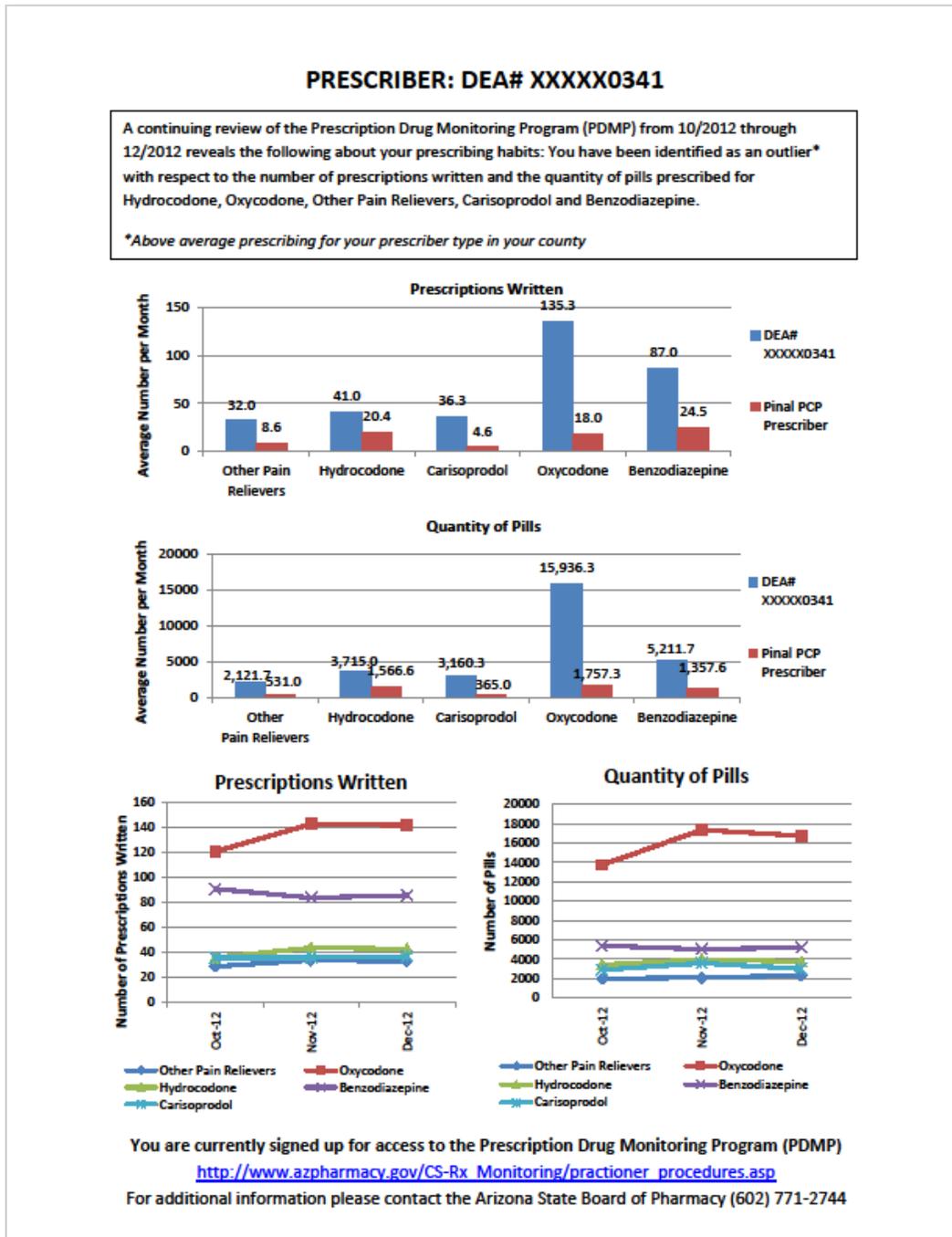
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Andrew Holt, Tennessee

Sherry Wright, Texas

## Appendix A Arizona Prescriber Report Card\*



\*From slide 17 in the presentation available at [http://www.azcjc.gov/ACJC.Web/Rx/Presentations/RxInitiative\\_general.pptx](http://www.azcjc.gov/ACJC.Web/Rx/Presentations/RxInitiative_general.pptx)

Prescription Drug Monitoring Program Center of Excellence at Brandeis

Guidance on PDMP Best Practices BP 01

## Options for Unsolicited Reporting

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### Guidance on PDMP Best Practices

## Options for Unsolicited Reporting

#### Overview

Unsolicited reporting of prescription drug monitoring program (PDMP) data to prescribers, dispensers, licensing boards, and law enforcement agencies is a recognized PDMP best practice. The Centers for Disease Control and Prevention (CDC) has recommended that PDMPs institute unsolicited reporting on “high-risk” patients and prescribers—those prescribed high doses of opioids or who meet criteria for questionable activity such as doctor shopping or reckless prescribing. A growing body of evidence suggests that the proactive dissemination of PDMP information about such individuals to appropriate end users helps to promote safe prescribing and limit diversion of controlled substances. However, for a variety of reasons, including regulatory restrictions, lack of resources, and concerns about unintended consequences, many PDMPs currently conduct only limited unsolicited reporting or none at all. Understanding the benefits and feasibility of unsolicited reporting may serve to encourage more widespread adoption of this practice by states.

This guidance document outlines the rationale and basic procedures for unsolicited reporting, including a discussion of criteria and thresholds in PDMP data used to select individuals for reporting. It then provides a menu of options for unsolicited reporting as illustrated by current PDMP practice. Unsolicited reports on patients meeting criteria for questionable activity, such as seeing multiple prescribers for the same drug, are typically sent to medical providers or law enforcement agencies, depending on a state’s policies and PDMP statutes (see “Unsolicited reporting to medical providers” and “Reports to law enforcement on doctor shopping” below). Some PDMPs also supply reports to licensing boards and law enforcement on prescribers who fall outside the norms for their type of practice (see “Reports on providers to licensing boards” and “Reports on providers to law enforcement” below). Examples of these types of unsolicited reporting, including selection and reporting mechanisms, are drawn from a sample of states (therefore, not all states conducting unsolicited reporting are mentioned below).

This guidance document also includes examples of promising practices and innovations in unsolicited reporting that may expand the options available to states (see “Promising practices and innovations” below). Some involve technological innovations in making PDMP data available to end users, some expand the range of end users receiving reports, and others expand the criteria for unsolicited reporting to include indicators of unsafe prescribing that go beyond doctor shopping alone.

Barriers to adopting unsolicited reporting are examined, as well as possible means to overcome them (see “Barriers to unsolicited reporting” below). The “Summary and conclusions” section lists some characteristics of unsolicited reporting, exemplified by current state practice, that appear to contribute to its effectiveness and efficiency. Overall, experience among states suggests that, given statutory support and adequate resources, unsolicited reporting is feasible for most PDMPs. Adopting unsolicited reporting can confer substantial benefits to states by

increasing utilization of PDMP data, helping to reduce prescription drug abuse, diversion, overdoses, and deaths.

### Background

PDMPs are effective tools in mitigating prescription drug abuse and diversion, but only when they are well utilized. Virtually all PDMPs provide prescription history reports to authorized end users on request (solicited reports), but if reports are not requested, potentially useful information goes unseen and unused. A prescriber who does not conduct regular checks on his or her patients using the PDMP might fail to detect a possible doctor shopper (a patient obtaining multiple overlapping and medically unnecessary prescriptions for the same controlled substance) or possibly harmful drug interactions.

To ensure that prescription history information is more fully utilized, and to assist PDMP end users in carrying out their responsibilities, some PDMPs proactively send reports of data suggestive of questionable activity involving controlled substances, such as doctor shopping or illicit prescribing. Recipients of unsolicited reports or alerts<sup>1</sup> ordinarily include prescribers, pharmacists, law enforcement agencies, and licensing boards. These reports notify prescribers and pharmacists that patients may be abusing or diverting controlled substances and help practitioners make better decisions about prescribing and dispensing controlled substances, thus improving clinical care. Unsolicited reporting to law enforcement agencies and health professions licensing boards concerning questionable activity by patients, prescribers, and pharmacists can also assist in reducing drug diversion and ensuring safe, effective, and legal medical practice. Unsolicited reporting can also inform potential end users about the PDMP and its value, resulting in increased use of the data.

### Unsolicited reports as a PDMP best practice

Prominent stakeholders in the fight against prescription drug abuse have concluded that unsolicited reporting constitutes a best practice for PDMPs. To receive funding under the National All Schedules Prescription Electronic Reporting (NASPER) Act, the Substance Abuse and Mental Health Services Administration (SAMHSA) established that PDMPs must provide unsolicited reports to medical practitioners (SAMHSA, 2005).<sup>2</sup> The Bureau of Justice Assistance (BJA) included adoption of unsolicited reporting as a priority consideration for states seeking funding under the Harold Rogers Prescription Drug Monitoring Program.<sup>3</sup> The CDC recommended that “state prescription drug monitoring programs should routinely send reports to providers on patients less than 65 years old if they are being treated with opioids for more than six weeks by two or more providers or if there are signs of inappropriate use of

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<sup>1</sup> Alerts notify the recipient that an individual meets criteria for questionable activity as identified in the PDMP database, but do not include prescription data and therefore are less likely to compromise patient confidentiality. The recipient of the alert is advised to consult the database to view the prescription history information.

<sup>2</sup> The NASPER grant program is currently unfunded but has provided support to PDMPs in earlier years.

<sup>3</sup> See BJA's [Harold Rogers PDMP FY 2012 Competitive Grant Announcement \(www.bja.gov/Funding/12PDMPsol.pdf\)](http://www.bja.gov/Funding/12PDMPsol.pdf).

controlled substances.”<sup>4</sup> In a recent briefing, the CDC also suggests that PDMPs should “provide unsolicited reports on high-risk providers and patients to the appropriate providers, regulatory boards, as well as law enforcement agencies under certain circumstances, such as an active investigation, court order or subpoena.”<sup>5</sup>

A growing body of evidence supports unsolicited reporting as a PDMP best practice. Nevada initiated its PDMP in 1997 by sending unsolicited reports to prescribers about possible doctor shoppers, a first for any PDMP. These reports quickly generated interest in the PDMP among prescribers, sparking further requests for data (solicited reports).<sup>6</sup> Analyses of Nevada PDMP data from 1997 to 2002 indicate that individuals for whom unsolicited reports were sent exhibited declines in the average number of dosage units and numbers of pharmacies and prescribers visited subsequent to the reports. This suggests the reports may have influenced prescribing by providers treating these patients. Similarly, analyses of data from the Wyoming PDMP suggest that unsolicited reports helped to raise awareness of the PDMP, leading to greater requests for data, with a subsequent decline in numbers of individuals identified in the PDMP database who met thresholds for potential doctor shopping.<sup>7</sup>

Preliminary data from a Massachusetts survey of prescribers receiving unsolicited reports show that just eight percent were aware of all or most of the other prescribers listed on the reports, and only nine percent judged that the prescriptions listed were medically necessary.<sup>8</sup> This indicates that unsolicited reporting of PDMP data provides new information to prescribers about possible doctor shopping. Prescribers in Maine who received automatic threshold reports on patients took a variety of clinical actions in response, suggesting that the reports helped to guide their medical practice.<sup>9</sup> A cross-state evaluation of PDMPs by Simeone and Holland indicated that states with PDMPs that engaged in unsolicited reporting reduced sales of controlled substances by 10 percent compared to states without PDMPs, potentially reducing diversion and abuse.<sup>10</sup> Preliminary findings from a Massachusetts study comparing individuals who were subjects of unsolicited reports to prescribers (cases) to a matched non-intervention comparison group (controls) show that in the year following the reports the cases exhibited greater declines than controls in the number of prescriptions, number of prescribers, number of pharmacies, average dosage units, and average days supply (how many days the supply of dispensed medication will last), with the greater decline in number of

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<sup>4</sup> Centers for Disease Control, Unintentional drug poisoning in the United States, <http://www.cdc.gov/homeandrecreationalsafety/pdf/poison-issue-brief.pdf>

<sup>5</sup> Centers for Disease Control, “What States Can Do to Reverse the PDO Epidemic,” <http://www.sa4docs.org/wp-content/uploads/2013/07/What-States-Can-Do-to-Reverse-the-PDO-Epidemic.pdf>

<sup>6</sup> Prescription Drug Monitoring Program Center of Excellence. (2011). Nevada’s proactive PDMP: the impact of unsolicited reports. NFF 2.5. Heller School, Brandeis University. Waltham, MA. [http://www.pdmpexcellence.org/sites/all/pdfs/nevada\\_nff\\_10\\_26\\_11.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf).

<sup>7</sup> Prescription Drug Monitoring Program Center of Excellence. (2010). Trends in Wyoming PDMP prescription history reporting: evidence for a decrease in doctor shopping? NFF 1.1. Heller School, Brandeis University. Waltham, MA. [http://www.pdmpexcellence.org/sites/all/pdfs/NFF\\_wyoming\\_rev\\_11\\_16\\_10.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf)

<sup>8</sup> Massachusetts Department of Public Health. (2012, February). PDMP Advisory Council presentation. Public Health Advisory Council Meeting, Boston, MA.

<sup>9</sup> Sorg, M., Labrie, S., & Parker, W. (2009). Analysis and evaluation of participation by prescribers and dispensers in the Maine state prescription monitoring program. Margaret Chase Smith Policy Center, University of Maine.

<sup>10</sup> Simeone, R. & Holland, L. (2006). An evaluation of prescription drug monitoring programs. Simeone Associates, Inc. Albany, NY. [www.simeoneassociates.com/simeone3.pdf](http://www.simeoneassociates.com/simeone3.pdf)

pharmacies and average days supply reaching statistical significance.<sup>11</sup> Gonzalez and Kolbasovsky report that possible doctor shoppers whose providers in a managed care organization were sent unsolicited prescription data exhibited greater reductions in opioid prescribers, pharmacies, and opioid prescriptions compared to possible doctor shoppers whose providers were not sent such information.<sup>12</sup> More such studies are needed to measure the impact of unsolicited reports, determine how they are best distributed and to whom, and validate the criteria of questionable activity that trigger them.<sup>13</sup> However, existing research and experience of states thus far (more examples will be discussed below) support unsolicited reporting as a PDMP best practice worthy of adoption by all PDMPs.<sup>14</sup>

### Current status of unsolicited reporting

The number and proportion of PDMPs conducting unsolicited reporting has been increasing. A 2006 survey of PDMPs by the BJA/IJIS Institute PMP Committee found that 25 of the 31 existing PDMPs were authorized to provide unsolicited reports to one or more categories of end users, but only 13 (42 percent) were actually doing so.<sup>15</sup> According to surveys conducted by the PDMP Training and Technical Assistance Center in 2012, 38 of the 49 existing PDMPs were authorized to provide unsolicited reports or alerts to one or more categories of end users, and 26 (53 percent) were actually doing so. Of the PDMPs providing reports in 2012, 20 were sending them to prescribers, 10 to dispensers, 12 to law enforcement, and 13 to health professional licensing boards. In 2006, only nine were sending them to prescribers, five to dispensers, seven to law enforcement, and six to licensing boards.

Currently just three states—Delaware, Louisiana, and West Virginia—are sending unsolicited reports to all categories of recipients, and only a quarter of PDMPs (12 of 49) are submitting reports to law enforcement. However, the fact that half of the states are now engaged in at least some unsolicited reporting suggests that it is within the capacity of PDMPs, hence an attainable best practice. The benefits and feasibility of unsolicited reporting are inducements for states to amend their PDMP legislation to authorize it, or to implement it should authorization already be in place.

The remainder of this report presents examples of states conducting unsolicited reporting to various PDMP recipients under a variety of protocols, including some innovative approaches only recently adopted. They illustrate options for unsolicited reporting, one or more of which may be

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<sup>11</sup> Young, Leonard, "Massachusetts Prescription Monitoring Program," presentation for the 2012 PDMP National Meeting, [http://www.pdmpassist.org/pdf/PPTs/National2012/3\\_Young\\_StatePanelInnovationsMassachusetts.pdf](http://www.pdmpassist.org/pdf/PPTs/National2012/3_Young_StatePanelInnovationsMassachusetts.pdf).

<sup>12</sup> Gonzalez, A.M. & Kolbasovsky, A. (2012). Impact of a Managed Controlled-Opioid Prescription Monitoring Program on Care Coordination, *Am J Manag Care*. 2012;18(9):516-524.

<sup>13</sup> The CDC has funded Abt Associates to conduct a randomized controlled trial of the effects of unsolicited reporting in Nevada on the medical claims of Medicaid patients. Results from this study will likely not be available for two years.

<sup>14</sup> See PDMP Center of Excellence, 2012. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, pp. 31-33. [http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis\\_PDMP\\_Report.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf).

<sup>15</sup> PMP Committee Phase II PMIX Pilot Project Survey of State Prescription Monitoring Programs at: [http://www.kms.ijis.org/db/share/public/PMIX/ijis\\_pmix\\_survey\\_ta\\_report\\_20070204.pdf](http://www.kms.ijis.org/db/share/public/PMIX/ijis_pmix_survey_ta_report_20070204.pdf), and Appendix E: Survey Tabulation Worksheets—available upon request from IJIS Institute or PDMP Center of Excellence at Brandeis University: [www.pdmpexcellence.org](http://www.pdmpexcellence.org).

currently feasible for a state, though they might require regulatory changes and/or development of the necessary capacity. It is important to note that some PDMPs not mentioned in this guidance document are conducting unsolicited reporting to various end users in ways that may be similar to the selected examples.

### Options for unsolicited reporting

#### Procedures for unsolicited reporting to prescribers and dispensers

*Criteria for questionable activity.* The process of unsolicited reporting to prescribers and dispensers begins with analyses of PDMP data to flag patients meeting criteria or thresholds for questionable activity, such as doctor shopping, or for receiving possibly dangerous quantities and/or combinations of controlled substances. Criteria ordinarily include receiving prescriptions for the same drug type from multiple prescribers and pharmacies in a relatively short time period, resulting in overlapping prescriptions, or being prescribed more than a certain average daily dose of opioids (e.g., above 100 morphine milligram equivalents).<sup>16,17</sup> Individuals who meet these thresholds may be doctor shopping or be at risk of abuse, medical complications, overdose, or death; this justifies unsolicited reporting as a public health and safety intervention. Although a particular threshold for doctor shopping or unsafe prescribing or dispensing may produce false positives, prescribers and dispensers following up on a PDMP report make the final determination on whether a patient's controlled substance behavior warrants intervention. Unsolicited reporting can, therefore, err somewhat on the side of greater sensitivity, identifying all or most questionable activity, without compromising good medical care. However, too many false positives might produce "alert fatigue" among recipients and undermine the credibility of the PDMP, so a reasonable degree of specificity is needed. Research on criteria for questionable activity as identified in PDMP and other data is ongoing and will serve to inform and improve best practices in unsolicited reporting.<sup>18</sup> Optimal criteria for unsolicited reporting may vary by state.

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<sup>16</sup> Dunn, K.M., Saunders, K.W., Rutter, C.M., Banta-Green, C.J., Merrill, J.O., Sullivan, M.D., Weisner, C.M., Silverberg, M.J., Campbell, C.I., Psaty, B.M., & Von Korff, M. (2010). Opioid prescriptions for chronic pain and overdose. *Annals of Internal Medicine*, 152(2), 85--93.

<sup>17</sup> Maine's PDMP statute specifies criteria for its unsolicited reporting: "The Office shall review prescription monitoring information related to individual patients to determine which patients have surpassed threshold levels of controlled substances. These threshold levels may include any of the following:

- high number of prescribers in a short time period, as determined by the Office [of Substance Abuse];
- high number of doses during a short time period, as determined by the Office;
- days supply of prescriptions for the same drug overlapping by more than a few days;
- unhealthy combinations of controlled substances, as determined by the Office;
- more than one method of payment within a short time period;
- more than one out of state prescriber for the same patient, during a short time period, as determined by the Office;
- more than one pharmacy on the same day;
- more than one pharmacy in different public health districts within one month; AND/OR
- dangerous levels of specific drugs, as determined by the Office."

<sup>18</sup> See PDMP Center of Excellence, 2011, "Identifying probable doctor shopping and other questionable activity using prescription monitoring data: some preliminary findings," [http://www.pdmpexcellence.org/sites/all/pdfs/COE\\_rpt\\_dr\\_shopping\\_6.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/COE_rpt_dr_shopping_6.pdf) and PDMP Center of Excellence, 2012. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, pp. 21-24, [http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis\\_PDMP\\_Report.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf).

*Setting a threshold.* A given threshold for questionable activity—for example, being prescribed opioids by four prescribers and being dispensed those prescriptions from four pharmacies in a three-month period—will flag a certain number of individuals for reporting. Depending on the threshold and the population of the state, individuals flagged can number in the thousands. To make unsolicited reporting manageable, states can set an initial threshold commensurate with their capacity to send reports or alerts. That capacity will, of course, depend on the reporting mechanism itself, which may be conducted via mailed paper reports, fax, email, or automated flags in an electronic medical record. As a state increases its capacity and as the number of individuals meeting a particular threshold declines,<sup>19</sup> the threshold can be lowered as appropriate.

### Unsolicited reporting to medical providers

*Paper-based reporting in Maine.* Since 2005, Maine has sent prescribers quarterly threshold notification reports via U.S. mail. Reports are sent to prescribers when a patient 1) has exceeded a certain number of prescribers and pharmacies in a three-month period; 2) has exceeded a specified average daily dose of acetaminophen coming from prescriptions of opioid-acetaminophen combination drugs (e.g., Vicodin, Percocet); or 3) is prescribed buprenorphine (a partial opioid agonist used in treating opioid dependence in office-based settings) and another opioid in a 30-day period. (For further details on Maine's unsolicited reporting criteria, see note 16 above.) Reports list the other providers who have prescribed to the patient, the pharmacies that dispensed to the patient, and details of prescriptions dispensed for the past three months. Reports are sent both to prescribers who are enrolled and to those not enrolled in the PDMP. The automated data analyses, report production, and mailing are currently handled by Maine's PDMP vendor. The fee for reporting is built into the vendor contract, not charged on a per-report basis. A 2009 survey of prescribers who received threshold reports found that substantial proportions of respondents took action in response, including looking up the patient's prescription history in the PDMP, calling other prescribers, talking to the patient, and conducting a substance abuse screening and brief intervention.<sup>20</sup> Recent numbers of reports, determined by the number of individuals meeting the questionable activity threshold, have ranged from 1,686 for the third quarter of 2011, to 778 for the third quarter of 2012, to 1,139 for the fourth quarter of 2012. The threshold has remained constant, so the number of likely doctor shoppers as measured by this criterion (those meeting the threshold) declined 32 percent from the third quarter of 2011 to the fourth quarter of 2012.

*Faxed alerts in Arizona.* Since 2009, the Arizona PDMP has been alerting prescribers every month about possible doctor shopping via faxed letters on patients meeting a relatively high threshold, one unlikely to generate false positives. The letters contain the patient's name and date of birth, and the prescriber is encouraged to access the PDMP to review that patient's

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<sup>19</sup> The number of individuals meeting a threshold can decline in response to use of PDMP, including both unsolicited and solicited reports. See PDMP Center of Excellence, NFF 1.1, [http://www.pdmpexcellence.org/sites/all/pdfs/NFF\\_wyoming\\_rev\\_11\\_16\\_10.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf).

<sup>20</sup> Sorg et al., 2009, op cit., p. 34.

prescription history. The alerts thus serve as an inducement to use the database (Arizona currently mandates that prescribers enroll with the PDMP, but not that they use it). In 2009, over 40 individuals met the threshold in one month, requiring alerts to over 200 prescribers; since then, the number meeting the threshold has declined, plateauing in the mid-teens, which still generates over 100 letters to prescribers each month. The decline in the number of possible doctor shoppers since 2009 suggests that the alerts, by encouraging use of the PDMP, may prompt providers to take action to curtail medically unnecessary or dangerous prescribing. The generation and faxing of letters takes approximately three days per month, so the PDMP is considering ways to streamline the process—for instance, via emailed alerts (see the examples below regarding Massachusetts and Louisiana electronic alerts). In consultation with its advisory committee, Arizona is also considering moving to a lower threshold, in particular for its rural areas. This would flag more likely doctor shoppers, but would require additional resources to disseminate the additional alerts.

At the recent request of Arizona's Medicaid program, the Arizona Health Care Cost Containment System (AHCCCS), the PDMP now reviews the prescription histories of all those meeting the threshold to see if any individuals have obtained controlled substances via Medicaid. If they have, their prescription information is forwarded to AHCCCS, which then undertakes its own reviews. The PDMP data assist in these reviews since they contain an individual's entire prescription history, including information not usually visible in Medicare claims data, such as prescriptions paid for in cash and by other insurers. Thus far, approximately one to three patients per month have been referred to AHCCCS.

*Electronic alerts in Massachusetts.* From January 2010 to December 2012, the Massachusetts Prescription Monitoring Program (MA PMP) sent paper-based unsolicited reports on over 100 individuals exceeding thresholds for doctor and pharmacy shopping. A total of 2,087 unsolicited reports were sent to the prescribers associated with these individuals' prescriptions, with some prescribers receiving reports on two or more individuals. As noted above in the section "Unsolicited reports as a PDMP best practice," a large majority of prescribers responding to a survey reported being unaware of all the other providers prescribing to these patients, indicating that the reports functioned to notify them about possible clinically inappropriate use of controlled substances.

The MA PMP has discontinued paper-based unsolicited reports to prescribers and now issues electronic notifications (alerts); the first alerts were sent out in July 2013. The PDMP system identifies individuals meeting a threshold based on experience with the database, peer-reviewed literature, and recommendations from the MA PMP's Medical Review Group (MRG). (The MRG, composed of physicians, dentists, and pharmacists, is charged with assisting the Massachusetts Department of Public Health in the evaluation of prescription information.) Alerts for each flagged individual are generated and emailed automatically to all the prescribers registered with the PDMP who issued prescriptions to those individuals. The system is designed to allow the PDMP to set the repeat interval for when a prescriber would receive another email alert concerning the same patient (to avoid "alert fatigue"). Costs associated with the system were primarily generated during the design,

testing, and implementation phases; operating costs are anticipated to be minimal. Once alerts are fully operational, the MA PMP plans to assess its impact by monitoring recipients' queries to the database and via a web-based survey of prescribers.

*Electronic and mailed alerts in Louisiana.* Louisiana's PDMP has conducted unsolicited reporting to both prescribers and dispensers since January 2010. As in Massachusetts' electronic system described above, patients meeting a threshold for questionable activity are flagged via an automated search of the PDMP database. A prescription history profile for each patient is generated and made available for download in the relevant provider's PDMP account. If a prescriber is enrolled in the PDMP, an alert is sent via email to the prescriber informing them that the profile is available for viewing, along with the profile's query number and the patient's name and date of birth. If a prescriber is *not* enrolled, they receive a hard-copy letter notifying them about the patient and suggesting they enroll in the PDMP so they can view the profile.<sup>21</sup> Dispensers only receive hard-copy letters, addressed to the pharmacist-in-charge. As in Massachusetts, no prescription data are transmitted in any alerts; this serves to protect patient confidentiality and incentivize enrollment and system use. Before alerts are released, each patient's prescription history is reviewed by the PDMP administrator to ensure that it is truly indicative of questionable activity, helping to prevent false positives. The design and implementation costs for the unsolicited reporting system were estimated at approximately \$40,000.

When alerts were first sent in 2012, the alert threshold flagged 1,106 patients, which would have resulted in 5,817 alerts to prescribers and 5,784 to dispensers. However, after review, enough reports were judged false positives (patients for whom alerts were *not* sent after their prescription histories were reviewed) that the decision was taken to raise the threshold. Fewer individuals are automatically flagged at this higher threshold, but their prescription histories are more likely to merit alerts, thus reducing the administrator's time spent weeding out likely false positives. Recently, the Louisiana Medical Board requested a list of prescribers not enrolled in the PDMP that received the most alert letters—that is, those that had the most possible doctor shoppers in their practice. The Medical Board then contacted those physicians to encourage enrollment, after which they registered with the PDMP and began requesting patient profiles. Only the PDMP's proactive identification of possible doctor shoppers in these practices enabled the Medical Board to take such action.

### **Unsolicited reporting to law enforcement and licensing boards**

#### Reports to law enforcement on doctor shopping

Some states either require or permit unsolicited reporting of possible doctor shoppers to law enforcement. Here are four examples:

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<sup>21</sup> A presentation on Louisiana's unsolicited reporting that includes the text of the letter can be viewed at <http://www.pdmassist.org/pdf/PPTs/South2012/UnsolicitedReportingLA.pdf>.

*North Carolina.* The North Carolina PDMP statute requires that “unusual patterns” of patient behavior be reported to the Attorney General. The North Carolina PDMP flags patients who meet a threshold of prescribers and pharmacies suggestive of doctor shopping and controlled substance diversion. Before forwarding prescription history reports on these patients to the Attorney General, the information is carefully reviewed to rule out explanations other than doctor shopping and to find any recent indications of behavior change, such as prescriptions for buprenorphine used in office-based opioid addiction treatment. Over the past three years, approximately 100 such reports have been forwarded. The threshold used and the careful review in North Carolina’s unsolicited reporting to the Attorney General help to focus law enforcement attention on the most serious cases of possible doctor shopping and drug diversion detectable in PDMP data.

*Kansas.* Kansas recently passed legislation<sup>22</sup> creating a PDMP Advisory Committee empowered to “identify patterns and activity of concern” using PDMP data. A volunteer panel of six prescribers and pharmacists drawn from the advisory committee—the Peer Review Committee—reviews PDMP reports (“patient profiles”) suggestive of possible doctor shopping sent to them by PDMP staff. The Peer Review Committee determines whether further action is warranted (the decision must be unanimous) and, if so, sends the reports to medical providers or law enforcement, depending on the level of prescription activity. Over the past year, it has sent unsolicited reports to law enforcement on just four individuals, those with the highest numbers of prescribers and pharmacies according to analyses of PDMP data. As judged by the committee, this level of activity was indicative of organized diversion for which criminal investigation would be appropriate.

*Wyoming.* Wyoming’s PDMP will sometimes notify local law enforcement officials about individuals in their area who exhibit patterns of suspicious behavior that show up in PDMP data, such as traveling out of state to obtain prescriptions while simultaneously using local providers. Such individuals may or may not meet a standard threshold for questionable activity used for sending out unsolicited reports to medical providers. The decision to report to law enforcement is based upon the accumulated experience and discretion of PDMP staff in deciding which prescription histories indicate likely instances of diversion that merit criminal investigation, as opposed to instances of possible addiction or abuse best brought to the attention of medical providers.

*Texas.* The Texas PDMP routinely conducts data analyses to identify possible doctor shoppers for law enforcement investigation. For further details, see “Reports on providers to law enforcement” below.

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<sup>22</sup> [http://www.kslegislature.org/li\\_2012/b2011\\_12/measures/documents/summary\\_sb\\_134\\_2012.pdf](http://www.kslegislature.org/li_2012/b2011_12/measures/documents/summary_sb_134_2012.pdf)

### Unsolicited reporting on medical providers

Unsolicited reporting is applicable concerning medical providers who, whether intentionally or not, may be engaging in risky or illegal prescribing or dispensing. The CDC recommends that PDMPs focus on “prescribers who clearly deviate from accepted medical practice in terms of prescription painkiller dosage, numbers of prescriptions for controlled substances, and proportion of doctor shoppers among their patients.”<sup>23</sup> Alerts concerning questionable activity by providers may be appropriately addressed to licensing boards, peer review committees, third-party payers, Medicare and state Medicaid, and other bodies charged with monitoring medical practitioners. When analysis of PDMP data identifies probable criminal activity, such as prescribing and/or dispensing by pill mills, referral to law enforcement agencies is appropriate.

Indicators of possible problematic *prescribing* detectable in PDMP data might include, for example, opioid prescriptions and/or doses in excess of accepted norms for the type of practice (e.g., a dentist routinely prescribing and renewing a month’s supply of 80 mg oxycodone); primarily prescribing combinations of drugs known to be “drug cocktails” (e.g., the combination of hydrocodone or oxycodone, alprazolam, and carisoprodol); having many patients in a practice that meet criteria for doctor shopping; and prescribing for many out-of-state or geographically distant patients. Data on deaths, overdoses, and other adverse health outcomes associated with prescription drug abuse among a prescriber’s patients would also be relevant. Signs of possible problematic *dispensing* by pharmacists and physicians include high proportions of cash payments for prescriptions dispensed, especially for prescriptions that duplicate those covered by Medicaid, filling what are obviously forged prescriptions, and filling duplicate or excessive prescriptions without seeking confirmation from prescribers. Reliable criteria in PDMP and other data of questionable activity by providers need further research and validation.<sup>24</sup>

As PDMPs review provider prescription records that might trigger unsolicited reports, they should consider possible legitimate reasons for what might appear to be problematic prescribing or dispensing, such as pain management specialists practicing in a hospital-based pain clinic. Even after such review, it is important to note that unsolicited reports on providers are only preliminary, possible indicators of a problem. Determining whether a problem exists and any further investigation is appropriate is a matter for further consideration by the body receiving the report (e.g., licensing board, peer review committee, or law enforcement agency). Such investigations can involve coordination among some or all of those bodies charged with maintaining good medical practice and ensuring public safety.

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<sup>23</sup> CDC, Policy Impact: Prescription Painkiller Overdoses, at <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/>.

<sup>24</sup> See, for instance, DuBose, P., Bender, A., & Markman, J.W. (2011, June). Rank-ordering physicians by opioid abuse and diversion risk. Poster presented at the International Narcotics Research Conference, Hollywood, FL.

### Reports on providers to licensing boards

Even if possible problematic prescribing or dispensing does not reach a level or type meriting law enforcement investigation, it may nevertheless be appropriate for reporting to medical and pharmacy licensing boards. Here are two instances of such reporting:

*Kentucky.* As part of its recent legislative mandate for proactive use of PDMP data, Kentucky's PDMP—the Kentucky All Schedule Prescription Electronic Reporting system (KASPER)—conducts unsolicited reporting on prescribers in coordination with the Drug Enforcement and Professional Practices branch of the Office of the Inspector General (OIG). Reporting is based upon criteria established by the Governor's KASPER Advisory Council, which is composed of representatives from Kentucky licensing boards, professional associations, law enforcement, and other key stakeholders. Prescription history reports on the top prescribers of the most commonly abused and diverted controlled substances are sent to OIG investigators, who evaluate the reports to see if further investigation of potentially inappropriate or illegal prescribing is warranted. Initial prescriber reviews were conducted based on KASPER Advisory Council criteria specifying the top two percent of prescribers issuing prescriptions for oxycodone, hydrocodone, oxymorphone, methadone, alprazolam, and the drug “cocktail” (see “Unsolicited reporting on medical providers” above). The OIG investigators are registered pharmacists and certified peace officers in Kentucky who review the provider's prescribing history, the type of practice, prior record of disciplinary action, and several other factors. If the review indicates a substantial likelihood of problematic prescribing, the information is forwarded to the appropriate licensing board for further review. A second set of prescriber reviews is underway based upon revised criteria provided by the KASPER Advisory Council after evaluating the results of the initial reviews.

If a report forwarded to a licensing board results in a prescriber investigation, the licensing board notifies authorized personnel in the OIG, Attorney General's office, and Kentucky State Police Drug Enforcement/Special Investigations unit. Such notifications assist in case coordination and de-confliction (such as identifying when an investigation of the same provider is underway by a sister agency). Since unsolicited reporting began in July 2012, KASPER reports have triggered over 80 licensing board investigations of prescribers. These have resulted in retirements, agreed orders setting out sanctions and terms to be imposed upon the prescriber, and controlled substance license revocations, with the result that some problematic prescribers have modified their practices or have been removed from the system. Without proactive analysis of KASPER data and reporting to boards, these prescribers would likely have gone undetected.

*Tennessee.* The Tennessee PDMP currently provides data to licensing board investigators on the most frequent prescribers, both for numbers of prescriptions and total dosage units of certain controlled substances. The PDMP is in the process of incorporating refinements to these criteria, such as data on how a provider's prescribing compares to norms for a particular type of practice (e.g., general medicine or orthopedics) and how practices vary in the types and dosages of prescribed controlled substances. The PDMP has added staff with analytical and epidemiological expertise to develop these measures using PDMP data. At the

time of this report, no data were available on outcomes of unsolicited reporting of prescribers to Tennessee licensing boards.

### Reports on providers to law enforcement

Some states conduct unsolicited reporting on medical providers to law enforcement, usually in coordination with licensing boards so that cases are referred to the most appropriate agency. Here are three examples:

*Texas.* The Texas PDMP, the Texas Prescription Program<sup>25</sup> housed in the Department of Public Safety (DPS), conducts frequent analyses of its database to detect possible problematic prescribing and dispensing, as well as doctor shopping. Automated algorithms generate reports on providers meeting pre-defined criteria suggestive of diversion, such as being among the most frequent prescribers or dispensers of certain controlled substances. Prescription data are reviewed to help rule out legitimate reasons for what seems to be diversionary prescribing or dispensing, as well as to scan for indicators warranting further exploratory or targeted data analyses. When a provider or a possible doctor shopper is identified as reportable to law enforcement, staff decides whether to refer the case to investigators within the DPS or to another law enforcement agency—federal, state, county, or local. Investigators receive a complete prescription history report; in some cases, copies of prescriptions are included. Cases on medical providers not deemed appropriate for law enforcement investigation are referred to licensing boards. Care is taken to coordinate with other agencies in order not to compromise investigations already underway (de-confliction) and to supply PDMP data relevant to those investigations. The Texas PDMP has produced an average of 20-25 prescription drug cases a month for law enforcement investigation, making it among the most active PDMPs for this type of unsolicited reporting. Recently, several doctor shopping cases have been initiated and successfully prosecuted with the help of PDMP data.

*New Jersey.* The New Jersey statute enabling the PDMP, which started in September 2011, permits unsolicited reporting of medical providers to law enforcement. Quarterly analyses are conducted to look for concerning patterns of prescribing and dispensing, such as identifying the state's top prescribers and pharmacies for controlled substances commonly encountered in cases of illegal prescribing. Database searches are conducted using drug therapeutic codes and dosage types (e.g., 30 mg Roxycodone) and payment type. If suspicious departures from normal prescribing practice are detected, the appropriate law enforcement agency (or licensing board, depending on the level and type of activity) is contacted. Recent analyses related to possible diversion have focused on top prescribers of oxycodone where payments for prescriptions are made in cash. The PDMP also runs ad hoc analyses to further explore patterns identified in quarterly reviews or investigate developments reported to the PDMP by other agencies. For example, law enforcement agencies may report that

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<sup>25</sup> [http://www.txdps.state.tx.us/RegulatoryServices/prescription\\_program/](http://www.txdps.state.tx.us/RegulatoryServices/prescription_program/)

promethazine with codeine syrup is turning up on the street, so analyses are run for promethazine. The PDMP hopes to add more regular analyses using preset criteria as resources permit.

*Louisiana.* In addition to its unsolicited reporting of doctor shoppers (see “Unsolicited reporting to medical providers” above), the Louisiana PDMP occasionally notifies law enforcement (e.g., narcotics investigators) about individual prescribers engaging in suspected diversionary prescribing, such as operating a pill mill.

### Promising practices and innovations

Besides the types of unsolicited reporting surveyed above, some PDMPs have explored novel approaches to proactive dissemination of data that expand the range of analyses, end users receiving reports, and means of dissemination. Although the efficacy and general applicability of these approaches are yet to be determined, they are worth noting as examples of how states develop and test innovative applications of PDMP data.

*North Carolina alerts to pharmacies and physicians on suspect prescriptions.* In collaboration with pharmacies and prescribers, the North Carolina PDMP is developing and validating analyses to detect possible prescription forgeries. For example, if an individual fills a number of prescriptions of a controlled substance from a single doctor at different pharmacies in a week’s time, this may suggest passing forged prescriptions, especially if there is no prior history of being prescribed controlled substances. The North Carolina PDMP staff will contact the pharmacies that dispensed the suspect prescriptions to see if they were verified with the prescriber and, if not, suggest they do so. If the prescription cannot be verified with the prescriber, this alerts both the pharmacy and prescriber that forgery may have occurred. These unusual prescription pattern cases are referred to the Office of the Attorney General for review to determine the appropriate course of action.

*Massachusetts outreach to at-risk prescribers.* As a strategy to increase provider enrollment in the MA Online PMP, Massachusetts’ Drug Control Program, identified so-called “at-risk” prescribers: those with significant numbers of patients meeting criteria for possible doctor and pharmacy shopping. In 2012, the PDMP sent an outreach letter to 150 at-risk prescribers who were not yet enrolled to use the online PDMP. The letter informed the provider that MA PMP data showed that their practice had a high proportion (relative to the state average) of doctor and pharmacy shoppers and suggested they enroll in the MA Online PMP. As of April 2013, approximately 40 percent of these prescribers had registered with the PDMP. To assess the impact of PDMP enrollment of at-risk prescribers on doctor shopping, analyses of PDMP data were conducted comparing a group of at-risk prescribers enrolled in the PDMP for at least one year (N=20) to a non-enrolled group of at-risk prescribers (N=70). From 2009 to 2012, prescribers who eventually enrolled had a 65 percent decrease in the number of patients who met criteria for doctor and pharmacy shopping, while prescribers who did not

enroll had a 35 percent decline.<sup>26</sup> These findings suggest that use of the PDMP by at-risk prescribers can help reduce the prevalence of doctor and pharmacy shopping.<sup>27</sup>

*Mississippi unsolicited reporting to patients.* In a 2011 pilot project,<sup>28</sup> the Mississippi PDMP sent letters to 40 individuals who had used more than one pharmacy, visited more than 10 practitioners, and received more than 24 controlled substance prescriptions in a 180-day period. The letter notified recipients that it was “a good faith effort to prevent you from circumventing state and federal laws in obtaining prescription drugs and assist you if you need medical help.” It included a toll-free number for the Mississippi Department of Mental Health’s helpline on drug prevention and treatment resources. Prior to notification, these individuals on average were receiving eight prescriptions and 278 dosage units per month. Dosage units for these patients in the month prior to sending the letters totaled 11,435. Three months after the letters were sent, this total dropped to 7,295, a 36 percent decline. Follow up on these individuals showed that in May 2013, 10 had no PDMP prescription activity, while the 30 who did have activity averaged two prescribers, two pharmacies, and four prescriptions in that month. These data suggest that the letters may have had an effect on these individuals’ access to controlled substances, at least as measured by PDMP data (there were no data gathered in this study on comparable individuals who were not sent letters).

*Indiana user-led unsolicited reports.* In Indiana, a practitioner who has retrieved PDMP data suggestive of a patient’s questionable activity has the option to email alerts to prescribers and dispensers mutually treating the patient. The alerts contain a hyperlink to the patient’s prescription history report that registered users can use to view the report. If an alert recipient is *not* registered with the PDMP, they must register before the link enables them to view the report. The alerts thus function to encourage enrollment in the program as well as to notify those already enrolled that a patient may be involved in medically unnecessary prescription drug use or controlled substance diversion. In May 2012, 140 practitioners sent 2,284 alerts on 214 unique patients; recipients of alerts included 770 registered PDMP users and 1,690 unregistered users.<sup>29</sup> By enabling providers to send alerts as part of their medical practice, Indiana increases the proactive dissemination of PDMP data at virtually no cost to the program.

*Automated delivery of prescription data: Kansas/Via Christi and NarxCheck™.* In a pilot project funded by a SAMHSA 2012 PDMP Electronic Health Record Integration and Interoperability grant,<sup>30</sup> the Kansas PDMP is collaborating with Via Christi Health System (the state’s largest health care services provider) to make PDMP data continuously available to its six Kansas

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<sup>26</sup> The fact that non-enrolled prescribers also exhibited a decline, albeit not as great, in the percentage of doctor and pharmacy shoppers in their practices indicates that there are likely other factors involved in these downward trends. Further research is necessary to identify these factors and determine the relative contribution to changes in doctor shopping measures. Unsolicited reports on patients were also being sent to some prescribers during this time.

<sup>27</sup> A presentation on this study can be viewed at: <http://www.slideshare.net/OPUNITE/new-focuses-forpdmpseffortsfinal> (see slides 47-66).

<sup>28</sup> A presentation on this program can be viewed at: <http://www.pdmpassist.org/pdf/PPTs/South2012/UnsolicitedReportingMS.pdf>.

<sup>29</sup> A presentation on this initiative can be viewed at [http://www.pdmpassist.org/pdf/PPTs/National2012/2\\_Allain\\_StatePanelInnovationsIndiana.pdf](http://www.pdmpassist.org/pdf/PPTs/National2012/2_Allain_StatePanelInnovationsIndiana.pdf).

<sup>30</sup> <http://www.samhsa.gov/grants/2012/TI-12-011.pdf>

hospital emergency departments (EDs). A revised summary screen of patient information for ED admissions will add a cell for each patient containing a snapshot of his or her PDMP data, including recent numbers of prescriptions and providers and a link to the patient's complete prescription history. The cell will also include an alert system, with a red flag indicating that the patient meets a threshold for questionable activity as set by Via Christi practitioners (the same threshold will be used by all six Via Christi EDs). The system is due for testing with live patient data in the summer of 2013. The pilot project was undertaken partially in response to concerns from ED practitioners that threshold letters (unsolicited reports) coming from the Kansas PDMP were not timely enough to inform their prescribing.

A similar approach, now available in Indiana and Ohio, is offered by the NarxCheck™ system, which automatically provides summary prescription history information to prescribers as they view a patient's electronic health record. Utilizing PDMP data and proprietary algorithms to detect possible doctor/pharmacy shopping, the system displays risk scores for patients on three categories of drugs: narcotics, sedatives, and stimulants. The patient's full prescription history is accessible in both graphical and tabular formats.<sup>31</sup>

It should be noted that prescription information integrated with electronic health records, whether in EDs or other facilities, will only be seen by a prescriber when retrieving those records. This prescriber-initiated mode of access to PDMP data is therefore not equivalent to proactively delivered alerts, which notify medical providers about a possible problem independently of patient visits. Efforts to increase provider use of PDMP information by integrating it into electronic health records and medical workflow will be the focus of a separate PDMP Center of Excellence report.

*Other criteria for unsolicited reporting in Maine.* As noted above in "Unsolicited reporting to medical providers," the Maine PDMP sends unsolicited reports not only for patients who meet a threshold for doctor shopping, but for those exceeding a certain average daily dose of acetaminophen from prescribed controlled substances that would put them at risk of liver failure and death. It also reports on patients prescribed buprenorphine and any other opioid, which could compromise addiction treatment or indicate diversion. This suggests that PDMPs can improve prescribing by searching for and reporting instances of possibly harmful drug combinations, such as overlapping prescriptions for opioid and benzodiazepines, or for simultaneous prescriptions of drugs in the same therapeutic class that if taken as directed might result in an overdose. PDMPs can, therefore, contribute to good medical practice by proactively reporting potentially unsafe prescribing that may not be directly related to suspected doctor shopping.

*Arizona unsolicited reporting to Medicaid.* As described above in "Unsolicited reporting to medical providers," Arizona's PDMP forwards prescription history reports to the state's Medicaid agency for individuals meeting criteria for questionable activity who have purchased prescriptions via Medicaid. Public and private third-party payers can benefit from such

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<sup>31</sup> A presentation on Narxcheck™ is available at <http://www.pdmpassist.org/pdf/PPTs/National2013/25-6-A%20Allain.pdf>.

unsolicited reporting in monitoring patient and prescriber behavior because PDMP data capture the full range of non-hospital dispensed prescriptions, including those paid for in cash.<sup>32</sup>

### Barriers to unsolicited reporting

As noted above in “Current status of unsolicited reporting,” many states do not conduct unsolicited reporting despite the fact that it is considered a PDMP best practice. There are a variety of barriers to adopting unsolicited reporting that need to be addressed, including:

*Legislative restrictions.* Some states either expressly forbid unsolicited reporting to one or more types of end users in their PDMP-enabling legislation or do not specifically provide for it in legislative or regulatory language. Amending legislation and/or regulations to permit such reporting requires building support for such a change among stakeholders and finding legislators and policy makers who understand the issue and will support the needed changes. (North Carolina recently enacted changes to its legislation to permit unsolicited reporting to medical providers and licensing boards.) The evidence in favor of the efficacy and positive impact of unsolicited reporting, some of which is mentioned above, can help build such support. Washington State’s 2007 enabling legislation<sup>33</sup> was farsighted in its inclusion of specific language permitting the PDMP to provide data to a wide range of end users, including medical providers, law enforcement, licensing boards, Medicaid, workers’ compensation, and the Department of Corrections. States considering legislation bearing on unsolicited reporting may wish to consult the PMP Model Act 2010 revision Section 7 on providing prescription monitoring information.<sup>34</sup>

*Resource limitations.* Even if their legislation permits unsolicited reporting, many PDMPs are under-resourced, whether in staff, funding, or analytical and reporting capacities, so they cannot undertake new initiatives. For a PDMP to adopt unsolicited reporting as a best practice, among other PDMP best practices, it may be necessary to secure additional resources. Again, marshaling evidence for the effectiveness of unsolicited reporting can help a PDMP make the case for the requisite staffing or operational capacity. There is also a range of approaches to unsolicited reporting, some described above, which involve relatively little ongoing expense once the necessary systems and software are in place. States embarking on unsolicited reporting can learn from other PDMPs’ experience and perhaps improve on original designs and find ways to reduce costs.

*Concerns about unintended consequences.* Use of PDMPs to monitor possible questionable activity by patients and practitioners, including sending unsolicited reports, sometimes sparks concerns about unintended consequences. For example, some have suggested that practitioners might worry about becoming a target of a licensing board or law enforcement

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<sup>32</sup> For other examples of PDMP data sharing with third-party payers, see PDMP Center of Excellence, 2013, “Using PDMPs to improve medical care: Washington state’s data sharing initiative with Medicaid and worker’s compensation,” [http://www.pdmpexcellence.org/sites/all/pdfs/washington\\_nff\\_final.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/washington_nff_final.pdf).

<sup>33</sup> See <http://apps.leg.wa.gov/RCW/default.aspx?cite=70.225.040>.

<sup>34</sup> See <http://www.pdmpassist.org/pdf/PMPModelActFinal20100628.pdf>.

investigation triggered by a PDMP report and thus could choose to cease prescribing controlled substances altogether; or patients whose prescriber misinterpreted a PDMP report and wrongly accused them of doctor shopping could be fired by their doctors, leaving them without access to needed pain medications. Examining the validity of such concerns is beyond the scope of this report, but it should be noted that PDMPs, cognizant of the downsides of false positives, are generally conservative in setting thresholds for detecting questionable activity among patients, using higher rather than lower numbers of providers and pharmacies. In reporting possible questionable activity by medical providers, PDMPs consult with licensing boards, peer review and advisory committees, and law enforcement agencies to ensure that the criteria for reporting only flag cases meriting their attention. Moreover, unsolicited reports (and PDMP data in general) are themselves never conclusive evidence of aberrant behavior, but simply one piece of information considered by their recipients in determining whether an investigation or intervention should be initiated. PDMPs are careful to note the limitations of their data when providing them to end users. Such considerations may help allay fears among providers and patients that PDMPs are overzealous in unsolicited reporting and thus inadvertently discouraging legitimate medical practice. However, if instances of such outcomes resulting from unsolicited reporting or other PDMP activity occur, they should be examined and taken into appropriate account in setting PDMP policy.

### Summary and conclusions

The examples of unsolicited reporting surveyed here provide a menu of options for states wishing to adopt this PDMP best practice.<sup>35</sup> They illustrate the feasibility of unsolicited reporting and its benefits in helping to improve medical care and reduce aberrant prescribing and dispensing. Given sufficient funding, one or more of the approaches to unsolicited reporting described above, involving mail, fax, and email notifications, are within the capabilities of most PDMPs and will help them maximize the utilization of their data for public health and safety. Elements of effective unsolicited reporting by PDMPs include:

- Choosing a threshold for questionable activity commensurate with PDMP capacity to issue unsolicited reports or alerts.
- Carefully and periodically reviewing criteria for unsolicited reporting and the reports themselves to ensure that false positives are minimized but that most questionable activity is reported.
- Educating and training recipients of reports to ensure they understand the meaning, uses, and limitations of prescription history data.
- Regularly communicating with recipients of unsolicited reports to help validate their criteria and assess their utility, so that reporting can be improved.

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<sup>35</sup> Note that other PDMPs unmentioned in this guidance document also conduct unsolicited reporting in ways similar to the selected examples.

## Options for Unsolicited Reporting

- Consulting with practitioner groups and law enforcement agencies to determine the level and types of possible questionable activity suitable for criminal investigation instead of a medical or pre-criminal intervention.
- Facilitating cross-agency communication on unsolicited reports concerning practitioners to ensure that cases of possible aberrant prescribing or dispensing are referred to the appropriate agency (e.g., licensing board vs. drug control) and that existing or planned investigations are not compromised.
- Tracking the outcomes and impact of unsolicited reporting—for instance, on PDMP utilization, doctor shopping, and aberrant prescribing—using PDMP and other data sources.

Although unsolicited reporting is a recognized PDMP best practice, promising and innovative approaches to unsolicited reporting being explored by states still need to be evaluated for efficiency and effectiveness. As new information technologies become available and PDMP information is better integrated into health care systems, more cost-effective means to alert end users of questionable controlled substance activity will likely be developed (e.g., see *Electronic alerts in Massachusetts* in “Unsolicited reports to medical providers” and *Automated delivery of prescription data: Kansas/Via Christi and NarxCheck™* in “Promising practices and innovations”). The menu of options for unsolicited reporting will likely expand to incorporate newly proven approaches, and the range of standard criteria for triggering reports may expand as well to include, for example, acetaminophen dose thresholds, dangerous drug combinations, and simultaneous prescriptions for drugs in the same therapeutic class.

Universal adoption of unsolicited reporting and its identified best practices will require overcoming legislative, regulatory, and resource barriers and addressing possible concerns about unintended consequences. The experience of states engaged in unsolicited reporting, some of which is summarized above, can provide direction for PDMPs seeking to become more proactive in disseminating prescription history information to help mitigate the prescription drug abuse epidemic.

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# The Prescription Opioid Epidemic: An Evidence-Based Approach

THE PRESCRIPTION OPIOID EPIDEMIC:  
AN EVIDENCE-BASED APPROACH  
November 2015

PREPARED BY

Johns Hopkins Bloomberg School of Public Health,  
Johns Hopkins Center for Drug Safety and Effectiveness,  
and Johns Hopkins Center for Injury Research and Policy



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# Executive Summary

Prescription drugs are essential to improving the quality of life for millions of Americans living with acute or chronic pain. However, misuse, abuse, addiction, and overdose of these products, especially opioids, have become serious public health problems in the United States. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.

At the invitation of the Johns Hopkins Bloomberg School of Public Health and the Clinton Foundation, a diverse group of experts were convened to chart a path forward to address these issues. After a town hall meeting at the School, featuring an inspiring call to action from President Bill Clinton<sup>1</sup>, the group — including clinicians, researchers, government officials, injury prevention professionals, law enforcement leaders, pharmaceutical manufacturers and distributors, lawyers, health insurers and patient representatives — spent the next day and a half:

- Reviewing what is known about prescription opioid misuse, abuse, addiction and overdose;
- Identifying strategies for reversing the alarming trends in injuries, addiction, and deaths from these drugs; and
- Making recommendations for action.

Following this meeting, the group released a consensus statement with three guiding principles for translating the meeting discussion into actionable recommendations.<sup>2</sup>

### **INFORMING ACTION WITH EVIDENCE.**

Some evidence-based interventions exist to inform action to address this public health emergency; these should be scaled up and widely disseminated. Furthermore, many promising ideas are evidence-informed, but have not yet been rigorously evaluated. The urgent need for action requires that we rapidly implement and carefully evaluate these promising policies and programs. The search for new, innovative solutions also needs to be supported.

### **INTERVENING COMPREHENSIVELY.**

We support approaches that intervene all along the supply chain, and in the clinic, community and addiction treatment settings. Interventions aimed at stopping individuals from progressing down a pathway that will lead to misuse, abuse, addiction and overdose are needed. Effective primary, secondary and tertiary prevention strategies are vital. The importance of creating synergies across different interventions to maximize available resources is also critical.

### **PROMOTING APPROPRIATE AND SAFE USE OF PRESCRIPTION OPIOIDS.**

Used appropriately, prescription opioids can provide relief to patients. However, these therapies are often being prescribed in quantities and for conditions that are excessive, and in many cases, beyond the evidence base. Such practices, and the lack of attention to safe use, storage and disposal of these drugs, contribute to the misuse, abuse, addiction and overdose increases that have occurred over the past decade. We support efforts to maximize the favorable risk/benefit balance of prescription opioids by optimizing their use in circumstances supported by best clinical practice guidelines.

Meeting participants formed seven working groups to make recommendations on: 1) prescribing guidelines, 2) prescription drug monitoring programs, 3) pharmacy benefit managers and pharmacies, 4) engineering strategies, 5) overdose education and naloxone distribution programs, 6) addiction treatment, and 7) community-based prevention.

1. [www.jhsph.edu/rxtownhall2014](http://www.jhsph.edu/rxtownhall2014)

2. [www.jhsph.edu/2014consensusstatement](http://www.jhsph.edu/2014consensusstatement)

# Recommendations for Action

### #1 PRESCRIBING GUIDELINES

- 1.1 Repeal existing permissive and lax prescription laws and rules.
- 1.2 Require oversight of pain treatment.
- 1.3 Provide physician training in pain management and opioid prescribing and establish a residency in pain medicine for medical school graduates.

### #2: PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

- 2.1 Mandate prescriber PDMP use.
- 2.2 Proactively use PDMP data for enforcement and education purposes.
- 2.3 Authorize third-party payers to access PDMP data with proper protections.
- 2.4 Empower licensing boards for health professions and law enforcement to investigate high-risk prescribers and dispensers.

### #3: PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

- 3.1 Inform and support evaluation research.
- 3.2 Engage in consensus process to identify evidence-based criteria for using PBM and pharmacy claims data to identify people at high risk for abuse and in need of treatment.
- 3.3 Expand access to Prescription Drug Monitoring Programs.
- 3.4 Improve management and oversight of individuals who use controlled substances.
- 3.5 Support restricted recipient (lock-in) programs.
- 3.6 Support take-back programs.
- 3.7 Improve monitoring of pharmacies, prescribers and beneficiaries.
- 3.8 Incentivize electronic prescribing.

### #4: ENGINEERING STRATEGIES

- 4.1 Convene a stakeholder meeting to assess the current product environment (e.g., products available, evidence to support effectiveness, regulatory issues) and identify high-priority future directions for engineering-related solutions.
- 4.2 Sponsor design competitions to incentivize innovative packaging and dispensing solutions.
- 4.3 Secure funding for research to assess the effectiveness of innovative packaging and designs available and under development.
- 4.4 Use research to assure product uptake.

---

## RECOMMENDATIONS FOR ACTION

### #5: OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS

- 5.1 Engage with the scientific community to assess the research needs related to naloxone distribution evaluations and identify high-priority future directions for naloxone-related research.
- 5.2 Partner with product developers to design naloxone formulations that are easier to use by nonmedical personnel and less costly to deliver.
- 5.3 Work with insurers and other third-party payers to ensure coverage of naloxone products.
- 5.4 Partner with community-based overdose education and naloxone distribution programs to identify stable funding sources to ensure program sustainability.
- 5.5. Engage with the healthcare professional community to advance consensus guidelines on the co-prescription of naloxone with prescription opioids.

### #6: ADDICTION TREATMENT

- 6.1 Invest in surveillance of opioid addiction.
- 6.2 Expand access to buprenorphine treatment.
- 6.3 Require federally-funded treatment programs to allow patients access to buprenorphine or methadone.
- 6.4 Provide treatment funding for communities with high rates of opioid addiction and limited access to treatment.
- 6.5 Develop and disseminate a public education campaign about the important role for treatment in addressing opioid addiction.
- 6.6 Educate prescribers and pharmacists about how to prevent, identify and treat opioid addiction.
- 6.7 Support treatment-related research.

### #7: COMMUNITY-BASED PREVENTION STRATEGIES

- 7.1 Invest in surveillance to ascertain how patients in treatment for opioid abuse and those who have overdosed obtain their supply.
- 7.2 Convene a stakeholder meeting with broad representation to create guidance that will help communities undertake comprehensive approaches that address the supply of, and demand for, prescription opioids in their locales; implement and evaluate demonstration projects that model these approaches.
- 7.3 Convene an inter-agency task force to ensure that current and future national public education campaigns about prescription opioids are informed by the available evidence and that best practices are shared.
- 7.4 Provide clear and consistent guidance on safe storage of prescription drugs.
- 7.5 Develop clear and consistent guidance on safe disposal of prescription drugs; expand access to take-back programs.
- 7.6 Require that federal support for prescription drug misuse, abuse and overdose interventions include outcome data.

# Background

In May 2014, a diverse group of experts — including clinicians, researchers, government officials, injury prevention professionals, law enforcement leaders, pharmaceutical manufacturers and distributors, lawyers, health insurers and patient representatives — gathered at the Johns Hopkins Bloomberg School of Public Health. The group gathered to review what is known about prescription opioid misuse, abuse, addiction and overdose; to identify strategies for reversing the alarming trends in injuries and deaths from these drugs; and to make recommendations for action. The group convened at the invitation of the Clinton Foundation and two of the School's centers: the John Hopkins Center for Drug Safety and Effectiveness and the John Hopkins Center for Injury Research and Policy. Prior to the meeting, the School hosted a public town hall meeting during which President Bill Clinton provided an inspiring call to action.

During the day-and-a-half meeting, participants identified opportunities for intervention along the supply chain (including the development and production process, legal and illegal markets, and insurance coverage); and within the clinical, community and addiction treatment settings. The result was a commitment to develop and implement a plan of action that utilizes the multi-disciplinary skills and expertise of the many stakeholders committed to addressing the issue.

In the months that followed this initial gathering, the group divided into work groups to review the available evidence and make recommendations based on that literature. This process was guided by the following principles:

#### **INFORMING ACTION WITH EVIDENCE.**

Some evidence-based interventions exist to inform action to address this public health emergency; these should be scaled up and widely disseminated. Furthermore, many promising ideas are evidence-informed, but have not yet been rigorously evaluated. The urgent need for action requires that we rapidly implement and carefully evaluate these promising policies and programs. The search for new, innovative solutions also needs to be supported.

#### **INTERVENING COMPREHENSIVELY.**

We support approaches that intervene all along the supply chain, and in the clinic, community and addiction treatment settings. Interventions aimed at stopping individuals from progressing down a pathway that will lead to misuse, abuse, addiction and overdose are needed. Effective primary, secondary and tertiary prevention strategies are vital. The importance of creating synergies across different interventions to maximize available resources is also critical.

#### **PROMOTING APPROPRIATE AND SAFE USE OF PRESCRIPTION OPIOIDS.**

Used appropriately, prescription opioids can provide relief to patients. However, these therapies are often being prescribed in quantities and for conditions that are excessive, and in many cases, beyond the evidence base. Such practices, and the lack of attention to safe use, storage and disposal of these drugs, contribute to the misuse, abuse, addiction and overdose increases that have occurred over the past decade. We support efforts to maximize the favorable risk/benefit balance of prescription opioids by optimizing their use in circumstances supported by best clinical practice guidelines.

This report is the result of the work group process.

# Overview

Prescription drugs are essential to improving the functioning and quality of life for patients living with acute or chronic medical conditions. Although all prescription drugs have some misuse risk, of particular concern is the misuse and abuse of the drugs identified by the Drug Enforcement Administration (DEA) as controlled substances. These products, such as prescription opioids, have high abuse potential and can lead to life-threatening adverse events when taken in excess or in combination with other drugs.<sup>1,2</sup>

Prescription drug abuse and overdose is a serious public health problem in the United States. Drug overdose death rates in the U.S. increased five-fold between 1980 and 2008, making drug overdose the leading cause of injury death.<sup>3</sup> In 2013, opioid analgesics were involved in 16,235 deaths — far exceeding deaths from any other drug or drug class, licit or illicit.<sup>4</sup> According to the National Survey on Drug Use and Health (NSDUH), in 2012 an estimated 2.1 million Americans were addicted to opioid pain relievers and 467,000 were addicted to heroin.<sup>5</sup> These estimates do not include an additional 2.5 million or more pain patients who may be suffering from an opioid use disorder because the NSDUH excludes individuals receiving legitimate opioid prescriptions.<sup>6</sup>

A public health response to this crisis must focus on preventing new cases of opioid addiction, early identification of opioid-addicted individuals, and ensuring access to effective opioid addiction treatment, while at the same time continuing to safely meet the needs of patients experiencing pain. It is widely recognized that a multi-pronged approach is needed to address the prescription opioid epidemic. A successful response to this problem will target the points along the spectrum of prescription drug production, distribution, prescribing, dispensing, use and treatment that can contribute to abuse; and offer opportunities to intervene for the purpose of preventing and treating misuse, abuse and overdose.

This report provides a comprehensive overview of seven target points of opportunity, summarizes the evidence about intervention strategies for each, and offers recommendations for advancing the field through policy and practice.

- #1: Prescribing Guidelines
- #2: Prescription Drug Monitoring Programs
- #3: Pharmacy Benefit Managers and Pharmacies
- #4: Engineering Strategies
- #5: Overdose Education and Naloxone Distribution Programs
- #6: Addiction Treatment
- #7: Community-Based Prevention

The remainder of this report is organized by these seven topic areas.

# The Prescription Opioid Epidemic: An Evidence-Based Approach

### STATEMENT OF THE PROBLEM

More than 100,000 people in the United States have died — directly or indirectly — from prescribed opioids since prescribing policies changed in the late 1990's.<sup>7</sup> At that time, patient advocacy groups and pain specialists successfully lobbied state medical boards and state legislatures to change statutes and regulations to lift any prohibition of opioid use for non-cancer pain. In at least 20 states, these new guidelines, statutes, regulations and laws dramatically liberalized the long-term use of opioids for chronic non-cancer pain, reflecting the prevailing thought at the time that there is no clinically appropriate ceiling on maximum opioid dosing.<sup>8</sup> An example of such permissive language can be found in Washington State Administrative code (WAC) 246-919-830 from December 1999, which states: “no disciplinary action will be taken against a practitioner based solely on the quantity or frequency of opioids prescribed.”

With the introduction of pain as the “fifth vital sign,”<sup>9</sup> accompanied by pharmaceutical company efforts to market directly to prescribers,<sup>10</sup> there has been a dramatic increase in prescription opioid sales. Studies have documented a strong and consistent linear relationship between opioid sales volume and morbidity and mortality associated with these products.<sup>11</sup>

### SYNTHESIS OF AVAILABLE EVIDENCE

As opioid-related deaths continued to accelerate, constituting a national epidemic and public health emergency,<sup>12,13</sup> an increasing number of systematic reviews surfaced assessing the efficacy and effectiveness of opioids for chronic non-cancer pain. These systematic reviews concluded that the overall effectiveness of chronic opioid treatment for chronic non-cancer pain is limited, the effect on improved human function is very small and the safety profile of opioids is poor.<sup>14,15,16</sup> Briefly stated, the evidence on efficacy and effectiveness of these drugs for chronic non-cancer pain has demonstrated:

1. A variety of adverse events associated with opioid use, including: hypogonadism and infertility; neonatal abstinence syndrome; sleep breathing disorders; cardiac arrhythmias; opioid-induced hyperalgesia; and falls and fractures among the elderly;
2. High rates of healthcare utilization associated with these adverse events, including emergency department visits and hospitalizations from non-fatal overdoses;
3. High rates of deaths from unintentional poisonings, especially at doses at or above 100–120 morphine milligram equivalents (MME) per day, which generally occur at home during sleep;
4. Minimal improvement in pain and function associated with long-term opioid use for chronic non-cancer pain; and
5. An overall unfavorable risk/benefit balance for many current opioid users.

The evidence on state policy strategies and their effect on prescribing patterns demonstrates that state governments are willing to promote safe and effective pain management while taking precautions to curtail the alarming increase of opioid related morbidity and deaths.<sup>17</sup> However, policy language varies: Some states emphasize the need to prevent illicit trafficking and drug abuse,<sup>18</sup> while others encourage appropriate pain management while avoiding undue burdens on practitioners and patients.<sup>19</sup> Some states follow the advice of specialty societies. However, position papers of expert groups differ, as does the soundness of their recommendations, including some recommendations under investigation by the U.S. Senate at the time of this writing.<sup>20</sup>

The Washington State experience is particularly informative to prescribing guideline policies. In 2007, the State responded to epidemic opioid-related morbidity and mortality by engaging the public state agencies to collaborate with academic and practicing pain clinicians to promulgate opioid dosing guidelines for the local community. The core recommendation developed was to seek specialty consultation if a patient reaches 120 morphine milligram equivalents (MME) per day without improved pain or function. Many states, as well as the Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ), adopted these guidelines as universal precautions.<sup>2</sup> The Centers for Disease Control and Prevention recently engaged in a comprehensive, evidence-based process to develop guidelines for prescribing opioids for chronic pain. The resulting Guideline will be released early in 2016. (<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>)

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## #1 PRESCRIBING GUIDELINES

Following the initial success of these guidelines and an initial “bending of the curve” of mortality among beneficiaries of these agencies,<sup>22</sup> Washington State passed a landmark bill (ESHB 2876) in 2010. The bill mandated that the boards and commissions representing prescribing providers in the state repeal all prior rules governing opioid prescribing and create new ones by 2011. The bill, which received bi-partisan support, required that the new rules must include:

- Dosing criteria;
- Guidance on when and how to seek consultation (including the use of peer-to-peer video conferencing);
- Guidance on the use of a state prescription drug monitoring program (PDMP); and
- Guidance on tracking clinical progress by using assessment tools focusing on pain, mood, physical function and overall risk for poor outcomes.<sup>23</sup>

Lessons learned from the Washington State policy experience:

- Facilitate collaboration among state agencies and medical boards.
- Establish dosing and best practice rules and incentivize those rules.
- Implement an effective prescription drug-monitoring program that includes real-time data.
- Initiate education programs.
- Evaluate the impact of prescribing guideline interventions regularly.

### RECOMMENDATIONS FOR ACTION

#### 1.1 REPEAL EXISTING PERMISSIVE AND LAX PRESCRIPTION LAWS AND RULES.

Federal and state agencies, state medical boards and medical societies should work to repeal previous permissive and lax prescription laws and rules.

*Rationale:* Previous prescription policies, guidelines, statutes and rulings have been too permissive and have contributed to the current opioid epidemic. They require revision.

*Current Status:* In 2010, Washington State repealed prior rules related to prescribing and ordered new rules promulgated by 2011. State laws on this topic vary. A list of statutes, regulations, and other state policies relevant to opioid prescribing is available from the Pain and Policy Studies Group at University of Wisconsin.<sup>24</sup>

#### 1.2 REQUIRE OVERSIGHT OF PAIN TREATMENT.

Federal and state agencies, state medical boards and medical societies should require mandatory tracking of pain, mood and function through use of a brief validated survey at every patient medical visit; use of patient treatment agreements, urine drug screening; PDMP use when prescribing long-term opioids for non-chronic pain; and specialty consultation (via peer-to-peer video conferencing when in-person is unavailable) when prescribing over 120 morphine milligram equivalents (MME) per day without pain and function improvement.

*Rationale:* Given the risks associated with prescription opioids, protocols and tools for monitoring them, and decision-making when prescribing them, are needed to improve the safety of prescribing practices.

*Current Status:* These guidelines have been adopted by Washington State and appear in whole or in part in many other guidelines endorsed by the Department of Defense (DoD), Veteran’s Administration (VA), and the AHRQ, as well as by professional societies like the American College of Occupational and Environmental Medicine (ACOEM), American Pain Society (APS), American Academy of Pain Medicine (AAPM), and American Society of Interventional Pain Physicians (ASIPP). A comparative table of guideline recommendations published by the CDC has been published.<sup>25</sup>

### 1.3 PROVIDE PHYSICIAN TRAINING IN PAIN MANAGEMENT AND OPIOID PRESCRIBING AND ESTABLISH A RESIDENCY IN PAIN MEDICINE FOR MEDICAL SCHOOL GRADUATES.

Federal and state agencies, state medical boards, and medical societies should assure pre-graduate and post-graduate training in pain management and opioid prescription, including: continuing medical education (CME); graduate medical education (GME); post graduate education; and creation of a full three-year residency training program in pain medicine, which currently does not exist.

*Rationale:* Training in pain management is needed in order to move toward more effective, less risky treatments. An estimated 10,000 pain specialists cannot meet the treatment needs of the millions of chronic pain sufferers in the U.S.

*Current Status:* The American Association of Medical Colleges (AAMC) has endorsed efforts to increase the instruction of pain medicine in medical schools, however standards have not yet been defined. There is no full three-year residency training program in pain medicine in the U.S., and although legislation to support such a residency has been proposed and endorsed by leadership of the American Medical Association, it has been refused by the American Board of Medical Specialties.<sup>26</sup> Accredited post-graduate fellowship training in pain medicine is available only for specialists in select fields, such as anesthesiology, neurology, psychiatry and rehabilitation medicine and not for general practitioners or specialists in family or internal medicine. Also available are continuing medical education (CME) courses, generally sponsored by pharmaceutical manufacturers, through the FDA's Risk Evaluation and Mitigation Strategies (REMS).

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## #2 PRESCRIPTION DRUG MONITORING PROGRAMS

### STATEMENT OF THE PROBLEM

Prescription Drug Monitoring Programs (PDMPs) collect data regarding controlled substances prescriptions from in-state pharmacies and, for most PDMPs, mail order pharmacies that ship prescriptions into the state. There are 51 PDMPs, in all states except Missouri, plus the District of Columbia and Territory of Guam. Through online access to their state's database, physicians and other prescribers can obtain clinical information regarding their patients' controlled substance prescriptions to inform treatment decisions. Typically, information available through the PDMP includes drug name, type, strength and quantity of drugs from previous prescriptions. Physicians and prescribers can also identify patients who may need substance abuse treatment. Similarly, pharmacists can access PDMP data prior to dispensing a controlled substance prescription. These programs are valuable tools to improve patient safety and health outcomes.

PDMPs are under-utilized by prescribers. More than a quarter (28 percent) of primary care physicians in one study reported not being aware of their states' PDMPs.<sup>27</sup> While a majority of clinicians (53 percent) reported having obtained data from their PDMP at some point, data are accessed in fewer than a quarter of the instances when these physicians prescribed an opioid. Performance measures reported by 17 states for the first quarter of 2012 indicate that the median percent of prescribers who issued controlled substance prescriptions who registered to use their states' PDMPs was 31 percent,<sup>28</sup> and the median number of reports requested by all prescribers who issued one or more controlled substance prescriptions was 3.28. Even the highest rates of PDMP registration did not ensure use. For example, during the first quarter of 2012, Kentucky had the fifth highest proportion of registered prescribers at 49 percent,<sup>28</sup> yet prescribers and pharmacists requested information for only 6 percent of 2.9 million controlled substance prescriptions dispensed.<sup>29</sup> Physicians identify a number of barriers to PDMP use, including that retrieving the information is too time consuming and difficult.<sup>30</sup>

This underutilization of PDMPs is particularly troubling because PDMPs can help identify persons who may be engaged in high-risk behavior, such as doctor shopping and prescription forgery, indicating possible abuse of or dependence on controlled substances. PDMP data can be used to alert health care professionals if a patient is at risk for addiction or overdose, since certain indicators are known risk factors for high-risk utilization. For example, persons who doctor shop are seven times more likely to die of opioid overdoses than persons who do not; those who pharmacy shop are more than 13 times more likely to suffer an overdose death.<sup>31</sup> People who ingest 100 milligrams of morphine milligram equivalents or more per day have an almost nine-fold increase in overdose risk.<sup>32</sup>

### SYNTHESIS OF AVAILABLE EVIDENCE

In response to the problem of inadequate utilization of PDMPs described above, state lawmakers and PDMP administrators have made several adjustments, including:

- Authorization of delegates (approved clinical professionals) to request PDMP data. As of 2014, 36 states had laws authorizing delegates to request PDMP data.
- Establishment of interoperability with electronic health records and the Affordable Care Act's health information exchanges. The Substance Abuse and Mental Health Services Administration (SAMHSA) is providing grants to support this work in 16 states.<sup>33, 34</sup>
- Proactive analysis of PDMP data and forwarding of unsolicited reports to prescribers and pharmacists; when these professionals receive unsolicited reports from PDMP administrators, they increase their own data requests.<sup>35, 36</sup>
- Increased speed of data collection. Twenty-two states require pharmacies to submit data daily, 27 collect data on a weekly basis or less, and one collects data bi-weekly. By June 30, 2015, only one state remains at the old standard of monthly data submission.
- Increased interstate PDMP data sharing so prescribers can observe prescriptions dispensed in other states; 28 states<sup>37</sup> are engaged in interstate data sharing and others are working toward these agreements.

States, faced with low prescriber utilization, are increasingly mandating that prescribers use PDMPs. Sixteen states<sup>38, 39</sup> mandate that prescribers use PDMPs under certain circumstances; an additional 11 states have comprehensive mandates as of December 2014.<sup>40, 41</sup> Kentucky was the first state to mandate comprehensive PDMP use. Prescribers' PDMP use increased following the mandate, and decreases in opioid prescribing, doctor shopping and prescription overdose hospitalizations were noted in a 2015 evaluation — although heroin treatment admissions rose during the study period.<sup>42</sup>

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## #2 PRESCRIPTION DRUG MONITORING PROGRAMS

Additional information about the Kentucky law and the impacts measured to date follow.

- Prescribers must review PDMP data prior to issuing a patient's first opioid prescription, and at least every three months thereafter for continued therapy and new or refill opioid prescriptions, with some exceptions. This requirement went into effect in July 2012. The 2015 evaluation found that the mean number of prescribers' requests increased by 650 percent annually compared to the period prior to the law's effective date.<sup>43, 44</sup>
- Prior to the mandate, Kentucky clinicians' report requests had increased by about 85,000 reports annually. At that rate it would have taken approximately 38 years to reach the level achieved within three months of the new law.<sup>45</sup>
- Opioid prescriptions decreased by 8.6% in the year following implementation of the law.<sup>3</sup>
- According to data provided by the Kentucky Office of Drug Control Policy, from 2011 to 2013, overdose hospitalizations due to prescription opioids declined by 26 percent, emergency department visits related to prescription opioids declined by 15 percent,<sup>46</sup> and prescription opioid deaths declined by 25 percent, the first declines in 10 years.<sup>47</sup>

Like Kentucky, other comprehensive mandate states (Tennessee, New York, Ohio) experienced rapid increases in PDMP registrations, increases in PDMP data use (up to 10,000 percent in New York),<sup>48</sup> decreases in prescribing commonly abused controlled substances, and decreases in multiple provider, or "doctor-shopping" episodes.

Additional professional groups that could use PDMP data to intervene and interrupt harmful prescription-controlled substance behaviors include:

*Third-party healthcare payers and their pharmacy benefit managers (PBMs)* that have the ability to intervene with prescribers, dispensers and patients. Medicaid programs and some of the private third-party payers use Patient Review and Restriction (PRR), such as "Lock-in". Typically, these programs restrict high-risk patients to one doctor and one pharmacy for the controlled substance prescriptions. These programs can effectively protect patient health and safety as well as prevent program fraud, especially when augmented by access to PDMP data.<sup>49, 50</sup>

*Professional licensing boards* that oversee clinicians and have an interest in identifying who is abusing controlled substances and/or who has high-risk prescribing or dispensing patterns. Recent findings identify a small number of prescribers as responsible for a disproportionate number of opioid prescriptions.<sup>51</sup> Oregon's PDMP found that the top 4 percent of prescribers issued 60 percent of all controlled substance prescriptions.<sup>52</sup> In New York City, 1 percent of prescribers wrote 31 percent of opioid prescriptions. A large chain pharmacy found 42 outlier prescribers out of more than 1 million. Within that chain alone, the 42 each issued prescriptions for about 5,000 average monthly doses of high-risk drugs over 21 months. On an annual basis that would cumulatively total more than 4 million dosage units.<sup>53</sup>

*Law enforcement agencies* that can identify possible criminal activity, such as "doctor shopper" rings and pill mills. Jung, et al found that among 47 physicians arrested by the Drug Enforcement Agency (DEA) in 2003 and 56 whose DEA registrations were revoked in 2003–2004, there was not sufficient information in the majority of cases to confirm the existence of a documented doctor/chronic pain patient relationship.<sup>54</sup>

*Public health agencies* that provide an early warning system for communities about the risks of opioid overdoses and deaths. PDMP data can also be analyzed at the county and community level within a short time of actual prescription dispensing and provide warnings to states and communities of the risk of increasing opioid overdoses and deaths. The Prescription Behavior Surveillance System (PBSS) was developed by the PDMP Center of Excellence (COE) in conjunction with the National Center for Injury Prevention and Control (NCIPC) and the Food and Drug Administration (FDA) to help identify communities at risk for harmful opioid outcomes. A variety of measures — such as mean daily dosage of opioids per patient, multiple provider episode rates, percentage of days with overlapping prescriptions for opioids and benzodiazepines and median distance in miles from patient to prescriber — can be tracked and followed over space and time.<sup>55</sup> By using PDMP data for public health surveillance, states and communities can monitor prescribing trends.<sup>56</sup> In turn, they can take actions to protect against opioid addiction, overdoses and deaths, as demonstrated by Project Lazarus in North Carolina.<sup>57</sup> Given the limited resources available to states and communities, this type of information is essential for targeting prevention and other resources to areas of greatest need, according to substance abuse prevention specialists and others.<sup>58</sup>

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## #2 PRESCRIPTION DRUG MONITORING PROGRAMS

### RECOMMENDATIONS FOR ACTION

#### 2.1 MANDATE PRESCRIBER PDMP USE.

Through regulation or legislation, states should mandate prescriber use of PDMPs in order to achieve more comprehensive and effective use of PDMP data in treating patients.

*Rationale:* Mandatory PDMP use policies are associated with increased use.<sup>59</sup>

*Current Status:* Sixteen states mandate that prescribers use PDMPs under certain circumstances; an additional seven states have comprehensive mandates.

#### 2.2 PROACTIVELY USE PDMP DATA FOR ENFORCEMENT AND EDUCATION PURPOSES.

States should analyze their PDMP data to identify: 1) potential inappropriate or illegal activities and forward the information in unsolicited reports to the relevant professional groups to increase oversight of controlled substance prescribing; and 2) hot spots of inappropriate and/or illegal use so that prevention efforts are data-driven and evidence-informed. Primary recipients of PDMP data reports should include prescribers, dispensers, professional licensing boards, law enforcement agencies, and state and community prevention and treatment programs.

*Rationale:* Many PDMPs underutilize the data and do not engage in proactive reporting, nor do they participate in PBSS or state-based equivalent reporting. Better use of PDMP data will aid identification of opportunities for intervention, and prevent misuse, abuse and overdose through enforcement and education.

*Current Status:* Twenty-eight states<sup>60</sup> engage in proactive data analysis and reporting activities as of 2014. Only four states provide unsolicited reports to all four primary recipient groups (prescribers, dispensers, professional licensing boards and law enforcement agencies).<sup>61</sup>

Twelve states<sup>62</sup> participate in PBSS by sending de-identified PDMP data to and receiving reports from the Brandeis PDMP Center of Excellence (COE). The CDC and FDA fund the project through an agreement with the Bureau of Justice Assistance.<sup>63</sup> States not participating in PBSS can initiate their own data analysis and sharing with state and community prevention and treatment programs.

#### 2.3 AUTHORIZE THIRD-PARTY PAYERS TO ACCESS PDMP DATA WITH PROPER PROTECTIONS.

States should authorize Medicaid, Medicare, the Veterans Administration, Department of Defense, Indian Health Service, workers compensation carriers and private third-party healthcare payers to access PDMP data for their enrollees, with proper protections. The authorization should also allow Pharmacy Benefit Managers (PBMs) (See Section 3 of this report for more information on PBMs) to access the data as agents of the third-party payers for whom they manage benefits.

*Rationale:* Such access can provide third-party payers with valuable information to inform internal policies that address the misuse, abuse and overdose associated with controlled substance prescriptions.

*Current Status:* Thirty-two states and one territory<sup>64</sup> authorize some combination of third-party payers to access PDMP data. Only five states provide access to Medicare and three states<sup>65</sup> to commercial third-party payers. States should consider the Washington State model that authorizes Medicaid and Workers Compensation to access the PDMP data in bulk.<sup>66</sup>

#### 2.4 EMPOWER LICENSING BOARDS FOR HEALTH PROFESSIONS AND LAW ENFORCEMENT TO INVESTIGATE HIGH-RISK PRESCRIBERS AND DISPENSERS.

All states should direct their PDMPs to proactively analyze these data to identify possible misconduct and criminal activities and to provide the information unsolicited to licensing boards and law enforcement in order to develop and inform investigations.

*Rationale:* Licensing boards need access to PDMP data to investigate possible misconduct involving controlled substances. Authority to enforce controlled substance laws is the responsibility of federal, state and local law enforcement. Law enforcement should have access to PDMP data in order to inform this authority.

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## #2 PRESCRIPTION DRUG MONITORING PROGRAMS

*Current Status:* Forty-six states, Guam, and the District of Columbia permit their licensing boards to access PDMP data; three states do not.<sup>67</sup> Eleven states send unsolicited reports to licensing boards.<sup>68</sup>

Three states<sup>69</sup> report they permit specially trained investigators to directly access PDMP data on-line. Thirty states<sup>70</sup> require probable cause, search warrants, subpoenas or other judicial processes in order for law enforcement officers to access data. One state does not authorize law enforcement officers to have access. Seventeen states proactively analyze and send unsolicited reports to law enforcement agencies.<sup>71</sup>

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## #3 PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

### STATEMENT OF THE PROBLEM

PBMs and pharmacies possess different types of data that are relevant to reducing prescription drug abuse and diversion. Since PBMs manage the pharmacy benefits for health plans and large employers, they possess members' claims data for prescription drugs, and at times, other healthcare goods and services. PBMs do not have visibility of prescriptions paid with cash or those paid by another insurer. Pharmacies, on the other hand, only possess information about a patient's prescriptions if the patient filled his or her medicine with that pharmacy or pharmacy chain. The fact that PBMs and pharmacies may lack a comprehensive view of an individual patient's prescription history is one reason that it is essential for state-run prescription drug monitoring programs (PDMPs) to have comprehensive controlled substances information for an individual, and for this information to be shared with payers, as well as with other states. As described in Section 2 of this document, PDMPs can have comprehensive controlled substances prescription records for an individual regardless of whether the individual paid cash or filled prescriptions through multiple insurers and pharmacies. However, not all insurers/PBMs are allowed to access the PDMP information, nor are PDMPs comprehensively interconnected among all states.

### SYNTHESIS OF AVAILABLE EVIDENCE

There are many methods that PBMs and pharmacies can use to reduce inappropriate prescribing and to intervene upon individuals likely to be abusing or diverting prescription drugs.<sup>72, 73, 74</sup> Evidence of the impact of PBMs' procedures and programs has been summarized.<sup>75, 76</sup> Importantly, as pointed out by Haegerich and colleagues in their report on studies of state policy or systems-level interventions to prevent drug misuse and abuse,

*“Overall study quality is low. Knowledge and prescribing practices were measured more often than health outcomes (e.g., overdoses). Limitations include lack of baseline data and comparison groups, inadequate statistical testing, small sample sizes, self-reported outcomes, and short-term follow-up. Evidence of improved health outcomes, particularly from safe storage and disposal strategies and patient education, is weak.”<sup>73</sup>*

Many PBMs perform prescription claims reviews using software algorithms to identify individuals, pharmacies and prescribers that are potentially fraudulently using or dispensing controlled substances. In addition, PBMs' prescription claims surveillance and prescriber intervention programs often use retrospective analysis to identify members meeting excessive controlled substance use criteria, such as some combination of the use of multiple prescribers, multiple dispensing pharmacies, exceeding a threshold of morphine milligram equivalent (MME) dose, and multiple controlled substance claims over a period of three to six months. Most PBMs' internal controlled substance claim surveillance criteria are not disclosed or validated to be associated with controlled substance adverse events, mortality, health care utilization or costs. However, some criteria used by PBMs have been published.<sup>77, 78</sup> Prescriber letter interventions through PBMs have been shown to decrease members' controlled substance score and controlled substance drug claims.<sup>79, 80</sup> These programs could be enhanced if the PBM has complete controlled substance claims history, including cash claims, through access to states' PDMPs.

Examples of PBMs' controlled substances utilization management programs include prior authorization, precertification and maximum quantity limits per prescription. The health insurer Aetna reported in 2014 that its PBM “Pharmacy Misuse, Waste and Abuse” program monitors access to opioids through precertification and reviews of pharmacy and medical claims and quantity limits to find patterns of above-normal use. Further, members who have had frequent emergency room visits are identified. Other signs, and suspicion of developing substance abuse problems or a history of controlled substance abuse, also are noted. The program reduced opioid prescriptions among 4.3 million members by 14 percent between January 2010 and January 2012.<sup>81</sup>

An Aetna-run Behavioral Health Medication Assistance Program involves nurses and psychologists working with physicians to evaluate members who could be at risk for addiction and those with a history of opioid abuse or who are in treatment. According to Aetna, this program has shown “a 30 percent improvement in opioid abstinence rates; a 35 percent reduction of in-patient hospital admissions and a 40 percent decrease in total paid medical costs.”<sup>82</sup> Blue Cross Blue Shield of Massachusetts reported in 2014 that its program implemented in July 2012 to require a prior authorization for more than 30 days of opioid therapy reduced prescriptions by 20 percent for common opioids such as Percocet (oxycodone and acetaminophen) and 50 percent for longer-acting drugs such as OxyContin (extended-release oxycodone), and cut total prescriptions of narcotic painkillers by an estimated 6.6 million pills in 18 months.<sup>83</sup>

For patients who have particularly high-risk controlled substance use and whose utilization cannot be safely addressed using other mechanisms, insurers or PBMs may enroll the member in a pharmacy and/or prescriber restriction program. These

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## #3 PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

programs, also known as “lock-in” programs, are applied to fewer than 1 in 1,000 controlled substance-using individuals, and have been used by state Medicaid programs for years. Restricted recipient programs limit an individual to receiving their controlled substance prescriptions from one prescriber and one pharmacy for allowed insurance payment, or else the individual must pay cash. As stated by the Academy of Managed Care Pharmacy:

*“Prescriber and pharmacy restricted access programs help to mitigate the issues associated with doctor or pharmacy shopping and may reduce the number of inappropriate controlled substance prescriptions. In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with a savings of \$600 per person in costs. As demonstrated in Medicaid and other programs and recommended by the General Accountability Office in 2011, to reduce incidence of doctor or pharmacy shopping, a common way that Medicare beneficiaries obtain inappropriate controlled substances, CMS should consider restricted access to certain prescribers and pharmacies for Medicare beneficiaries.”<sup>84, 85</sup>*

Formulary controls are also used by PBMs to guide patients and prescribers toward the safest, most cost effective medications and then to cover these drugs at a lower member cost share to encourage their use. Exclusion of a controlled substance drug from a formulary results in the drug not being covered by the insurance policy. For example, the product Zohydro ER has been excluded from some formularies due to concerns about its potential for abuse and overdose. Minnesota Medicaid chose to exclude promethazine with codeine syrup and carisoprodol beginning in 2015 due to the potential for concomitant abuse of these three drugs and insufficient evidence to support their clinical benefit when used together.<sup>86</sup> Research is needed to understand the impact of these types of policies.

Pharmacies can also remove prescriber dispensing privileges to curtail both diversion and inappropriate controlled substance prescribing, and they can require pharmacists to provide patient counseling to help those with controlled substance dependence.<sup>87, 88, 89</sup> The removal of prescriber dispensing privileges to curtail both diversion and inappropriate controlled substance prescribing is feasible and supported by state and federal law.<sup>90</sup> With the goal of ensuring that prescriptions for controlled substances are appropriate, one pharmacy chain identified 42 controlled substance outlier prescribers out of more than 1 million prescribers. After allowing for appeal, 36 prescribers had their prescriber dispensing privileges removed,<sup>91</sup> reducing more than 100,000 doses of high-risk drugs prescribed per month.

Electronic prescribing (e-prescribing) is the process by which a prescriber generates and transmits an “accurate, error-free and understandable” prescription directly to a pharmacy through a special secure network. E-prescribing for controlled substance drugs has the potential to reduce forgery and fraudulent controlled substance prescriptions.<sup>92</sup> Research indicates that few controlled substance prescriptions are e-prescribed.<sup>93</sup> It is anticipated that e-prescribing will soon become commonplace, especially with new laws like New York’s iSTOP law. The e-prescribing requirements were a part of the State’s Internet System for Tracking Over Prescribing (I-STOP) laws, enacted in 2012. I-STOP requires all prescribers to: 1) consult the Prescription Monitoring Program (PMP) prior to prescribing Schedule II, III and IV controlled substances and 2) electronically transmit all prescriptions. Evaluations to monitor the impact of such initiatives will be critical to maximizing the use of e-prescribing as a tool for more effectively controlling the supply of controlled substances.

The Drug Enforcement Administration (DEA) and state boards of pharmacy require pharmacists to use sound professional judgment when determining whether or not to fill controlled substance prescriptions. After reviewing the prescription, pharmacists will use their professional judgment on handling any issues that may come up. This professional activity is enhanced through pharmacist access to and use of PDMPs to review a member’s claims history in questionable cases. Interstate PDMP data access with infrastructure supporting high utilization and rapid response times is essential to ensure that PDMP data are optimally used by prescribers and pharmacists.<sup>94</sup>

Although they have not yet been widely enacted, “take-back” programs that foster safer medication disposal by allowing for patients to return unused or unwanted opioids may also help to reduce the potential for diversion of opioids and other controlled prescription drugs from licit to illicit channels. Pharmacies provide a convenient site for individuals to dispose of their unused controlled substance prescriptions. Evidence supporting the effectiveness of allowing pharmacies to take back and destroy prescription drugs is anecdotal. Additional discussion of this strategy is included in Section 7 of this report.

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## #3 PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

### RECOMMENDATIONS FOR ACTION

#### 3.1 INFORM AND SUPPORT EVALUATION RESEARCH.

Pharmacies and PBMs are engaged in controlled substance interventions. Research funded by the federal government, non-profit and for profit entities is needed to evaluate the clinical and economic impact of these efforts. A stakeholder meeting to review research that is in progress and to identify priorities for new research is needed to inform investment in this area.

*Rationale:* Without high quality evaluations of interventions, pharmacies and PBMs will lack a reliable evidence base to inform how best to invest prevention dollars.

*Current Status:* The Patient-Centered Outcomes Research Institute (PCORI) has no funded projects. The Centers for Disease Control and Prevention (CDC) and the National Institute on Drug Abuse (NIDA) have sponsored modest extramural funding in this realm. The private sector is conducting research, much of which goes unpublished. We are unaware of any other funding sources active in this area.

#### 3.2 ENGAGE IN CONSENSUS PROCESS TO IDENTIFY EVIDENCE-BASED CRITERIA FOR USING PBM AND PHARMACY CLAIMS DATA TO IDENTIFY PEOPLE AT HIGH RISK FOR ABUSE AND IN NEED OF TREATMENT.

This can be accomplished through a consensus process that brings together experts in the field to identify criteria to include.

*Rationale:* Criteria currently in use to identify individuals at high risk for abuse or overdose requires further validation and refinement. It is essential that scientific evidence be applied to reduce false positive or false negative identification.

*Current Status:* State Medicaid, managed care plans and PBMs are using varying methods with varying degrees of evidence to support them.

#### 3.3 EXPAND ACCESS TO PDMP.

Amend state PDMP laws to allow managed care plans and PBMs access to PDMPs to ensure complete claims history for covered members. These laws must include proper protections for patient privacy.

*Rationale:* Allowing managed care plans and PBMs access to PDMP data will improve upon their current controlled substances interventions that have been shown to positively influence controlled substances utilization.

*Current Status:* PDMP legislation generally prohibits managed care plans and PBMs from accessing PDMP data. State legislatures will need to change their state PDMP laws to allow managed care plans and PBMs access to data.

#### 3.4 IMPROVE MANAGEMENT AND OVERSIGHT OF INDIVIDUALS WHO USE CONTROLLED SUBSTANCES.

Encourage the states and Centers for Medicare & Medicaid Services (CMS) to incentivize PBMs, through the Medicaid Innovation Accelerator Program and CMS Innovation Center, to implement and rigorously evaluate innovative medication management strategies for targeted management of individuals who use controlled substances.

*Rationale:* Managed care plans and PBMs are uniquely positioned to efficiently aggregate data and take action.

*Current Status:* A systematic assessment of how plans and PBMs are currently implementing and evaluating management and oversight of individuals who use controlled substances does not exist.

### 3.5 SUPPORT RESTRICTED RECIPIENT (LOCK-IN) PROGRAMS.

The federal government should amend the Medicare Part D to allow prescriber and pharmacy restricted recipient (lock-in) programs.

*Rationale:* Demonstrated success with the Medicaid restricted recipient programs should be shared with legislators to inform them of the opportunity to prevent opioid abuse in Medicare.

*Current Status:* Prescriber and pharmacy restricted recipient programs are legislatively prohibited in Medicare. Federal legislators will need to change the Medicare Part D law to allow managed care plans and PBMs to implement prescriber and pharmacy restricted recipient programs.

### 3.6 SUPPORT TAKE-BACK PROGRAMS.

Pharmacies should encourage their patients to return unused controlled substances.

*Rationale:* Pharmacies are a convenient site for individuals to dispose of their unused controlled substance prescriptions.

*Current Status:* Some pharmacies are taking back controlled substances. However, pharmacies are not universally providing this service or advertising this service to their patients. Whether the public is aware of the need to properly dispose of these medications is unknown.

### 3.7 IMPROVE MONITORING OF PHARMACIES, PRESCRIBERS AND BENEFICIARIES.

All PBMs should provide a list of suspicious pharmacies, prescribers and beneficiaries to the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). Using the actionable PBM data they are receiving, MEDICs should be reporting potential providers for removal to the CMS.

*Rationale:* Most PBMs are providing a list of suspicious pharmacies, prescribers and beneficiaries to NBI MEDIC.

*Current Status:* To our knowledge, CMS is not systematically using the PBM data to exclude providers from being covered and reimbursed by CMS.

### 3.8 INCENTIVIZE ELECTRONIC PRESCRIBING.

Encourage private insurers and the CMS to incentivize electronic prescribing for controlled substances.

*Rationale:* E-prescribing for controlled substance drugs has the potential to reduce forgery and fraudulent controlled substance prescriptions.

*Current Status:* Although controlled substances e-prescribing is infrequent as of this writing, the expectation is that e-prescribing will increase with new state laws and electronic medical record connectivity with pharmacies.

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## #4 ENGINEERING STRATEGIES: PRESCRIPTION DRUGS AND PACKAGING

### STATEMENT OF THE PROBLEM

Although prescription drug abuse is a complex, multi-faceted issue, the data strongly indicate that the vast majority of prescription drugs that are abused come from legitimate prescriptions.<sup>95</sup> However, once they are dispensed, prescription drugs are frequently diverted to people using them for nonmedical purposes.<sup>96</sup> Indeed, approximately 70 percent of people who report nonmedical use of prescription opioid pain relievers state they got their most recently used drug from a friend or family member.<sup>97</sup> One component of a comprehensive approach to the problem is to leverage engineering strategies to inform the development of innovative packaging for prescription drug dispensing that can reduce nonmedical use and diversion.

The concept of engineering solutions to improve product safety is a cornerstone of injury prevention. Research indicates that changing products to make them safer is often more effective at reducing injury and death compared to trying to change personal behaviors.<sup>98</sup> Successful examples that have resulted in reductions in morbidity and mortality include the introduction of child-resistant caps to reduce pediatric poisonings; and reductions in motor vehicle crash deaths after mandatory implementation of collapsible steering wheels, energy-absorbing vehicle frames and other physical modifications to motor vehicles.<sup>99, 100, 101, 102</sup> These product-oriented approaches can serve as a model for engineering solutions for prescription drug abuse.

### SYNTHESIS OF AVAILABLE EVIDENCE

The U.S. Food and Drug Administration (FDA) highlighted the potential for innovative packaging solutions to be a part of the Agency's response to prescription drug abuse when it published a notice for public comment in the Federal Register in April 2014. The FDA stated that designs for drug packaging have evolved significantly in the past decade and now include many technology-based features — such as electronic systems for monitoring, accessing and improving adherence to medication regimens — that also could help to prevent prescription drug abuse and diversion. Examples of design strategies mentioned by the FDA include: systems that remind patients to take a dose, track when a dose is taken, and limit further access until the next dose is due; radio-frequency identification-based systems; and microchips embedded within tablets. Often these technologies are packaged with data capture systems to provide feedback to providers on adherence, use and potentially tampering.<sup>103</sup>

Although most prescription drug packaging solutions have been designed to improve medication compliance among patients using non-controlled substances for chronic conditions<sup>104, 105</sup>, these solutions could be adapted to help prevent prescription drug abuse and diversion. For example, these products could reduce serious complications such as overdose by facilitating appropriate dosage and administration, and could help providers monitor for signs of abuse or diversion. In addition, products that limit access to the medication during non-dosing periods could help prevent use of the medication by someone for whom it was not prescribed. The concept of personalization, i.e., use of a personal identification number, radio-frequency device, fingerprint or other biometrics, has been proposed to prevent other types of injuries<sup>106</sup> and could be applied to prescription drug packaging as well. An example is a pill dispenser that requires a specific fingerprint before releasing the appropriate pain medication at the appropriate time.

Data on the effectiveness of packaging designs on prescription drug abuse is limited. One study of 37 individuals assessed the impact of an electronic medicine dispenser on diversion of buprenorphine-naloxone among patients receiving the drug for opioid addiction treatment. The researchers found 68 percent of patients preferred to use the electronic dispenser to store their tablets compared to the traditional prescription container; 16 percent stated that the dispenser had prevented them from diverting their buprenorphine; 23 percent stated the dispenser prevented others from diverting their buprenorphine; and 58 percent believed the dispenser could prevent diversion. Additionally, 19 percent stated that it was difficult to tamper with the dispenser and 58 percent stated it was impossible to tamper with the dispenser.<sup>107</sup> Another product, which couples a flow-controlled, tamper-resistant medication dispenser with a Web and phone accessible treatment portal, has demonstrated sufficient promise to obtain funding from the National Institute on Drug Abuse. A phase II randomized controlled trial will assess use of the device and opioid misuse among patients from two pain management clinics.<sup>108</sup> However, results from this trial were not available as of June 2015.

A review of the currently available and in-development opioid packaging designs by Lehigh University concluded that many of the commercialized technologies such as locking caps, tamperproof packages and pill-dispensing products are most likely to deter unintentional misuse by elderly people or children and have limited abilities to prevent intentional abuse. However, newer technologies, such as radio-frequency identification wireless technologies and simple technologies combined with radio-frequency identification — as well as other types of smart technologies — have the potential to play a role in deterring intentional opioid abuse by increasing communication between healthcare professionals and patients.<sup>109</sup> As part of their senior mechanical

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## #4 ENGINEERING STRATEGIES: PRESCRIPTION DRUGS AND PACKAGING

engineering design course, students at Johns Hopkins University successfully created a prototype of a new design that is tamper-resistant, personalized with fingerprint technology and programmed to deliver a one-month supply of an opioid in the right time and dosage. Only a pharmacist would be able to open and lock the device.<sup>110</sup>

Despite the very limited data on effectiveness, there are a number of products currently being marketed to consumers. There is a pressing need for research to understand the impact of these products on prescription drug abuse. In addition to research questions on effectiveness, there are a number of outstanding questions that need to be explored before widespread adoption of these products can occur. These questions include:

- Where will these products enter the medication prescribing and use process? Will they be made available for purchase by patients for use in their homes? Will pharmacists use them instead of traditional pharmacy dispensing vials? Will manufacturers move away from bulk product distribution and incorporate these packaging designs for direct dispensing from the doctor's office or pharmacy?
- How will these products be regulated? As consumer products? As medical devices? As a combination drug-device?
- Who will take on the costs for these products? Pharmacies? Patients? Insurers/PBMs?
- Who will control, monitor and have access to the data available from these devices?

### RECOMMENDATIONS FOR ACTION

#### 4.1 CONVENE A STAKEHOLDER MEETING.

Work with the FDA to convene a meeting with product developers and key stakeholders to assess the current product environment (e.g., products available, evidence to support effectiveness, regulatory issues) and identify high priority future directions for engineering-related solutions.

*Rationale:* Engineering solutions to deter nonmedical use of prescription opioids are promising and under development. There is a need for coordination of and support for the current efforts to ensure this line of innovation is adequately supported, quickly brought to market and rigorously evaluated.

*Current Status:* There is no national organizing effort underway; the FDA could promulgate rules or guidance to industry that will affect these innovations and the FDA is a logical stakeholder to convene a meeting or to serve as a partner to convene such a meeting.

#### 4.2 SPONSOR DESIGN COMPETITIONS.

Partner with stakeholders to develop design competitions to incentivize innovative packaging and dispensing solutions.

*Rationale:* Design competitions have been used to encourage and support innovation in many areas. Engineering strategies for prescription packaging are a logical candidate for such a competition.

*Current Status:* We are unaware of any design competitions on this subject.

#### 4.3 SECURE FUNDING FOR RESEARCH TO ASSESS THE EFFECTIVENESS OF INNOVATIVE PACKAGING AND DESIGNS AVAILABLE AND UNDER DEVELOPMENT.

*Rationale:* Data on the effectiveness of packaging interventions is limited. Research is needed to evaluate the engineering innovations under development and to inform future development.

*Current Status:* We are unaware of any funding source dedicated to evaluating engineering designs for prescription packaging.

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## #4 ENGINEERING STRATEGIES: PRESCRIPTION DRUGS AND PACKAGING

### 4.4 USE RESEARCH TO ENSURE PRODUCT UPTAKE.

Engage with key stakeholders, such as product developers, drug manufacturers, pharmacies, payers, regulators, chronic opioid therapy patients and the public to explore potential barriers and incentives to product uptake, including a tiered reimbursement structure based on packaging designs with demonstrated effectiveness.

*Rationale:* Innovations in prescription packaging are promising, but little is known about how to ensure the public will use these products and that the products will be integrated into existing payment policies. Research is needed to ensure that these aspects of translation are understood.

*Current Status:* We are unaware of any efforts to gather empirical data about how to ensure innovative engineering packaging for prescriptions is effectively integrated into the consumer market.

### STATEMENT OF THE PROBLEM

Naloxone has been used for many years by healthcare and emergency medical services providers to reverse the potentially fatal respiratory depression associated with opioid overdoses. Community-based overdose education and naloxone distribution (OEND) programs that provide naloxone and train at-risk individuals and their friends, family members or caregivers on overdose prevention and response have been implemented in the U.S. in recent years. As of July 2014, at least 644 sites were in existence in the U.S.<sup>111</sup> In addition, some healthcare providers co-prescribe naloxone to patients taking high doses of opioids or to patients who are otherwise at risk for opioid overdose. However, there is limited evidence about the effectiveness of these applications of naloxone, and questions with regard to the sustainability of distribution programs remain, since third-party payers do not universally reimburse for naloxone.

### SYNTHESIS OF AVAILABLE EVIDENCE

The majority of the available evaluations of OEND programs report on program implementation; training lay persons to recognize and respond to an overdose event, including the administration of naloxone; and provide information on the number of individuals trained, number of naloxone vials distributed and the number of overdose reversals reported by individuals who were trained.

The settings for OEND evaluations have primarily been in large urban center syringe exchange or harm reduction programs, methadone programs or other addiction treatment or detoxification programs, and have focused on heroin users. Evaluations of programs in New York City, Massachusetts, Los Angeles, San Francisco, Chicago, Rhode Island, Pittsburgh and Baltimore have been reported in the published literature.<sup>112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123</sup> Because the focus of the evaluations has been on the number of trained individuals and overdose reversals reported, it is not possible to describe the population-level impact of these individual programs. Data from a 2014 survey found that OEND programs in the U.S. had trained and provided naloxone to more than 150,000 individuals between 1996 and 2014, and reported more than 26,000 opioid overdose reversals during this time.<sup>124</sup> Additional evaluations have reported on changes in overdose recognition and response knowledge and/or behaviors as a result of OEND program training.<sup>125, 126, 127, 128, 129, 130</sup> Taken together, these data demonstrate that people at high risk for opioid-related overdose and their friends or family members can successfully be trained to recognize and respond to an overdose and appropriately administer naloxone in an overdose situation.

The literature examining the broader public health impact of naloxone programs is limited. Two identified studies described the Project Lazarus program in North Carolina, which was created in 2008. One component of this program is the co-prescription of naloxone to people at risk for opioid overdose. An initial evaluation of Project Lazarus in Wilkes County, North Carolina, found significant declines in the unintentional drug overdose death rate from a peak of 46.6 deaths per 100,000 population in 2009 to 29.0 deaths per 100,000 in 2010 and 14.4 deaths per 100,000 in 2011.<sup>131, 132</sup> However, because Project Lazarus includes overdose prevention components unrelated to naloxone, it is difficult to determine the exact role naloxone played in the reduction of Wilkes County's unintentional drug overdose deaths.

Walley et al., provide the most robust evaluation examining changes in health outcomes as a result of OEND program implementation. They conducted an interrupted time-series analysis to evaluate the impact of Massachusetts' OEND program on opioid-related overdose deaths and non-fatal opioid overdose-related acute care hospital utilization rates from 2002 to 2009. They found that communities that implemented OEND programs during the study time had statistically significant reductions in opioid-related overdose death rates compared to communities that did not implement OEND programs. Acute care hospital utilizations did not differ between OEND program communities and those that did not implement one.<sup>130</sup> Based on recent systematic analyses, the available evidence suggests that naloxone is a promising strategy with some evidence of effectiveness in reducing opioid overdose mortality rates.<sup>133</sup> However, the data almost exclusively pertain to reversals of overdoses from heroin and not among people using prescription opioids. Overall the quality of evidence for the impact of naloxone on opioid overdose is low. Limitations of the available studies include lack of randomization of distribution methods; lack of generalizability because the data are almost exclusively based on people who inject drugs, primarily heroin; self-reported outcomes; short-term follow-up; significant loss to follow-up; and lack of control over other events occurring simultaneously that could be responsible for effects.<sup>134</sup>

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## #5 OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS

### RECOMMENDATIONS FOR ACTION

#### 5.1 ENGAGE WITH THE SCIENTIFIC COMMUNITY TO ASSESS THE RESEARCH NEEDS RELATED TO NALOXONE DISTRIBUTION EVALUATIONS AND IDENTIFY HIGH PRIORITY FUTURE DIRECTIONS FOR NALOXONE-RELATED RESEARCH.

*Rationale:* Naloxone is a promising strategy for reversing overdose. Rigorous, high quality research is needed to explore the relative effectiveness of naloxone use in different settings, through different OEND mechanisms (including care and follow-up after overdose reversal events), and on prescription opioid (as opposed to heroin) overdose.

*Current Status:* There are several evaluations currently underway. However, available funding to evaluate the various types of programs being implemented is insufficient. The scientific community needs to further engage in a discussion on the various research approaches to evaluate naloxone programs being implemented in a variety of settings.

#### 5.2 PARTNER WITH PRODUCT DEVELOPERS TO DESIGN NALOXONE FORMULATIONS THAT ARE EASIER TO USE BY NONMEDICAL PERSONNEL AND LESS COSTLY TO DELIVER.

*Rationale:* As the legal landscape changes to allow broader access to naloxone, different populations may prefer different delivery mechanisms for naloxone. Having multiple products that are easy for nonmedical personnel to use would likely increase uptake and reduce costs. Price is consistently raised as a concern impacting the sustainability of various naloxone distribution programs, and recent reports indicate that the cost of the drug is increasing dramatically.<sup>135</sup>

*Current Status:* An auto-injector formulation of naloxone (Evzio) was approved by the FDA in April 2014. Several drug manufacturers have submitted applications to the FDA for approval of intranasal naloxone products as well.

#### 5.3 WORK WITH INSURERS AND OTHER THIRD-PARTY PAYERS TO ENSURE COVERAGE OF NALOXONE PRODUCTS.

*Rationale:* One approach to sustaining expanded access to naloxone is through pharmacy dispensing and coverage through third parties.

*Current Status:* Some states and localities have made progress in gaining coverage for certain naloxone products. However, this has not been accomplished in a systematic way.

#### 5.4 PARTNER WITH COMMUNITY-BASED OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS TO IDENTIFY STABLE FUNDING SOURCES TO ENSURE PROGRAM SUSTAINABILITY.

*Rationale:* Some community-based programs have little to no dedicated funding for the purchase and provision of naloxone. These programs provide critical access to naloxone among high-risk populations.

*Current Status:* The federal government has identified some grant program funding that can be used to purchase naloxone. However, it is not clear exactly how these funds will impact community-based programs. Other community-based programs have worked with local and state agencies to develop a sustainable funding model and their experience could be informative to other programs across the country.

#### 5.5. ENGAGE WITH THE HEALTHCARE PROFESSIONAL COMMUNITY TO ADVANCE CONSENSUS GUIDELINES ON THE CO-PRESCRIPTION OF NALOXONE WITH PRESCRIPTION OPIOIDS

*Rationale:* There is no consensus on the patients who should be co-prescribed or prescribed naloxone in general medical settings. Recent studies show a number of logistical and attitudinal barriers to naloxone co-prescription.

*Current Status:* Several medical societies have adopted resolutions supporting naloxone co-prescription to patients, and some health systems such as the Veterans Administration have begun implementing campaigns to increase naloxone co-prescription. However, there is no consensus on the most appropriate patients for naloxone co-prescription.

### STATEMENT OF THE PROBLEM

Opioid addiction can develop from repeated exposure to opioids. Left untreated, opioid addiction commonly results in serious psychosocial problems, medical problems and death from accidental overdose. Since 1997, the number of Americans seeking treatment for addiction to opioid painkillers increased by 900 percent.<sup>136, 137</sup> The sharp increase in the prevalence of opioid addiction has been associated with a parallel increase in opioid-related overdose deaths and with increasing use of heroin.<sup>138</sup> Other health and social problems associated with the epidemic of opioid addiction include rising rates of neonatal abstinence syndrome, HIV and hepatitis C infections;<sup>139</sup> decreased life expectancy in white women; decreased workforce readiness; and decreased availability of parenting in the affected child-raising demographic.

Treatment of opioid addiction is similar to the management of other chronic conditions<sup>140</sup> and involves a bio-psycho-social approach. Unfortunately, the need for opioid addiction treatment is largely unmet.<sup>141</sup> In regions of the country where the epidemic is most severe, there are waiting lists for treatment, especially with buprenorphine. Evidence-based treatment for opioid addiction often involves the use of buprenorphine and methadone, which are currently underutilized. Despite strong evidence supporting the use of buprenorphine and methadone, and evidence that more than 5 million Americans are suffering from opioid addiction, fewer than 1 million are receiving these treatments.<sup>142</sup> A variety of barriers must be removed to allow adequate access to appropriate care.

### SYNTHESIS OF AVAILABLE EVIDENCE

Pharmacotherapies for opioid addiction include agonist maintenance with methadone, partial-agonist maintenance with buprenorphine and antagonist treatment with naltrexone. Although some evidence exists supporting use of naltrexone in specific populations,<sup>143</sup> safety and efficacy has not been well established. However, multiple well-designed randomized controlled trials provide strong evidence that buprenorphine maintenance and methadone maintenance are safe, efficacious and cost-effective treatments for opioid addiction.<sup>144</sup> Both buprenorphine and methadone maintenance treatment are associated with reduced overdose risk, reduced risk of HIV infection and improved maternal and fetal outcomes in pregnancy.<sup>145, 146</sup> However, when used short term, especially in detoxification regimens, evidence of enduring benefit is lacking.<sup>147</sup>

Psychosocial approaches to treating opioid addiction include therapeutic communities, cognitive-behavioral therapies and 12-step facilitation, either provided in professional treatment or by mutual support groups (e.g., Narcotics Anonymous). While 12-step programs are valued by many addiction professionals, it has been difficult to determine which elements of these programs may be of greatest therapeutic value. Psychosocial interventions, like medication treatments, may occur in outpatient or inpatient settings. While some studies support improved effectiveness of combining psychosocial therapies with buprenorphine and methadone maintenance, abstinence-based psychosocial approaches that shun medication-assisted treatment are lacking evidence to support the practice.<sup>148, 149</sup>

- The ability to expand access to treatment with methadone is limited by a short supply of licensed programs in non-urban communities and requirements such as daily attendance. Unlike methadone maintenance, buprenorphine can be prescribed in an office-based setting. Unfortunately, there are a variety of barriers to treatment with buprenorphine that include:
- Federal limits on the number of opioid-addicted patients a physician may treat with buprenorphine. A physician is limited to treating up to 30 patients in the first year following receipt of a buprenorphine waiver, after which the physician may apply to treat up to 100 patients.
- Prohibition against nurse practitioners' and physician assistants' prescribing. Nurse practitioners and physicians assistants are ineligible to apply for a buprenorphine waiver, even under the supervision of an addiction specialist.
- Inadequate integration of buprenorphine into primary care treatment. Physicians, nurse practitioners, physicians assistants and other allied health care professionals have little training in the recognition and treatment of opioid addiction.
- Stigma against maintenance treatment for opioid addiction. The misperception that maintenance medications are inappropriate because they substitute one drug for another is a commonly held view. These treatments have suffered from misunderstandings and negative attitudes of the public, patients and providers.<sup>150</sup> Less than half of all licensed addiction treatment programs offer these medications, and less than half of the eligible patients in those programs receive them.<sup>151</sup>

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## #6 ADDICTION TREATMENT

### RECOMMENDATIONS FOR ACTION

#### 6.1 INVEST IN SURVEILLANCE.

Improve epidemiologic surveillance of opioid addiction by revising the National Survey on Drug Use and Health (NSDUH) questions to capture opioid use disorders in patients receiving opioids for the treatment of chronic pain and by identifying other strategies to track the incidence and prevalence of opioid addiction. This effort will involve collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Centers for Disease Control and Prevention (CDC).

*Rationale:* Understanding the size and scope of the opioid addiction problem is essential for developing effective interventions. Revising an existing surveillance tool is a cost effective way to obtain needed information.

*Current Status:* This effort is not yet underway.

#### 6.2 EXPAND ACCESS TO BUPRENORPHINE TREATMENT.

Addiction specialist physicians are prohibited under federal law from treating more than 100 patients with buprenorphine — a restriction with no counterpart anywhere in medicine and which has led to waiting lists for patients to receive treatment. These federally imposed caps should be lifted. Additional training of prescribers on medication-assisted treatment should be offered and treatment guidelines, such as the American Society of Addiction Medicine (ASAM) Guideline for Medication Assisted Treatment, should be disseminated. Access to buprenorphine treatment across the country should be closely monitored by the federal government. This effort will involve collaboration with SAMHSA and the Drug Enforcement Agency (DEA).

*Rationale:* Federally imposed caps on the number of patients a physician can treat limit access to buprenorphine.

*Current Status:* Legislation seeking to lift the buprenorphine patient cap has been introduced in the U.S. Senate. In addition, the Department of Health and Human Services recently announced a plan to lift the cap through the regulatory process.

#### 6.3 REQUIRE FEDERALLY-FUNDED TREATMENT PROGRAMS TO ALLOW PATIENTS ACCESS TO BUPRENORPHINE OR METHADONE

Policies that prevent access to medication-assisted treatment are counter to the evidence and the current standard of care for effective treatment of opioid addiction. This effort will involve collaboration with the SAMHSA, the Centers for Medicare and Medicaid Services and the White House Office of National Drug Control Policy (ONDCP).

*Rationale:* Buprenorphine is an effective treatment for opioid addiction.

*Current Status:* In 2015, the ONDCP announced that drug court programs will be ineligible to receive future federal funding if they prohibit receipt of buprenorphine and methadone.

#### 6.4 PROVIDE TREATMENT FUNDING FOR COMMUNITIES WITH HIGH RATES OF OPIOID ADDICTION AND LIMITED ACCESS TO TREATMENT.

Advocate for a Targeted Capacity Expansion (TCE) program that will provide federal funding for increased access to buprenorphine and methadone in communities with high rates of opioid addiction and limited access to treatment. This effort will involve collaboration with SAMHSA.

*Rationale:* Treatment services are disproportionately distributed across communities and do not always reflect need. Using federal resources to identify communities most in need of treatment services and to expand treatment capacity will help to address this disparity.

*Current Status:* In 2015, SAMHSA issued a request for applications for prescription opioid and heroin addiction TCE programs. SAMSHA identified a total of \$11 million in funding to support the program. Additionally, bills have been introduced in Congress that increase funding to states for opioid addiction treatment.

### 6.5 DEVELOP AND DISSEMINATE A PUBLIC EDUCATION CAMPAIGN ABOUT THE ROLE OF TREATMENT IN ADDRESSING OPIOID ADDICTION.

Utilize information from Health and Human Services (HHS) and the National Institute on Drug Abuse (NIDA) through the CDC and ONDCP to educate providers, patients and their families; health plans; state level law enforcement; and policy makers on the nature of opioid addiction as a chronic brain disease, noting that the strongest evidence supports use of maintenance medication with either methadone or buprenorphine. This campaign should also aim to reduce the stigma associated with effective treatment options. A major public education campaign on appropriate treatment that is comprehensive, evidence-based, and follows best practices in health communication is needed and should be evaluated.

*Rationale:* There is a lack of awareness about the effectiveness of medication treatment options among providers, patients and their families, health plans, law enforcement, and policy makers, and there is stigma against medication treatment. Both the lack of information and the stigma associated with medication treatment are barriers to greater use of effective treatment. Medication treatment is the standard of care for opioid addiction and it should be known as such among providers and the public at large.

*Current Status:* Federal health officials from the CDC, National Institutes of Health (NIH) and SAMHSA have made public statements supporting medication-assisted treatment. The NIH and SAMHSA have also issued materials for healthcare providers and the public on treatment with buprenorphine. Some health departments, most notably the New York City Department of Health and Mental Hygiene and the Maryland Department of Health and Mental Hygiene, have sponsored efforts to raise awareness and improve access to treatment with buprenorphine and methadone.

### 6.6 EDUCATE PRESCRIBERS AND PHARMACISTS HOW TO PREVENT, IDENTIFY AND TREAT OPIOID ADDICTION.

Develop, evaluate and disseminate prescriber and pharmacist education to assist in better preventing, identifying and treating opioid addiction. Training should include both information as well as direct skill development in assessment and treatment of opioid addiction. Develop, evaluate and disseminate information about the standard of care for treatment of opioid addiction to substance abuse treatment providers.

*Rationale:* Prescribers and pharmacists receive little training on substance use disorders. With improved understanding of the etiology of opioid addiction and its treatment, they may be better able to prevent, recognize and care for patients suffering from this condition.

*Current Status:* The American Society of Addiction Medicine and the American Academy of Addiction Psychiatry are currently involved in efforts to improve medical education about substance use disorders. A coordinated national effort to educate prescribers and pharmacists about opioid addiction is not yet underway.

### 6.7 SUPPORT TREATMENT-RELATED RESEARCH.

Treatment programs that utilize the most efficacious and cost-effective protocols are needed; research is needed to identify and disseminate such interventions. Specifically, research is needed that answers questions about the relative effectiveness of different types of psychosocial interventions as additions to medication treatment, as well as trials of the enduring effectiveness of psychosocial interventions alone vs. maintenance medication therapies. This effort could include collaboration with the NIH, the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ), and the CDC.

*Rationale:* In order to maximize available treatment resources, research about the most effective ways to use medication treatment is needed. In parallel, more effective strategies to implement and disseminate proven efficacious strategies are needed.

*Current Status:* The NIH is currently funding some research on opioid addiction treatments, including comparisons of treatment interventions.

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## #7 COMMUNITY-BASED PREVENTION STRATEGIES

### STATEMENT OF THE PROBLEM

Prescription drug misuse, abuse and overdose impacts communities across the nation. It is a problem that involves a legal product that is manufactured, marketed and dispensed by professionals through a system that is subject at multiple points to government oversight from different agencies at the federal and state levels. That system has been ineffective in preventing the oversupply of prescription opioids to communities where demand for these products has grown. Whether the supply is in response to demand, a cause of the demand or some combination is unclear. Community engagement in efforts to reduce both the supply of prescription opioids and the demand for them is an under-used, but potentially important part of the solution to the problem. However, there is a dearth of evidence-based community initiatives for addressing prescription drug misuse, abuse and overdose. For the purposes of this report, we consider “communities” to be groups of people defined by a shared experience, such as college students or people living in the same town, or by professional affiliation, such as healthcare providers or pharmacists.

### SYNTHESIS OF AVAILABLE EVIDENCE

*Defining the problem.* Counts of overdose deaths are well publicized and in many ways have defined the concern about prescription opioids as a public health problem. However, additional information about the prevalence of these drugs in communities and homes, and about access to them by nonmedical users through family, friends and underground markets, is needed to better understand opportunities for intervention. Prescription Drug Monitoring Programs (PDMPs) are an important information source. The status of PDMP data, how they are being used, and the potential for greater application of these data are all detailed in Section 3 of this report. However, PDMP data capture information about the initial prescription, and not the dissemination of those drugs beyond the initial recipient. Other studies using cross sectional data provide some insight into the role of family, friends and illegal markets in supplying prescription opioids to people who are abusing, but these data are limited by time and geography. More comprehensive surveillance about prevalence and use is needed.

The supply of prescription opioids is connected to the manufacturing sector that controls production (the amount of product produced), chemistry (e.g., strength, composition, properties) and characteristics (e.g., crush resistance of pills, shelf life) of the drugs produced. Although these supply side issues are being addressed through legislative, regulatory and engineering strategies as discussed in previous sections of this report, an understanding of this supply side context is essential for planning effective community campaigns. The extent to which stakeholders from the supply side are engaged with community prevention advocates and/or involved in community public health campaigns is not known, and needs to be better understood.

*Defining solutions.* Several professional communities are important stakeholders in the prescription opioid matter. Prescribers, pharmacies and third-party payers are the focus of Sections 1 and 3 included in this document, and we will not duplicate those summaries and recommendations here. We note that those recommendations focus on identifying and intervening with high-risk patient groups who are already using prescription opioids. Here we focus on efforts to engage with patients and the general public about opioid risks and alternatives for pain management prior to the start of misuse or abuse.

Clinical interactions as an opportunity to educate patients about the risks of prescription opioids and alternatives to pain management are not documented in the literature. We are aware of one effort underway at the Johns Hopkins Center for Injury Research and Policy to develop a patient decision aid for emergency room patients who present for pain that would likely lead to an opioid prescription. However, that study is in the field and no results were available at the time of this writing. One community intervention included student nurses as part of a broader community coalition to address prescription drug overdose. The resulting paper focused more on process indicators than on outcome measures, and documents important impacts (e.g., prescription drugs turned in) but did not connect those impacts to overdose or poisoning outcomes. While promising, the intervention lacks the rigorous evaluation required to be considered evidence-based.<sup>152</sup>

Project Lazarus, a community-based initiative in North Carolina, offers perhaps the most insight with regard to population-based impacts on overdose. Included as part of the intervention are a number of strategies to address prescription opioid abuse, misuse and overdose (e.g., naloxone distribution, patient and provider education). Evaluation findings suggest significant declines in overdose deaths and hospital emergency department visits for overdose.<sup>127</sup>

Efforts to raise awareness about the risks associated with prescription opioids and alternatives available for pain management through public education campaigns are underway (e.g., The Medicine Abuse Project aimed at preventing teen misuse/abuse and promoting treatment; Rx for Understanding, a school-based curriculum; the JED Foundation’s college campus initiative; and the National Institute on Drug Abuse (NIDA) PEERx program), however, evaluations of such efforts are lacking. Raising

awareness is generally viewed as an important strategy for addressing prescription opioid misuse and offers an opportunity for prevention when combined with other strategies.

Best practices in health promotion suggest that awareness-raising efforts will have maximum impact when combined with other interventions that address the larger context in which the problem is occurring. For this issue, raising awareness could be enhanced with attention to the policy context (e.g., naloxone availability) as well as the need for other services (e.g., addiction treatment) and the supply side. To our knowledge, no community campaigns have engaged the public in efforts to address the supply side of the issue, nor have they engaged supply-side stakeholders to develop comprehensive prevention initiatives.

Primary prevention strategies targeting those who would use these drugs recreationally could adapt existing effective substance abuse prevention programs to the case of opioids. Primary prevention for patients with pain-related conditions will require effective patient education and access to alternative pain management resources (e.g. physical therapy). Assuring that public education initiatives are appropriately targeted, informed by evidence and rigorously evaluated is critically important to assuring that investments are well placed and effective.

*Evidence from another problem: Antibiotic overuse.* In 1995, the U.S. Centers for Disease Control and Prevention (CDC) launched the National Campaign for Appropriate Antibiotic Use in the Community, which was renamed Get Smart: Know When Antibiotics Work, in 2003. One important aim of the campaign was to decrease the demand for antibiotics by adults and parents of children with viral upper respiratory infections. Multiple studies have demonstrated the campaign's effectiveness, suggesting that improving patient knowledge of risks, benefits and alternatives may be a promising approach to reducing the number of prescriptions. Further studies have investigated the effectiveness of computerized patient education modules promoting awareness of appropriate antibiotic use and provided initial evidence that these interventions can be effective at reducing demand. For community prevention efforts, there are many parallels to the prescription opioid problem — i.e., the drugs are useful in certain circumstances but over-prescribed in many others and patients are generally unaware of the potential individual and societal impacts associated with over-prescribing. Thus, community prevention interventions would do well to draw from the strategies used to reduce antibiotic overuse.

### RECOMMENDATIONS FOR ACTION

#### **7.1 INVEST IN SURVEILLANCE TO INFORM HOW PATIENTS IN TREATMENT FOR OPIOID ABUSE AND THOSE WHO HAVE OVERDOSED OBTAIN THEIR SUPPLY. EXISTING SURVEILLANCE EFFORTS SUCH AS THE NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM (NEISS) CAN PROVIDE AN INFRASTRUCTURE TO ACCOMPLISH THIS TASK.**

*Rationale:* Information about the prevalence of prescription opioids in communities and homes, and access to them by nonmedical users through family, friends and underground markets, is needed to better understand opportunities for intervention. Cross-sectional data provide some insight into these questions, but these data are limited. More comprehensive surveillance about prevalence and use is needed.

*Current Status:* We are unaware of any ongoing surveillance effort to capture information about the source of prescription opioids for people who seek treatment for opioid abuse or overdose.

#### **7.2 CONVENE A STAKEHOLDER MEETING WITH BROAD REPRESENTATION TO CREATE GUIDANCE THAT WILL HELP COMMUNITIES UNDERTAKE COMPREHENSIVE APPROACHES THAT ADDRESS THE SUPPLY OF, AND DEMAND FOR, PRESCRIPTION OPIOIDS IN THEIR LOCALES; IMPLEMENT AND EVALUATE DEMONSTRATION PROJECTS THAT MODEL THESE APPROACHES.**

*Rationale:* Attention to the complex social and political context in which the problem of prescription misuse, abuse and overdose occurs has not been reflected in existing community campaign efforts. Broader stakeholder engagement may yield impactful new approaches.

*Current Status:* We are unaware of any systematic efforts to utilize community engagement to build comprehensive model programs that address both supply and demand.

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## #7 COMMUNITY-BASED PREVENTION STRATEGIES

### **7.3 CONVENE AN INTER-AGENCY TASK FORCE TO ASSURE THAT CURRENT AND FUTURE NATIONAL PUBLIC EDUCATION CAMPAIGNS ABOUT PRESCRIPTION OPIOIDS ARE INFORMED BY THE AVAILABLE EVIDENCE AND THAT BEST PRACTICES ARE SHARED.**

*Rationale:* Past success with reducing antibiotic use is generally attributed to a national campaign. Applying lessons learned from that success to the current prescription opioid challenge will increase the likelihood that public education strategies benefit from the available evidence.

*Current Status:* Public education about the risks of prescription opioids and alternatives for pain management is needed, and many efforts are underway and will likely be developed. The extent to which these efforts are informed by the available evidence is unknown, and there is no central repository for collecting this evidence and sharing best practices.

### **7.4 PROVIDE CLEAR AND CONSISTENT GUIDANCE ON SAFE STORAGE OF PRESCRIPTION DRUGS.**

*Rationale:* One source of prescription medications for nonmedical users is family and friends. Ensuring prescription medications are not easily accessible may reduce intentional misuse by teens and adults and unintentional misuse by young children.

*Current Status:* While engineering solutions to packaging hold great promise, as detailed earlier in this report, clear guidance about safe storage options for patients who bring prescription drugs home is needed. Messages should be appropriate for all populations, including those with low literacy and non-English speakers, and should be consistent across all sources — the prescriber, the pharmacist, in the drug packaging materials for patients, and in community campaigns.

### **7.5 DEVELOP CLEAR AND CONSISTENT GUIDANCE ON SAFE DISPOSAL OF PRESCRIPTION DRUGS; EXPAND ACCESS TO TAKE-BACK PROGRAMS.**

*Rationale:* There is a need for safe disposal options for prescription medications. Guidance from the federal government about how to accomplish safe disposal is needed and can serve to launch community-based take-back initiatives that are responsive to local needs and culture.

*Current Status:* Clear guidance on how to safely dispose of prescription drugs is lacking; access to take-back programs is also limited and highly variable across jurisdictions. Messages should be appropriate for all populations, including those with low literacy and non-English speakers, and should be consistent across all sources — the prescriber, the pharmacist, in the drug packaging materials for patients, and in community campaigns.

### **7.6 REQUIRE THAT FEDERAL SUPPORT FOR PRESCRIPTION DRUG MISUSE, ABUSE AND OVERDOSE INTERVENTIONS INCLUDE OUTCOME DATA.**

*Rationale:* Promising interventions are in the field, and have been demonstrated to be feasible and impactful. Population-based outcome data are lacking and needed to inform decisions about replication and scale-up of promising interventions.

*Current Status:* The federal government is funding a number of interventions to address prescription drug misuse, abuse and overdose. We are unaware of any requirement that outcome data be included with such initiatives.

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## Review

# What we know, and don't know, about the impact of state policy and systems-level interventions on prescription drug overdose



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## ABSTRACT

**Background:** Drug overdose deaths have been rising since the early 1990s and is the leading cause of injury death in the United States. Overdose from prescription opioids constitutes a large proportion of this burden. State policy and systems-level interventions have the potential to impact prescription drug misuse and overdose.

**Methods:** We searched the literature to identify evaluations of state policy or systems-level interventions using non-comparative, cross-sectional, before–after, time series, cohort, or comparison group designs or randomized/non-randomized trials. Eligible studies examined intervention effects on provider behavior, patient behavior, and health outcomes.

**Results:** Overall study quality is low, with a limited number of time-series or experimental designs. Knowledge and prescribing practices were measured more often than health outcomes (e.g., overdoses). Limitations include lack of baseline data and comparison groups, inadequate statistical testing, small sample sizes, self-reported outcomes, and short-term follow-up. Strategies that reduce inappropriate prescribing and use of multiple providers and focus on overdose response, such as prescription drug monitoring programs, insurer strategies, pain clinic legislation, clinical guidelines, and naloxone distribution programs, are promising. Evidence of improved health outcomes, particularly from safe storage and disposal strategies and patient education, is weak.

**Conclusions:** While important efforts are underway to affect prescriber and patient behavior, data on state policy and systems-level interventions are limited and inconsistent. Improving the evidence base is a critical need so states, regulatory agencies, and organizations can make informed choices about policies and practices that will improve prescribing and use, while protecting patient health.

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## 1. Introduction

In 2011, drug overdose was the leading cause of injury death, reaching epidemic levels in the United States. Among deaths where the drugs involved were specified, three quarters (over 16,000) of prescription drug overdoses involved opioid analgesics (CDC, 2014). While effective in treating cancer pain (Wiffen et al., 2013) and acute pain, such as in the perioperative setting (American Society of Anesthesiologists Task Force on Acute Pain Management, 2012), the evidence that opioids are effective at treating chronic, non-cancer pain safely over time is limited in quantity and quality (Haroutiunian et al., 2012; Noble et al., 2010). There are risks to opioid use including dependence, withdrawal, and overdose (Inturrisi, 2002). Because of their euphoric properties, they are also a candidate for diversion for nonmedical use. Yet, opioids are commonly prescribed: In 2010, an estimated 20% of patients presenting to physician offices in the United States with pain symptoms or diagnoses were prescribed opioids (Daubresse et al., 2013).

More than 125,000 people have died from overdoses involving prescription opioids during 1999–2010, and the number of such deaths per year quadrupled during this time period (CDC, 2011). Interestingly, opioid sales have increased in lock step during this period (CDC, 2011). While prescribing of opioids has increased and prescribing of non-opioid pain medications (e.g., non-steroidal anti-inflammatory drugs; NSAID) has decreased, changes in patient-reported pain severity seem to be insufficient in explaining shifts in prescribing (CDC, 2011; Chang et al., 2014).

Although it is a complicated picture, many overdose deaths can be linked to prescriptions from medical providers. For example, in a study of drug overdose fatalities in North Carolina, nearly half filled a prescription for at least one of the drugs that contributed to their death within 60 days of dying (Hirsch et al., 2014). In a study of opioid analgesic overdoses in an employer-sponsored insurance claims database, one-quarter of nonfatal overdoses were daily users with a prescription, 43.5% were other (intermittent) users with a prescription, and 31% used the opioid without a prescription (Paulozzi et al., 2014).

Several factors increase risk for drug overdose at the individual, community, and systems level. Individuals at higher risk include men; 35–54 year olds; whites and American Indians/Alaskan Natives; individuals at lower incomes; patients with mental health conditions; and patients receiving a high daily dose, prescriptions from multiple prescribers/pharmacies, and opioids combined with benzodiazepines. At the community level, those living in rural areas and communities with higher levels of use of prescription drugs prone to abuse are at higher risk (Paulozzi, 2012). Factors at the systems level include payer (with Medicaid incurring a higher rate of opioid prescriptions and adverse events such as ED visits and neonatal abstinence syndrome compared to other payers; Creanga et al., 2012; Raofi and Schappert, 2006) and prescriber volume (with those at high prescribing rates accounting for a greater proportion of patient deaths; Dhalla et al., 2011).

States operate the major levers that control access to drugs through prescription origination points (such as physician practices, emergency departments, hospitals, and pharmacies), payment and reimbursement (such as through insurers and pharmacy benefit managers), and public education (such as through campaigns and community initiatives). Innovative state policy and systems-level preventive interventions have been proposed to address the problem of opioid analgesic overdose at a population level. Table 1 summarizes these interventions and explains the state role. We sought to understand the evidence available on the effectiveness of such interventions on intermediate outcomes, such as provider and patient behavior, as well as health outcomes, such as fatal and nonfatal overdose. Previous reviews have investigated specific interventions (e.g., PDMPs), but none have integrated the strategies within one comprehensive, broad-scoped review across multiple strategies—a unique focus of the current paper.

## 2. Material and methods

### 2.1. Data sources and searches

With the assistance of a librarian, MEDLINE was searched for research articles evaluating on state policy and systems-level interventions published from 1946 to 2014 with search terms including, but not limited to, “drug overdose”, “analgesics/opioid”, “health education”, “patient education”, “organizational policy”, “prescription”, “monitoring”, “guideline”, “legislation”, “insurer”, “formulary”, and “drug utilization review”, resulting in over 500 citations. Additional articles were identified through searches of the references of retrieved articles, as well as relevant federal and organizational websites.

### 2.2. Selection criteria

Article abstracts were reviewed for relevance. Articles were selected for the review if they were written in English and evaluated a state or system policy or practice using a non-comparative, cross-sectional, before–after, time series, cohort, or comparison group study or a randomized/non-randomized trial. Studies were excluded if they were purely descriptive (e.g., characterized practices in a health system) without aiming to evaluate the influence of a state or system-level policy or practice. Eligible studies included the following intermediate and/or distal outcomes: provider behavior (e.g., controlled substance prescribing patterns, dose, guideline-concordant care), patient behavior (e.g., use of multiple providers or pharmacies, number of prescriptions), and health outcomes (e.g., adverse effects, misuse, abuse, non-fatal overdose, death). We prioritized interventions that offer prevention effects at a population level over substance abuse treatment interventions. Although there are effective strategies that focus on underlying substance use disorders and assist in recovery (e.g., expanding access to medication-assisted therapies; Volkow et al., 2014),

**Table 1**  
State policy and systems-level prevention toolbox.

Intervention	State role in implementation	Description
<b>Prescription drug monitoring programs</b>	Operated by state health departments; state law enforcement agencies; state boards of pharmacy	Programs that require state pharmacies to submit all information on prescriptions filled for controlled substances electronically to a central office, such as the health department or board of pharmacy; information is provided to prescribers about patients using multiple prescribers or pharmacies, and in some cases to law enforcement about aberrant prescribing
<b>Insurer and pharmacy benefit manager strategies</b>	Implemented by state Medicaid programs and pharmacy benefit managers that assist state Medicaid	Patient review and restriction programs that require patients suspected of misusing controlled substances to use a single prescriber/pharmacy; drug utilization review programs that review claims data to identify problematic use and notify prescribers; prior authorization and medication quantity limits
<b>State legislation</b>	Developed by the state legislature with education and information supplied by state health departments and law enforcement, among others	Pain clinic regulation that limits clinic ownership, prescribing, and dispensing combined with mandated registration and inspection; good samaritan laws that provide immunity from prosecution for possessing a controlled substance while seeking help for himself or another person experiencing an overdose; doctor shopping laws that prohibit patients from withholding information from providers about receipt of controlled substances from other providers
<b>Clinical guidelines</b>	Developed by state health departments in collaboration with other stakeholders for providers and health systems within the state	Guidance documents that provide recommendations to providers about clinical practice; focus on opioid prescribing; recommendations vary but typically include dose limits, medications and formulations, initiation and titration of dose, drug switching, drug interactions, screening tools, written treatment agreements, and urine drug testing
<b>Naloxone distribution</b>	Supported by state health departments and distributed by funded community organizations	Programs that provide naloxone and other opioid overdose prevention services to individuals who use drugs, their families and friends, and service providers; include education about overdose risk factors, signs of overdose, appropriate response, and administration of naloxone
<b>Safe storage and disposal</b>	Supported by state health departments and law enforcement agencies in collaboration with local stakeholders	Programs that inform the general public about safe storage and disposal of prescription drugs; collection of drugs by officials at permanent return programs or one-day events
<b>Education: patients and providers</b>	Supported by state health departments, in collaboration with community organizations, health systems, and schools	Programs that educate patients and providers about prescription opioid use and misuse; patient education ranges from informational materials to intensive family and school-based prevention; provider education focuses on opioid prescribing and includes tools, workshops, lectures, case discussions, consultant support, and continuing education credit

substance use treatment is part of a larger strategy to address drug overdose and has been reviewed at length in the published literature; as a result, it was determined to be beyond the scope of the current review. We primarily relied on studies that were conducted in the United States (with an exception for Canada) given the variation in state infrastructure and health systems across countries.

### 2.3. Data extraction and synthesis

Categories of state policy and systems-level interventions were identified through the literature search: prescription drug monitoring programs (PDMPs), insurer and pharmacy benefit manager strategies, state legislation, clinical guidelines, naloxone distribution programs, safe storage and disposal strategies, and patient/provider education (see Table 1). These interventions are broad and represent primary, secondary, and tertiary prevention approaches. For example, patient education interventions can be seen to represent primary prevention, aiming to teach about the dangers of opioid misuse. Clinical guidelines can represent secondary prevention when they aim to change provider behavior to mitigate potential harm for patients at risk for opioid misuse. Naloxone distribution programs represent tertiary prevention, aiming to reduce risk of death among those misusing prescription opioids.

Intervention evidence tables were constructed with effects categorized by provider behavior, patient behavior, and health outcome. For each outcome, the study designs, number of studies, and key outcomes were compiled. Only outcomes relevant to the purpose of this review were included. For some studies, particularly studies employing descriptive epidemiology or before/after designs, statistical testing was not conducted. To provide a thorough review, outcomes were included in evidence tables when statistical testing was employed and when change was noted but no tests of significance were performed. Statistical testing is noted

in the tables. Given the variation in interventions, study designs, and outcomes assessed, it was not practicable to synthesize the results through systematic analytic methods (e.g., meta-analysis) for any of the interventions evaluated. Hence, narrative reviews were constructed for each intervention, noting intervention components and key outcomes and summarizing process outcomes when feasible (e.g., implementation).

Quality of evidence judgments were made for each outcome type (provider behavior, patient behavior, health outcomes) for each intervention, inspired by the GRADE approach (see [Balslem et al., 2011](#) for more details). This validated approach weighs the quality of the evidence across studies from systematic reviews, typically in the context of making recommendations for practice. Observational studies (e.g., before–after; time series) are initially assigned a rating of low evidence quality, while randomized controlled trials are initially assigned a rating of high evidence quality. Ratings are modified downward based on study limitations, imprecision, inconsistency of results, indirectness of evidence, and publication bias; ratings are modified upward based on large magnitude of effect, dose response, and when confounders likely minimize the effect. Final ratings possible for each outcome are high, moderate, low, or very low, considering the set of the studies that address the outcome. For example, a set of observational studies with a high risk of bias (e.g., no adjustment for potential confounders) and inconsistent findings would result in an evidence rating of very low. A set of studies including one or two RCTs with study limitations that indirectly assess the outcome of interest mixed with a large number of observational studies with inconsistent results would result in an evidence rating of low. When quality of evidence is high, there is confidence that the true effect lies close to the estimate of the effect. When the quality of evidence is low, the confidence in the effect is limited and further research is likely to have an impact on our confidence in the estimate. Given that the overwhelming majority of studies were observational and a

limited number were RCTs, summary outcome tables were visually inspected by the authors to assign evidence ratings.

### 3. Results

Fig. 1 illustrates the number of studies reviewed by type of intervention, and the type of outcomes measured in the studies. There was substantial variation in the number of studies by intervention, with a greater number of studies found for PDMPs, naloxone education and distribution programs, and clinical guidelines than for insurer strategies, state legislation, safe storage and disposal, and provider/patient education. There also were large differences in the types of outcomes studied, with health outcomes being examined more often for naloxone distribution programs than for the other interventions.

#### 3.1. Prescription drug monitoring programs

**Background:** As of August, 2014, 49 states, the District of Columbia, and one U.S. territory (Guam) had statutes authorizing the creation of a PDMP, and 48 states and Guam had an operational PDMP. Missouri did not have a PDMP, and the PDMPs in New Hampshire and DC were not yet operational. The first PDMP began in California in the 1940s, but widespread adoption did not occur until the first decade of the 21st century. First-generation states (California, New York, and Texas) paired their PDMPs with requirements for use of special serialized triplicate prescription forms, a practice now largely abandoned. PDMPs now require state pharmacies to submit all the information on prescriptions filled for controlled substances electronically to a central office such as the health department or the board of pharmacy (Brandeis University Prescription Drug Monitoring Program Training and Technical Assistance Center, 2014a,b). All PDMPs other than Pennsylvania's monitor controlled substance schedules II–IV, and most monitor schedules II–V. Providers can proactively search PDMP data to determine if their patients are using multiple prescribers and/or pharmacies for these drugs. Some PDMPs report data on aberrant prescribing proactively to law enforcement or health care licensure boards. Some states require prescribers and dispensers to register with the PDMP, and a small but growing number now require prescribers to check the PDMP before prescribing. Efforts are underway to incorporate PDMP data into electronic health records.

**Findings:** Evaluations have focused on the prescribing of opioid analgesics, benzodiazepines, or both. Outcomes have included population-based prescribing rates for these drug classes, problematic prescribing (e.g., pill mills), or problematic use by patients (e.g., use of multiple prescribers or pharmacies). Less commonly, studies have evaluated health outcomes related to abuse of controlled prescription drugs such as fatal or nonfatal overdoses. Three

studies also used state rates of substance abuse treatment admissions as an additional outcome (Reifler et al., 2012; Reisman et al., 2009; Simeone and Holland, 2006; see Table 2).

Evaluation studies during the 1980s largely focused on the New York PDMP and its addition of benzodiazepines to the program in 1989. Those studies found dramatic declines (20–80%) in use and problematic use of benzodiazepines with this addition (Pearson et al., 2006; Ross-Degnan et al., 2004; Weintraub et al., 1991; Wolfe and Lurie, 1992). One study (Wastila and Bishop, 1996) examined the CA, TX, and NY PDMPs that used triplicate forms and found lower Schedule II prescribing, higher Schedule III prescribing, and overall lower use of any prescribed analgesics in those states, although part of this finding may be attributable to the fact that the PDMPs only tracked schedule II drugs at that point in time. Studies published after 2000, which focused on opioid analgesics, confirmed lower Schedule II rates in PDMP states in general (Curtis et al., 2006; Reisman et al., 2009; Simeone and Holland, 2006). Lower schedule II prescribing rates have been shown to be offset by higher Schedule III prescribing in other studies (Paulozzi et al., 2011; Simoni-Wastila and Qian, 2012). Again, results might have differed if PDMPs in all states had tracked Schedule II and III during the study periods. The most recent study found no significant overall difference in opioid prescribing (Brady et al., 2014). One study found no reduction of overdose mortality in PDMP states (Paulozzi et al., 2011) while another found a slower rate of increase in oxycodone overdoses in PDMP states (Reifler et al., 2012).

Overall, the earliest evaluation studies of PDMPs were unable to disentangle the use of special forms from the use of PDMPs, while later studies, using data through 2008 in one case, have not clearly established significant effects on total opioid prescribing or health outcomes with PDMPs. The largest limitation is the lack of detailed data on prescribing volume and patterns prior to PDMP implementation, which forced the use of cross-sectional, observational study designs. The effect sizes in the most recent studies have been small, making it conceivable that the differences are due to unaddressed confounding variables. There is yet little data to settle the question of whether specific actions of PDMPs (e.g., proactive reporting) add to their effectiveness. However, recent adoption of mandates for prescriber use of PDMP data could demonstrate substantial positive effects of PDMPs, including increased registration and use, and subsequent decreases in prescribing of controlled substances (Brandeis University Prescription Drug Monitoring Program Training and Technical Assistance Center, 2014a,b).

#### 3.2. Insurer and pharmacy benefit manager strategies

**Background:** Insurers (e.g., Medicaid, private insurance offered through employers) and pharmacy benefit managers (PBMs; groups that process prescriptions for insurers) have access to detailed medical and pharmacy claims data and therefore are a good source for identifying inappropriate prescribing by providers and prescription drug abuse by patients (Katz et al., 2013; Sacciccio, 2011). Patient Review and Restriction (PRR) programs (also called “Lock-In” Programs), Drug Utilization Review (DUR) programs, Prior Authorization (PA), and medication Quantity Limits (QL) may be potential levers to change provider and patient behavior (CDC, 2013; Academy of Managed Care Pharmacy et al., 2010). PRRs require patients suspected of misusing controlled substances to use a single prescriber and/or pharmacy to obtain controlled substance prescriptions. DUR programs include review of claims data retrospectively to identify problematic use and notify providers about such use. Prior authorization requires review of medical justifications before drugs are covered by the insurer. Medication quantity limits are used to limit the amount of drug that can be dispensed within a given time frame.

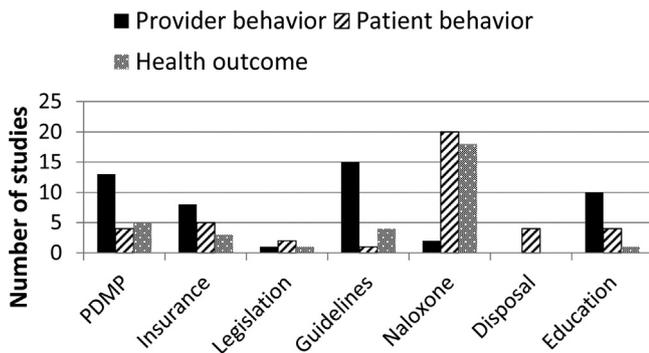


Fig. 1. Number of studies by strategy type and outcomes measured.

**Table 2**  
Prescription drug monitoring programs.

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b> <i>*Low</i>	Descriptive/before–after	3	<b>Lower use of CSII drugs</b> (Curtis et al., 2006; Simoni-Wastila and Qian, 2012; Wastila and Bishop, 1996) <sup>SS</sup>
	Time series	10	<b>Greater use of CSIII drugs</b> (Simoni-Wastila and Qian, 2012; Wastila and Bishop, 1996) <sup>SS</sup> <b>Decrease in CSII opioid prescribing</b> (Reisman et al., 2009; Simeone and Holland, 2006) <sup>SS</sup> (Sigler et al., 1984) <sup>NT</sup> <b>Increase in CSIII prescribing</b> (Sigler et al., 1984) <sup>NT</sup> <b>Decrease in benzodiazepine prescribing</b> (Pearson et al., 2006; Weintraub et al., 1991; Wolfe and Lurie, 1992) <sup>NT</sup> . (Ross-Degnan et al., 2004) <sup>SS</sup> <b>Decrease in “inappropriate” opioid use</b> (Dormuth et al., 2012) <sup>SS</sup> <b>Decrease in “problematic” benzodiazepine use</b> (Ross-Degnan et al., 2004) <sup>SS</sup> <b>No change in CSII-IV opioid prescribing</b> (Brady et al., 2014; Paulozzi et al., 2011) <sup>NS</sup>
	RCT	0	
<b>Patient behavior</b> <i>*Low</i>	Descriptive/before–after	0	
	Time series	4	<b>Decrease in benzodiazepine use by drug diverters</b> (Wolfe and Lurie, 1992) <sup>NT</sup> <b>Decrease in use of multiple pharmacies</b> (Ross-Degnan et al., 2004) <sup>SS</sup> <b>Decrease in use of multiple prescribers</b> (Pearson et al., 2006) <sup>NT</sup> , (Dormuth et al., 2012) <sup>SS</sup>
	RCT	0	
<b>Health outcomes</b> <i>*Low</i>	Descriptive/before–after	0	
	Time series	5	<b>Decrease in ED visits for benzodiazepines</b> (Wolfe and Lurie, 1992) <sup>NT</sup> <b>Decrease in substance abuse treatment admissions</b> (Simeone and Holland, 2006) <sup>SS</sup> , (Reifler et al., 2012; Reisman et al., 2009) <sup>NS</sup> <b>No change in drug overdose mortality</b> (Paulozzi et al., 2011) <sup>NS</sup> <b>Decrease in oxycodone poison center report rates</b> (Reifler et al., 2012) <sup>SS</sup>
	RCT	0	

Note: SS = Tested and statistically significant.

NS = Tested and not statistically significant.

NT = No statistical testing conducted.

\* = Evidence level.

**Findings:** The limited studies on the effectiveness of insurer and PBM strategies have examined cost savings and changes in utilizations; few have evaluated impact on health outcomes (See Table 3). A total of eight PRR evaluations were identified with the earliest studies beginning in the 1970s and the most recent in 2012. Four reports contain only information on cost savings (Chinn, 1985; Colburn et al., 2008; Medicaid, 2005; Singleton, 1977). An evaluation of Louisiana’s PRR found reductions in polypharmacy (use of multiple medications), use of Schedule II narcotics, and pharmaceutical costs after enrollment in the PRR (Blake, 1999). Ohio’s Medicaid PRR reported monthly dosage reductions of 40.8% for narcotic analgesics and 36.3% for sedatives after patients enrolled in the PRR (Tanenbaum and Dyer, 1990). A 2009 evaluation found decreased use of narcotic medications, multiple pharmacies and physicians, and emergency department visits among patients in Oklahoma’s Medicaid PRR (Mitchell, 2009). Among patients in Washington’s PRR in 2006, the average number of narcotic prescriptions decreased from 3.07 to 1.63 and total morphine milligram equivalent (MME) doses decreased from 312 MME/day to 185 MME/day following enrollment. A follow-up analysis found, after one year, significant reductions in hospital costs, ED visits for injuries from any cause, physician visits and costs, and narcotic prescriptions among PRR patients. No differences in mortality were seen between the PRR and comparison groups (CDC, 2013).

Four studies published between 2003 and 2013 evaluated DUR programs. A randomized trial evaluating the impact of proactive alerts sent to providers on patients receiving opioid prescriptions from  $\geq 3$  prescribers at  $\geq 3$  pharmacies in a 3-month period found that patients in the intervention group had a 24% reduction in number of prescribers, 16% reduction in number of dispensing pharmacies, and 15% reduction in filled opioid prescriptions over the one-year evaluation period compared to the control group (Gonzalez and Kolbasovsky, 2012). Daubresse et al. (2014) reported a significant decline in mean controlled substance score – a measure of controlled substance abuse risk – among patients whose providers were sent a letter describing the patients’ controlled

substance history compared to patients whose providers were not sent letters. Hoffman et al. and Zarowitz et al. also reported reduced drug utilization after DUR program intervention (Hoffman et al., 2003; Zarowitz et al., 2005). None of these studies examined changes in health outcomes.

Four evaluations of PA and/or QL programs were identified, published between 2004 and 2012. A 2008 study examined the impact of PA on controlled-release oxycodone use by Medicaid enrollees in 49 states and the District of Columbia. Twenty-one states implemented a PA for controlled-release oxycodone during the study period. States with more strict PA criteria experienced a significant 34% decrease in controlled-release oxycodone use, while states with more lenient PAs experienced a nonsignificant increase of 6% (Morden et al., 2008). Oregon Medicaid’s long-acting opioid PA and methadone dose limit programs reported a 32% reduction in use of long-acting opioids after the first year of the program, and the percent of patients taking  $\geq 100$  MME per day of methadone decreased from 29% to 9% (Oregon State University, 2012). Oregon Medicaid also implemented QL/PA programs for non-opioid drugs of abuse—carisoprodol and sedative/hypnotics. The carisoprodol QL/PA resulted in a decrease in the rate of prescriptions per 1000 members from 7.07 to 2.03; average daily dose from 1110 mg to 956 mg; and average number of tablets per prescription from 63 to 40 after program implementation. No significant increase or decrease in the rate of ED visits, hospitalizations, or office visits was observed among carisoprodol users after program implementation (Oregon State University, 2004a). The sedative/hypnotic QL/PA program was less robust. Minimal impact on utilization likely resulted from generous “grandfathering” for patients previously prescribed these medications (Oregon State University, 2004b).

Overall, the quality of evidence is low for the impact of insurer and PBM strategies on prescription drug abuse and overdose because of the lack of comparison groups in most studies, short-term follow-up, inadequate statistical testing in several studies, unassessed health outcomes, and other events occurring simultaneously that could be responsible for effects. Despite this limited

**Table 3**  
Insurer and pharmacy benefit manager strategies.

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b> *Low	Descriptive/before–after	4	<p>Decrease in mean number of CII-CV prescription drug claims PMPM (Hoffman et al., 2003)<sup>SS</sup></p> <p>Decrease in mean number of prescribers per patient (Hoffman et al., 2003)<sup>SS</sup></p> <p>No change in mean number of total prescriptions PMPM (Hoffman et al., 2003)<sup>NS</sup></p> <p>Decrease in long-acting opioid prescriptions and opioid duplication (Oregon State University, 2012)<sup>NT</sup></p> <p>Decrease in percent of patients taking <math>\geq 100</math> morphine milligram equivalents of methadone (Oregon State University, 2012)<sup>NT</sup></p> <p>Decrease in sedative/hypnotic prescriptions and quantities per prescription (Oregon State University, 2004b)<sup>NT</sup></p> <p>Decrease in carisoprodol prescriptions, quantities per prescription, and average daily dose (Oregon State University, 2004a)<sup>NT</sup></p>
	Time series	3	<p>Decrease in rates of poly-pharmacy events for opioids and benzodiazepines (Zarowitz et al., 2005)<sup>SS</sup></p> <p>Decrease in mean controlled substance score driven by reduced number of controlled substance prescriptions and reduced numbers of prescribers and pharmacies utilized (Daubresse et al., 2014)<sup>SS</sup></p> <p>Decrease in controlled-release oxycodone use in states with strict prior authorization criteria (Morden et al., 2008)<sup>SS</sup></p> <p>No change in controlled-release oxycodone use in states with lenient prior authorization criteria (Morden et al., 2008)<sup>SS</sup></p>
	RCT	1	<p>Greater reduction in number of prescribers, dispensing pharmacies, and filled opioid prescriptions compared to control group (Gonzalez and Kolbasovsky, 2012)<sup>SS</sup></p>
<b>Patient behavior</b> *Low	Descriptive/before–after	2	<p>Decrease in provider visits, number of opioid prescriptions, and mean daily morphine milligram equivalent dose (CDC, 2013)<sup>SS</sup></p> <p>Decrease in opioid and sedative use (Tanenbaum and Dyer, 1990)<sup>SS</sup></p>
	Time series	3	<p>Decrease in rates of poly-pharmacy events for opioids and benzodiazepines (Zarowitz et al., 2005)<sup>SS</sup></p> <p>Decrease in number of prescriber and pharmacies (Blake, 1999; Mitchell, 2009)<sup>SS</sup></p> <p>Decrease in poly-pharmacy and CII opioid prescriptions (Blake, 1999)<sup>SS</sup></p> <p>Decrease in number of opioid prescriptions (Mitchell, 2009)<sup>SS</sup></p>
	RCT	0	
<b>Health outcomes</b> *Low	Descriptive/before–after	2	<p>No change in rate of ED services, hospitalizations, or office visits among carisoprodol patients (Oregon State University, 2004a)<sup>NT</sup></p> <p>Decrease in ED visits for injuries from any cause (CDC, 2013)<sup>SS</sup></p> <p>No change in mortality (CDC, 2013)<sup>NS</sup></p>
	Time series	1	<p>Decrease in ED visits (Mitchell, 2009)<sup>SS</sup></p>
	RCT	0	

Note: SS = Tested and statistically significant

NS = Tested and not statistically significant

NT = No statistical testing conducted

\* = Evidence level.

evidence base, insurer and pharmacy benefit manager strategies do show promise for changing certain prescribing and use behaviors linked to prescription drug abuse and overdose.

### 3.3. State legislation

**Background:** Policies such as pain clinic regulation (“pill mill” laws), legislation that limits the use of multiple providers (“doctor shopping” laws), and laws that provide immunity from prosecution (“Good Samaritan” laws) are being considered by states to reduce diversion, abuse, and overdose. Eleven states have a pill mill law (as of January, 2014), 16 states have a specific doctor shopping law (as of August, 2010), and 18 states have a Good Samaritan law, including 9 that have laws that specifically create immunity from prosecution for people who call for help in the event of an overdose (as of September, 2012).

**Findings:** Published studies reporting on evaluations of state policy strategies are extremely limited (see Table 4). Informal evaluation reports of pill mill legislation in Louisiana and Texas suggests impacts on number of pain clinics and opioid analgesic supply (DeRosier, 2008; Forrester, 2011). In 2010, Florida enacted legislation that limited pain clinic ownership, mandated registration and inspection of pain clinics, placed limits on prescribing with cash transactions, and restricted on-site dispensing of controlled

substances; additional components were added to enhance implementation in 2011. A trend analysis revealed a significant decline in diversion for oxycodone, morphine, and methadone, as measured by prescription drug diversion investigations conducted by police departments, sheriff offices, state agencies, and drug task forces (Surratt et al., 2014). Another study showed that opioid analgesic overdose death rates decreased 27% from 2010 to 2012 after enactment of the law (Johnson et al., 2014). Although these findings are promising, several activities were occurring at the same time that could have contributed to changes in diversion and overdose (e.g., PDMP implementation, regional strike forces), making it difficult to identify effects uniquely attributable to the legislation.

There is very little evidence on immunity from prosecution or laws related to use of multiple providers (also known as “doctor shopping” laws). An initial evaluation of Washington’s Good Samaritan law found that drug users in Seattle were more comfortable calling 911 after implementation of the law, but law enforcement had low awareness of the law, and opinions on the law were mixed (Banta-Green et al., 2013, 2011). A study in West Virginia of general practice and emergency medicine physicians related to multiple provider laws found that 37% of the respondents had ever reported a patient to law enforcement, and 22% stated they currently report use of multiple providers. The physicians also reported that they would be more likely to report such behavior if they were granted immunity from reporting (Shaffer and Moss, 2010).

**Table 4**  
State legislation (Pill Mill, Doctor Shopping, Good Samaritan).

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b> *Very low	Descriptive/before–after	1	<b>Providers willing to report doctor shopping, particularly if immunity was granted (Shaffer and Moss, 2010)<sup>NT</sup></b>
	Time series	0	
	RCT	0	
<b>Patient behavior</b> *Low	Descriptive/before–after	1	<b>Users willing to call 911 (Banta-Green et al., 2011)<sup>NT</sup></b> <b>Decline in diversion for oxycodone, morphine, and methadone (trends for hydrocodone were not statistically significant) after pill mill legislation enactment (Surratt et al., 2014)<sup>SS</sup></b>
	Time series	1	
	RCT	0	
<b>Health outcomes</b> *Very low	Descriptive/before–after	1	<b>Decline in overdose death rates (Johnson et al., 2014)<sup>NT</sup></b>
	Time series	0	
	RCT	0	

Note: SS = Tested and statistically significant.

NS = Tested and not statistically significant.

NT = No statistical testing conducted.

\* = Evidence level.

Overall the quality of evidence for the impact of state legislation on provider behavior, patient behavior, and health outcomes is low. Evaluation data are only available from three states, multiple efforts were in place at the time legislation was enacted, and causal conclusions about the impact of specific strategies are limited.

### 3.4. Clinical Guidelines

**Background:** National medical organizations issue clinical practice guidelines to improve use of evidence-based strategies and quality of care (e.g., the American Pain Society and the American Academy of Pain Medicine joint guidelines on the use of chronic opioid therapy in chronic noncancer pain; Chou et al., 2009). Large health systems (e.g., Veteran's Administration/Department of Defense), health maintenance organizations, hospitals, and now states have followed suit in recommending ways to mitigate the risk of opioid therapy. Recommendations vary, but typically include dose limits, medications and formulations, initiation and titration of dose, drug switching, drug-interactions, screening tools to assess risk for misuse, written treatment agreements, and urine drug testing (Nuckols et al., 2014). Implementation strategies differ across states and systems, ranging from limited information dissemination efforts to intensive academic detailing, quality improvement, and enforcement through state regulation.

**Findings:** Limited evaluations have assessed both process and outcome measures, employing a range of study designs: non-comparative descriptive epidemiological, before–after, and time-series designs, as well as randomized trials (see Table 5). Descriptive epidemiological studies of adherence to state, university clinic system, and VA guidelines illustrate moderate knowledge of recommendations and low level of provider adoption, particularly the use of assessment tools, written treatment agreements, and drug testing; However, some studies report that smaller percentages of patients are managed with high dose opioids; higher percentages of providers report avoiding long-acting opioids for acute pain or in combination with benzodiazepines; and physicians are more likely to use tools like drug screens in patients with substance use disorder, all beneficial findings (Cochella and Bateman, 2011; Krebs et al., 2011; Morasco et al., 2011; Morse et al., 2012; Porucznik et al., 2013; Sekhon et al., 2013; Victor et al., 2009). Findings from before–after studies of state, emergency department, and hospital guidelines are promising, and show declines in number and rate of opioid prescribing, lower average daily doses, and decreases in ED visits and deaths (Cochella and Bateman, 2011; Fox et al., 2013; Franklin et al., 2013b; Gordon et al., 2000; Humphries et al., 1997). Yet, given the methodological

limitations of these studies, conclusions are uncertain. The most rigorous evaluations of the Washington State Opioid Dosing Guideline using time-series designs with a workers compensation population illustrated significant declines in the proportion of incident users who became chronic users and who received a dosage of >120 mg MED/day; however no significant changes were detected in opioid poisonings or adverse effects. Two randomized trials have investigated the use of training and education approaches in enhancing guideline adoption, revealing mixed effects: Although enhanced education approaches may lead to improvements in provider reports of recommendation knowledge and use, this does not necessarily translate to changes in guideline-concordant care (Corson et al., 2011; McCracken et al., 2012).

Overall, the quality of evidence for the impact of clinical guidelines at the state and system level on provider behavior and patient outcomes is low. Study limitations include lack of baseline data and comparison groups, inadequate statistical testing, small sample sizes, self-reported outcomes, short-term follow-up, and other events occurring simultaneously that could be responsible for effects. It is possible that more advanced methods of translating and disseminating guidelines could lead to increases in adoption and implementation; however, more translational research is needed to identify best practices.

### 3.5. Naloxone distribution programs

**Background:** Naloxone has been used for many years by health-care and emergency medical service providers to reverse the potentially fatal respiratory depression associated with opioid overdoses. Community-based overdose education and naloxone distribution (OEND) programs that provide naloxone and train at-risk individuals and their friends, family-members, or caregivers on overdose prevention and response have been implemented in the US in recent years. At least 188 community-based programs were in existence in the US in 2010 (Wheeler et al., 2012). In addition, some healthcare providers co-prescribe naloxone to patients taking high doses of opioids or to patients who are otherwise at risk for opioid overdose.

**Findings:** Evaluations of OEND programs in the US appearing in the 2000s have focused on program implementation; ability to train non-medical personal to recognize and respond to an overdose, including the proper administration of naloxone; and number of individuals trained, number of vials of naloxone distributed, and number of overdose reversals reported by trained individuals (See Table 6). The majority of individuals trained have been people who injected drugs, primarily heroin or other illicit opioids, and their

**Table 5**  
Clinical guidelines.

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b> *Low	Descriptive/before–after	12	<b>Increase in reading and/or applying guideline</b> (Franklin et al., 2013a) <sup>SS</sup> <b>Prescribes higher doses less often</b> (Franklin et al., 2013a) <sup>NT</sup> <b>Low percentage of providers with pharmacist collaborative drug therapy agreement</b> (Franklin et al., 2013a) <sup>NT</sup> <b>Decrease in/less opioid prescribing</b> (Fox et al., 2013; Franklin et al., 2013a; Franklin et al., 2013b; Gordon et al., 2000) <sup>NT</sup> <b>Increase in/higher prevalence of correct dose and frequency</b> (Humphries et al., 1997) <sup>SS</sup> <b>No differences in dose or long-acting opioid use for at-risk patients</b> (Morasco et al., 2011) <sup>NS</sup> <b>More likely to prescribe ER formulation for chronic episodes, but still underutilized</b> (Victor et al., 2009) <sup>SS</sup> <b>Limited actual use of recommended practices (e.g., treatment agreement, assessment of pain, urine testing)</b> (Cochella and Bateman, 2011; Krebs et al., 2011; Morse et al., 2012; Porucznik et al., 2013; Sekhon et al., 2013) <sup>NT</sup>
	Time series	1	<b>Less likely to prescribe high dose among new users</b> (Garg et al., 2013) <sup>SS</sup>
	RCT	2	<b>No changes in prescribing frequency</b> (McCracken et al., 2012) <sup>NS</sup> <b>Increase in self-report use of guidelines</b> (McCracken et al., 2012) <sup>SS</sup> <b>No differences between clinicians in the Assistance with Pain Treatment intervention and clinicians in the treatment as usual group (overall limited use of recommended practices)</b> (Corson et al., 2011) <sup>NS</sup>
<b>Patient behavior</b> *Low	Descriptive/before–after	0	
	Time series	1	<b>Lower number of incident users who become chronic and statistically significant reduced likelihood of receiving high dose opioids with incident users</b> (Garg et al., 2013) <sup>SS</sup>
	RCT	0	
<b>Health outcomes</b> *Very low	Descriptive/before–after	3	<b>Decrease in ED visits</b> (Fox et al., 2013) <sup>NT</sup> <b>Decrease in deaths</b> (Cochella and Bateman, 2011; Franklin et al., 2013b) <sup>NT</sup> <b>No changes in poisonings or opioid adverse effects</b> (Fulton-Kehoe et al., 2013) <sup>NS</sup>
	Time series	1	
	RCT	0	

Note: SS = Tested and statistically significant.

NS = Tested and not statistically significant.

NT = No statistical testing conducted.

\* = Evidence level.

friends or family members. Two reports provide information on naloxone as part of a broader prescription opioid overdose prevention strategy. A single study (Walley et al., 2013b) specifically evaluated changes in overdose mortality over time after OEND program implementation.

Evaluation settings have primarily been in large urban center syringe exchange or harm reduction programs, methadone programs, or other addiction treatment or detoxification programs. A total of 12 studies provided information on OEND program evaluations in New York City (Galea et al., 2006; Heller and Stancliff, 2007; Piper et al., 2007, 2008), Massachusetts (Doe-Simkins et al., 2009; Walley et al., 2013a), Los Angeles (Wagner et al., 2010), San Francisco (Enteen et al., 2010), Chicago (Maxwell et al., 2006), Rhode Island (Yokell et al., 2011), Pittsburgh (Bennett et al., 2011), and Baltimore (Tobin et al., 2009). The outcomes typically focused on the number of trained individuals and overdose reversals reported, making it difficult to describe the population-level impact of these individual programs. However, a 2010 survey reported that 48 OEND programs in the US had trained and provided naloxone to over 50,000 individuals between 1996 and 2010. Among these programs, over 10,000 opioid overdose reversals were reported during the same time period, likely an underestimate since reporting is voluntary. The programs also reported that nearly 40,000 vials of naloxone had been provided to participants over the past year (Wheeler et al., 2012).

Six additional studies evaluating changes in overdose recognition and response knowledge and/or behaviors as a result of training were identified (Doe-Simkins et al., 2014; Green et al., 2008; Jones et al., 2014; Lankenau et al., 2013; Seal et al., 2005; Sherman et al., 2009). Taken together, with the 12-program evaluation studies, these data demonstrate that people at high-risk for

opioid-related overdose (primarily heroin) and their friends or family members can successfully be trained to recognize and respond to an overdose and appropriately administer naloxone to reverse an opioid-related overdose. Importantly, the studies did not find an increase in drug use or high-risk behavior as a result of being provided naloxone.

Two studies describe the Project Lazarus program in North Carolina. The program, created in 2008, includes the co-prescription of naloxone to people at risk for opioid overdose as one component of a broader prescription opioid overdose strategy that included community coalition building and outreach, clinical practice changes, school-based education, surveillance, and evaluation (Albert et al., 2011; Brason et al., 2013). An initial evaluation of Project Lazarus in Wilkes County, North Carolina found significant declines in the unintentional drug overdose death rate from a peak of 46.6 deaths per 100,000 population in 2009 to 29.0 deaths per 100,000 in 2010 and 14.4 deaths per 100,000 in 2011. An evaluation of Project Lazarus that disentangles the impacts of its various components has not been published. Therefore, it is difficult to determine the exact role naloxone played in the reduction of Wilkes County's unintentional drug overdose deaths.

The most robust evaluation examining changes in health outcomes as a result of OEND program implementation is by Walley et al. (2013b). The authors employed an interrupted time-series analysis to evaluate the impact of Massachusetts' OEND program on opioid-related overdose deaths and non-fatal opioid overdose related acute care hospital utilization rates from 2002 to 2009. Communities that implemented OEND programs during the study time period trained 2912 individuals, and 327 overdose reversals were reported. In adjusted models, these communities had statistically significantly reduced opioid-related overdose death rates

**Table 6**  
Naloxone distribution programs.

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b> *Very low	Descriptive/before–after	2	<b>Healthcare provider willingness to co-prescribe naloxone in the primary care setting to at-risk patients</b> (Albert et al., 2011; Brason et al., 2013) <sup>NT</sup> <b>Decrease in the number of overdose decedents who received prescriptions for the substance(s) implicated in their overdose from physicians in the intervention county</b> (Albert et al., 2011; Brason et al., 2013) <sup>NT</sup>
	Time series	0	
	RCT	0	
<b>Patient behavior</b> *Low	Descriptive/before–after	19	<b>Number of individuals trained on overdose prevention, recognition, and response</b> (Bennett et al., 2011; Doe-Simkins et al., 2014; Doe-Simkins et al., 2009; Enteen et al., 2010; Galea et al., 2006; Heller and Stancliff, 2007; Piper et al., 2007; Piper et al., 2008; Seal et al., 2005; Wagner et al., 2010; Walley et al., 2013a; Wheeler et al., 2012; Yokell et al., 2011) <sup>NT</sup> <b>Number of naloxone vials, kits, prescriptions distributed to trained individuals</b> (Bennett et al., 2011; Doe-Simkins et al., 2014; Doe-Simkins et al., 2009; Enteen et al., 2010; Heller and Stancliff, 2007; Maxwell et al., 2006; Piper et al., 2007; Piper et al., 2008; Seal et al., 2005; Wagner et al., 2010; Walley et al., 2013a; Wheeler et al., 2012) <sup>NT</sup> <b>Number of individuals returning for naloxone refills</b> (Bennett et al., 2011; Doe-Simkins et al., 2009; Enteen et al., 2010; Galea et al., 2006; Piper et al., 2008; Walley et al., 2013a; Wheeler et al., 2012; Yokell et al., 2011) <sup>NT</sup> <b>Knowledge of overdose recognition and response knowledge and behaviors</b> (Galea et al., 2006) <sup>NT</sup> , (Piper et al., 2008) <sup>NT</sup> , (Wagner et al., 2010) <sup>SS</sup> , (Tobin et al., 2009) <sup>NT</sup> , (Seal et al., 2005) <sup>SS</sup> , (Green et al., 2008) <sup>SS</sup> , (Sherman et al., 2009) <sup>NT</sup> , (Lankenau et al., 2013) <sup>NT</sup> , (Jones et al., 2014) <sup>SS</sup> , (Doe-Simkins et al., 2014) <sup>SS</sup>
	Time series	1	<b>Number of individuals trained on overdose prevention, recognition, and response</b> (Walley et al., 2013b) <sup>NT</sup>
	RCT	0	
<b>Health outcomes</b> *Low	Descriptive/before–after	17	<b>Number of overdose reversals with naloxone reported</b> (Bennett et al., 2011; Doe-Simkins et al., 2014; Doe-Simkins et al., 2009; Enteen et al., 2010; Galea et al., 2006; Heller and Stancliff, 2007; Lankenau et al., 2013; Maxwell et al., 2006; Piper et al., 2008; Seal et al., 2005; Tobin et al., 2009; Wagner et al., 2010; Walley et al., 2013a; Wheeler et al., 2012; Yokell et al., 2011) <sup>NT</sup> <b>Temporal association with decreased overdose mortality</b> (Albert et al., 2011; Maxwell et al., 2006) <sup>NT</sup> (Brason et al., 2013) <sup>+NT</sup>
	Time series	1	<b>Number of overdose reversals with naloxone reported</b> (Walley et al., 2013b) <sup>NT</sup> <b>Decrease in overdose death rates in OEND program communities</b> (Walley et al., 2013b) <sup>SS</sup> <b>No change in acute opioid-related hospitalization rates</b> (Walley et al., 2013b) <sup>NS</sup>
	RCT	0	

Note: SS = Tested and statistically significant.

NS = Tested and not statistically significant.

NT = No statistical testing conducted.

+ = Naloxone distribution is one component of the Project Lazarus program. An evaluation to determine the effects of the naloxone component alone has not been conducted.

\* = Evidence level.

compared to communities that did not implement OEND programs. Acute care hospital utilization did not differ between OEND program communities and those that did not implement one.

Naloxone is a promising strategy with some evidence of effectiveness in reducing opioid overdose mortality rates. However, the data almost exclusively pertain to reversals of overdoses from heroin and not among people using prescription opioids. Overall, the quality of evidence for the impact of naloxone on opioid overdose is low. Study limitations include lack of randomization; lack of generalizability because the data are almost exclusively based on people who inject drugs, primarily heroin; self-reported outcomes; short-term follow-up; significant loss to follow-up; and lack of control for other events occurring simultaneously that could be responsible for effects.

### 3.6. Safe storage and disposal

**Background:** Safe storage and disposal of prescription drugs has been promoted traditionally as a strategy for reducing unintentional poisonings among young children. States, communities, and organizations have recognized more recently that the strategy might reduce access to and misuse of controlled substances by adults without a prescription. States have sponsored public media campaigns that incorporate messaging about safe storage and disposal; communities have sponsored “drug take-back” events to

allow for promote safe, convenient, and responsible disposal; and organizations have developed web-based interventions to educate patients.

**Findings:** Although such programs are popular, evaluations are extremely limited and employ non-comparative descriptive epidemiological designs or before–after designs with small sample sizes, and information about health outcomes is lacking (see Table 7). For example, the “Use Only as Directed” campaign in Utah targeted adults with TV and radio spots, posters, patient information cards, bookmarks, and a website. This campaign promoted storage of medications in a safe place and disposal of unused or expired medications. In a before–after evaluation of the campaign, 18% of respondents reported disposal of medications because of the media message, and 5% reported disposal of prescription medication at a drop box or collection event (compared to less than 1% prior to the campaign). Respondents were also less likely to take a prescription medication that was not prescribed to them by a physician after the campaign; however it is unclear whether the campaign components related to safe storage and disposal were responsible for this effect (Johnson et al., 2011). In a non-comparative descriptive epidemiological study of a drug take-back event in Tennessee and Virginia, 9% of donated prescription medications were controlled substances. Of these, 32% were hydrocodone combinations, 11% were oxycodone and oxycodone combinations, and 5% were methadone formulations (Gray and Hagemeyer, 2012).

**Table 7**  
Safe disposal and drug take-back.

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b>	Descriptive/before–after	0	<b>Statistically significant increase in knowledge regarding safe use of prescription opioids (McCauley et al., 2013)<sup>SS</sup></b> <b>Decrease in likelihood to lend or borrow pills from others, consume more than prescribed, or save unused medication (Johnson et al., 2011; McCauley et al., 2013)<sup>SS+</sup></b> <b>No change in saving or using medication for other reasons than prescribed (McCauley et al., 2013)<sup>NS</sup></b> <b>Disposal of medications, particularly in drop box/collection (Gray and Hagemeyer, 2012; Johnson et al., 2011; Ma et al., 2004)<sup>NT+</sup></b>
*None	Time series	0	
	RCT	0	
<b>Patient behavior</b>	Descriptive/before–after	4	
*Very low			
	Time series	0	
	RCT	0	
<b>Health outcomes</b>	Descriptive/before–after	0	
*None	Time series	0	
	RCT	0	

Note: SS = Tested and statistically significant.

NS = Tested and not statistically significant.

NT = No statistical testing conducted.

+ = Safe disposal one component of Utah's Prescription Safety Program. An evaluation to determine the effects of the safe disposal component alone has not been conducted.

\* = Evidence level.

A similar descriptive study in Hawaii found that 10% of drugs returned during take-back events at a health care expo and at Kaiser Permanente (KP) clinics were controlled substances; overall 6% were narcotic analgesics with the most common substances including hydrocodone/acetaminophen, oxycodone, oxycodone/acetaminophen, and codeine/acetaminophen (Ma et al., 2004). Finally, a before–after study of an outpatient, clinic-based web Script Safety Intervention that shared information with patients about proper handling and disposal of opioid medications illustrated significant increases in knowledge and behavior change. At one-month follow-up, patients showed increased knowledge regarding safe storage and disposal, reported that they were less likely to lend or borrow pills from others, consume more opioids than prescribed, or save unused medications; However, there was no change in saving or using medications for reasons other than those for which they were prescribed (McCauley et al., 2013).

Overall, the quality of evidence for the impact of safe storage and disposal efforts on prescription drug overdose is extremely low. Only a handful of studies have been reported, and study limitations include lack of baseline data and comparison groups, small sample sizes, self-reported outcomes, short-term follow-up, unassessed health outcomes, and other events occurring simultaneously that could be responsible for effects.

### 3.7. Patient education and provider education

**Background:** Education approaches attempt to change knowledge and attitudes in an effort to motivate behavior change. Patient education has included both primary prevention approaches (educating youth and young adults about the dangers of substance use prior to misuse or abuse) and secondary/tertiary prevention approaches (educating at-risk populations with substance use disorder or engaging in methadone treatment). Strategies range from limited awareness-raising efforts (e.g., leaflets, posters) to intensive family and school-based programs. Provider education has focused on opioid prescribing because the medical school curriculum is often limited and produces providers lacking comprehensive training in pain management (Heavner, 2009). Education approaches encompass a wide spectrum of content delivery modalities, including use of educational tools, workshops, lectures, interactive case

discussions, and consultant support. An incentive such as continuing medical education is usually offered for participation and is awarded after completing coursework, attending presentations, and trainings.

**Findings:** Published evaluations of education prevention efforts aimed at patients and providers are small in number (see Table 8). A targeted evaluation of opioid intravenous drug users and their knowledge gained from viewing posters and leaflets throughout an addiction treatment center illustrated improvements in knowledge for recognizing overdoses and how to deal with them (Branagan and Grogan, 2006). In a small randomized trial, mothers and daughters completed an online family-based interactive intervention and were assessed for past 30 day drug use, family communication, and skill building to avoid drug use at follow-up. Significant decreases in prescription drug nonmedical use were reported 2 years after the intervention, though the low potential for misuse and overdose in this population should be noted (Fang and Schinke, 2013). Both studies are limited by small sample sizes and difficulty in generalizing results beyond the target population. Spoth et al. (2013) reported on evaluation findings from three large randomized studies of universal, family and school-based drug prevention interventions to decrease risk factors for prescription drug misuse in adolescents. When adolescents participating in the prevention programs were followed into young adult hood, significant reductions were seen in prescription opioid misuse overall and among higher risk subsets, compared to adolescents not in the programs. Although these results are extremely promising, the sample sizes were small, there was an overall low rate of prescription opioid misuse, and it is yet unclear how such findings might generalize to populations broader than those studied.

For provider education, evaluations of Continuing Medical Education (CME) credit programs suggest a gain in knowledge but limited adoption of select safe opioid practices like assessing patient risk factors, treatment contracts, and referral to treatment when indicated (Crozier et al., 2010; Lofwall et al., 2011). Randomized case-based training among a small sample of Veterans Affairs providers facilitated the adoption of safe opioid prescribing practices, specifically among primary care clinicians, but did not improve patient response to pain treatment (Corson et al., 2011). A small pilot project in a Michigan community hospital targeted internal medicine residents with a pain management course over

**Table 8**  
Patient/public & provider education.

Type outcomes	Study design	Number of studies	Findings
<b>Provider behavior</b> <i>*Low</i>	Descriptive/before–after	7	<b>Improved provider confidence or knowledge</b> (Elhwairis and Reznich, 2010) <sup>NT</sup> <b>Limited adoption of select safe opioid prescribing practices</b> (Crozier et al., 2010) <sup>SS</sup> , (Srivastava et al., 2012; Ury et al., 2002; Young et al., 2012) <sup>NT</sup> <b>Decrease in/lower risky opioid prescribing practices</b> (Gugelmann et al., 2013; Hoffman et al., 2003) <sup>SS</sup>
	Time series	2	<b>Little to no change in opioid prescribing practices</b> (Kahan et al., 2013) <sup>NS</sup> <b>Improved provider knowledge</b> (Lofwall et al., 2011) <sup>SS</sup> <b>Change in safe opioid prescribing behavior</b> (Lofwall et al., 2011) <sup>SS</sup>
	RCT	1	<b>Limited adoption of select safe opioid prescribing practices</b> (Corson et al., 2011) <sup>NS</sup>
<b>Patient behavior</b> <i>*Moderate</i>	Descriptive/before–after	2	<b>Increased awareness of factors contributing to an opioid overdose</b> (Johnson et al., 2011) <sup>SS</sup> , (Branagan and Grogan, 2006) <sup>NT</sup> <b>Increased knowledge to manage an overdose</b> (Branagan and Grogan, 2006) <sup>NT</sup> <b>Decrease in providing medication to family/friends</b> (Johnson et al., 2011) <sup>NS</sup> <b>Decrease in taking medication not prescribed</b> (Johnson et al., 2011) <sup>SS</sup>
	Time series	0	
	RCT	2	<b>Lowered substance use intentions</b> (Fang and Schinke, 2013) <sup>SS</sup> <b>Decrease in/lower prescription drug nonmedical use</b> (Fang and Schinke, 2013; Spoth et al., 2013) <sup>SS</sup>
<b>Health outcomes</b> <i>*High</i>	Descriptive/before–after	0	
	Time series	0	
	RCT	1	<b>No improvement in pain</b> (Corson et al., 2011) <sup>SS</sup>

Note: SS = Tested and statistically significant.

NS = Tested and not statistically significant.

NT = No statistical testing conducted.

+ = Patient education is one component of Utah's Prescription Safety Program. An evaluation to determine the effects of the patient education component alone has not been conducted.

\* = Evidence level

several weeks complete with examinations (Elhwairis and Reznich, 2010). Case discussions and role-playing activities proved useful in raising confidence in managing chronic pain patients and pain management knowledge. Additionally, cased based teachings to medical residents and ED providers were successful in altering the quantity of opioids prescribed (Ury et al., 2002). HMO drug claim reviews lead to quarterly mailings of flagged patient prescription profiles and suggestions for treatment (Hoffman et al., 2003). Reductions in the number of high-abuse prescription drug claims were seen 6 months following intervention mailings. Changes in physician practices were also suggested following mailings of an opioid guide book (Young et al., 2012). A Canadian opioid prescribing course offering multiple educational approaches did not succeed in changing behavior and had no effect on opioid prescribing up to two years following the intervention (Kahan et al., 2013).

Overall, the quality of evidence for the effect of patient and provider education is moderate to low. Few studies evaluated patient education programs, the studies employed small sample sizes or special populations, and health outcomes (e.g., overdose) were not measured. Evaluations of provider education incorporate small samples and evaluate few provider specialties. Mixed findings have been found, with some changes in adoption of safer prescribing, but less impact on patient outcomes.

#### 4. Discussion

States have a variety of tools they can use with the potential for curbing the prescription drug overdose epidemic, particularly overdose due to opioid analgesics. Over the past several years, as the overdose epidemic has received increased attention, states have made astounding gains in prevention innovation. State and systems-level strategies have much promise for changing opioid prescribing, influencing patient misuse, and reducing nonfatal and fatal overdose from opioid analgesics. Optimistically, evaluations signal that prevention strategies can change provider and patient knowledge, attitudes, and behaviors.

For example, PDMP evaluations have detected some positive changes in prescribing patterns, decreased use of multiple providers and pharmacies, and decreased substance abuse treatment admissions and poison center report rates (although findings are mixed). Insurer strategies including PRR, DUR, PA, and QL have been associated with reduced prescribing, daily dose, and number of pharmacies and physicians utilized. Pain clinic regulation may reduce prescribing and diversion, as well as death rates. When clinical guidelines are implemented, physicians illustrate improved knowledge of prescribing recommendations. Naloxone distribution programs result in overdose reversals. Drug take-back events and campaigns can lead to the donation of controlled substances, and campaigns and clinic-based interventions can result in increased patient knowledge about safe storage and disposal, as well as likelihood of taking medications that are not prescribed and lending/borrowing pills from others. Education of patients can increase knowledge and awareness, and prevention programs that include communication and skill building may reduce non-medical use. Finally, continuing medical education can result in increased provider knowledge.

It is important to recognize, unfortunately, that there is much we do not yet know about the impact of these strategies. Findings are mixed, changes in health outcomes are detected less consistently, and there are open questions about how the strategies can be best implemented. For example, findings for the effects of PDMPs on prescribing and overdose mortality differ across studies, and there is no evidence for reductions in mortality for insurance strategies, drug take-back events and campaigns, or patient or provider education. Only a single study has looked at changes in mortality over time after implementation of naloxone distribution programs, and most of the reversals were among patients using heroin, limiting our understanding of applicability to prescription opioid abuse. Multiple efforts operating within states that occur in concert with legislation changes have limited the ability to draw causal conclusions about individual state policy effectiveness. In addition, although clinical guidelines can set a standard for practice, recommendation compliance could be improved, and it is not yet known

the degree to which high quality implementation could lead to decreases in overdose.

Thus, overall the quality of evidence for the effectiveness of the reviewed strategies is low. Our confidence in the effects is limited, the true effects may be different, and further research is likely to have an important impact in our confidence in the estimate of the effects. Few rigorous evaluations have been published in the empirical literature. Although there are a handful of time-series analyses, published evaluations include primarily descriptive epidemiology, pretest–posttest observational studies, and do not appropriately account for confounding variables and events occurring simultaneously with the interventions that could influence the outcomes of interest. Randomized controlled studies have provided indirect evidence about overdose (e.g., compare one intervention to another, rather than a true control, and measure proximal outcomes). Study limitations include lack of baseline data and comparison groups, inadequate statistical testing, small sample sizes, self-reported outcomes, and short-term follow-up. Common outcomes studied include knowledge, attitudes and prescribing practices of providers, and problematic use by patients; rarely, studies have evaluated health outcomes related to misuse and abuse, and fatal or nonfatal overdoses (see Fig. 1). A further challenge is the great heterogeneity in the structure, content, and focus of the policies and practices, even within the categories reviewed; hence, it is difficult to understand how state policy and systems level interventions are most effectively and efficiently structured.

The limitations of evaluations are not surprising – state policy and systems level interventions are difficult to evaluate. Randomization is rarely feasible, appropriate comparison groups are hard to identify, pre-intervention data can be challenging to obtain, and changes in the environment that are concurrent with intervention implementation are hard to measure. There are limitations in the availability and timeliness of data to allow for rigorous, real-time evaluation; it is possible that enhanced adoption of electronic health records could lead to more feasible evaluation protocols. Although states and systems have been leaders in innovation, professionals struggle to publish evaluation findings in the scientific literature due to capacity limitations (e.g., limited evaluation skills, competing priorities, funding, and time; and data quality, time lag, and availability).

Acknowledging the challenges, improvements in research and evaluation could strengthen the evidence base and provide states and organizations information they need to improve public health. Improvements in research would include the use of rigorous designs, including natural experiments, quasi-experimental designs with comparison groups, and time-series analyses. For example, an educational intervention for clinicians, such as one based on clinical guidelines, could be studied within a large randomized trial: one group of providers within a health system could be randomized to continuing education, academic detailing, and quality improvement activities, and compared with another group of providers that continue with traditional practice; patient outcomes could be measured through the electronic health record in the time periods before, during, and after intervention implementation. It is important to measure not only proximal outcomes (e.g., implementation, prescribing changes) but also distal health outcomes including nonfatal and fatal overdose, as well as unintended consequences (e.g., reduced access to pain treatment). Economic evaluation can estimate the costs and benefits of interventions. Very little information is available to inform states about the cost of implementing the reviewed interventions, as well as on return on investment. The limited information available on implementation costs (e.g., PDMP implementation; Maryland Advisory Council on Prescription Drug Monitoring, 2009) illustrates wide variation based on program requirements and structure. As we learn more about the costs, impacts, and return on investment of different

approaches, it will become more important to understand variations in findings, and the drivers behind these variations.

In the meantime, action must be taken to reverse the continued increases in morbidity and mortality, placing priority on promising strategies that show the potential for reducing inappropriate prescribing and patient visits to multiple providers, and improving overdose outcomes including prescription drug monitoring programs, insurer strategies, state legislation providing oversight of pain clinics, clinical guidelines, and naloxone distribution programs. States and systems are encouraged to act on strong evidence, consider promising strategies, and evaluate innovations to build knowledge where it is needed and make better decisions.

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No conflict declared.

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

**AGENDA REQUEST FORM**

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3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Annual Report – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 requirements of s. 961.36.			

**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.

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

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4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Kratom (Mitragynine) Scheduling - Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 letter requesting the Board begin the process to unschedule Kratom and its compounds.			



US Naturals, Inc.

October 27, 2015

Controlled Substances Board  
State of Wisconsin  
Department of Safety and Professional Services  
P.O. Box 8935  
Madison, WI 53708-8935

Dear Mr. Chairman and Members of the Board

Thank you for allowing US Naturals to attend to your October meeting. Although we are grateful for the opportunity to be there, we were disappointed in the Board's assertion that "*there is no science,*" for the Board to review regarding kratom and its safety, as that simply is not the case.

On August 14, 2015, Dr. Jack E. Henningfield provided a thorough independent scientific analysis to the board in both oral and written testimony. His presentation was based upon research conducted by his colleagues at Pinney Associates, Doctors Reginald Fant and Edward Cone, as well as himself.

As you may know, Pinney Associates and Doctors Henningfield, Fant and Cone are nationally recognized experts in their field. Collectively, the doctors have over one hundred years of scientific experience and boast formidable reputations. All three scientists are former members of the National Institute on Drug Abuse which specializes in the areas of chemistry, pharmacology, neuropharmacology, toxicology and potential addiction of substances—naturally occurring or lab created.

Pinney and Associates' analysis and Dr. Henningfield's testimony was based on a considerable body of published scientific literature, in addition to their own evaluation of the U.S. National drug surveillance system data, web substance abuse monitoring and specific product evaluation data assessing the alkaloid contents of various kratom products.

In contrast to the Board's conclusion on October 6, 2015 that it could not act to reverse an apparently inadvertent scheduling decision of kratom because "*there is no science,*" we believe that there is, in fact, an extensive body of scientific, clinical, and epidemiological data that have emerged over the past several decades from researchers and clinicians in South East Asia, Japan, Australia, and increasingly in the United States. For your reference, copies of Dr. Jack E. Henningfield's testimony originally submitted for the August 14, 2015 meeting of the Wisconsin Controlled Substance Board.

Further, we believe it is important to note that Wis. Stat. § 961.14 did not schedule "kratom," in its entirety, but rather scheduled two specific alkaloids, mitragynine and 7-hydroxy-mitragynine (7-OH). These are two of the dozens of alkaloids contained in kratom leaves. Although the scheduling was apparently inadvertent, it did identify specific alkaloids that have undergone extensive scientific study to isolate, characterize and determine which of the many naturally occurring substances in kratom plants account for the healthful effects that people seek.

Indeed, Mitragynine, and, to a lesser degree, 7-OH, have been examined in chemistry studies, preclinical studies and clinical studies, some of which were reviewed by Dr. Henningfield for the Board. The sum of this science reveals the pharmacokinetics of mitragynine which have been characterized in both preclinical and human studies. This research shows, for example, that the human bioavailability of orally ingested mitragynine is approximately 3 percent and that following oral consumption the time to maximal plasma levels is about 1 hour and the half-life is approximately 1 day. This science is a key factor in the labeling of VivaZen.

Current science also shows that kratom plants vary widely in their alkaloid composition, content, and concentration. This scientific knowledge has been particularly important to US Naturals in its ability to produce a consumer product that is devoid of 7-OH and that achieves a consistent target level of 22-23 mg per labeled serving. The science supports our claims that this serving is safe, has minimal adverse effects of any type (other than unpleasant taste), and provides benefits that consumers appreciate and willfully pay for. Further, our marketing data indicates that most consumers are using VivaZen within the levels recommended in our labeling (i.e., a few servings per week).

In summary, there is clear scientific evidence regarding kratom as evidenced in Dr. Henningfield's report and even more so in the key references he provided in that report given to the Board on August 14, 2015. We welcome providing clarification and further detail on the science already presented. Further, we would be pleased to provide additional science upon request. In that vein, we brought Dr. Henningfield to the October Board meeting to be available to answer specific questions regarding the science of kratom, though none were posed by the Board.

The conclusion that there is no science, and the assertion that no science was presented to the Board, stands in the face of the facts and the considerable evidence

that is available. We respectfully ask the Board to review the science on kratom and VivaZen that we have supplied the panel both in August and again with this correspondence and reconsider the scheduling of products that contain this beneficial botanical.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Eging". The signature is fluid and cursive, with the first name "Michael" being the most prominent part.

Michael J. Eging  
Vice President Government & Public Affairs

Enclosures:

August 14, 2015 Testimony of Dr. Jack E. Henningfield to the Wisconsin Controlled Substances Board

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

**AGENDA REQUEST FORM**

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4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>WI ePDMP Update – Discussion and Consideration</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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 progress on the development of the WI ePDMP.			

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

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4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>CMS Opioid Mapping Tool – Informational Only</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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:  FYI.			

**From:** [Trapskin Philip J](#)  
**To:** [Zadrazil, Chad J - DSPS](#)  
**Subject:** FW: CMS NEWS: New Medicare Part D Opioid Drug Mapping Tool Available  
**Date:** 03 Nov 2015 9:34:12 AM

May be of interest to CSB.

**From:** Centers for Medicare & Medicaid Services [mailto:[cmslists@subscriptions.cms.hhs.gov](mailto:cmslists@subscriptions.cms.hhs.gov)]  
**Sent:** Tuesday, November 03, 2015 9:19 AM  
**To:** Trapskin Philip J  
**Subject:** CMS NEWS: New Medicare Part D Opioid Drug Mapping Tool Available

Centers for Medicare & Medicaid Services



## CMS NEWS

FOR IMMEDIATE RELEASE  
November 3, 2015

Contact: CMS Media Relations  
(202) 690-6145 | [CMS Media Inquiries](#)

### **New Medicare Part D Opioid Drug Mapping Tool Available**

*Interactive online mapping tool allows public to search Medicare Part D opioid prescription claims data at the state, county, and ZIP code levels*

Today, the Centers for Medicare & Medicaid Services (CMS) released an interactive [online mapping tool](#) (<http://go.cms.gov/opioidheatmap>) which shows geographic comparisons at the state, county, and ZIP code levels of de-identified Medicare Part D opioid prescription claims – prescriptions written and then submitted to be filled – within the United States. This new mapping tool allows the user to see both the number and percentage of opioid claims at the local level and better understand how this critical issue impacts communities nationwide.

“The opioid epidemic impacts every state, county and municipality. To address this epidemic, while ensuring that individuals with pain receive effective treatment, we need accurate, timely information about where the problems are and to what extent they exist,” said CMS Acting Administrator Andy Slavitt. “This new mapping tool gives providers, local health officials, and others the data to become knowledgeable about their community’s Medicare opioid prescription rate.”

Deaths from drug overdose have risen steadily over the past two decades. In 2013, overdose from prescription opioid pain relievers claimed more than 16,000 lives, with more than 145,000 people dying from these overdoses in the last decade. Heroin deaths have also been climbing sharply, more than doubling between 2010 and 2013. The resulting health, social, and economic consequences for communities across the country are enormous.

“The opioid abuse and overdose epidemic continues to devastate American families,” said CDC Director Tom Frieden, M.D., M.P.H. “This mapping tool will help doctors, nurses, and other health care providers assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment. Informing prescribers can help reduce opioid use disorder among patients.”

The [data](#) used in this mapping tool is from 2013 Medicare Part D prescription drug claims prescribed by

health care providers and does not contain beneficiary information (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html>). The data set, which is privacy-protected, contains information from over one million distinct providers who collectively prescribed approximately \$103 billion in prescription drugs and supplies paid under the Part D program. The data characterizes the individual prescribing patterns of health providers that participate in Medicare Part D for over 3,000 distinct drug products. Of the 1.4 billion total Part D claims per year, there were approximately 80.7 million opioid claims for 116 distinct opioid products contributing to \$3.7 billion of the total Part D prescription drug costs. By openly sharing data in a secure, broad, and interactive way, CMS is supporting a better understanding of regional provider prescribing behavior variability and is adding insight to local health care delivery.

The tool includes interactive maps that allow users to mouse over an area and see its data. The data for each geographic region includes:

- Percentage of opioid claims
- State average
- National average
- Total providers
- Total opioid claims
- Total claims

CMS and the U.S. Department of Health and Human Services (HHS) believe that this level of transparency will inform community awareness among providers and local public health officials.

The Administration has made addressing opioid abuse, dependence, and overdose a priority, and work is underway within HHS on this important issue. [The evidence-based initiative](#) focuses on three promising areas: informing opioid prescribing practices, increasing the use of naloxone (a drug that reverses symptoms of a drug overdose), and using medication-assisted treatment to treat opioid addiction (<http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html>).

As part of this initiative, HHS is working through the Centers for Disease Control and Prevention (CDC) to develop opioid prescribing guidelines and supporting training and tools for providers to make informed prescribing decisions. The Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA), National Institutes of Health-National Institute on Drug Abuse (NIH-NIDA), and Office of the Assistant Secretary for Health (OASH) are active partners in implementing the Administration's opioid initiative.

For more information on CMS' efforts to address the growing problem of abuse of opioids in the Part D program, read the [Part D Overutilization Monitoring System Summary](#) (<http://cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-11-03.html>).

###

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3) Name of Board, Committee, Council, Sections:  <b>WISCONSIN CONTROLLED SUBSTANCES BOARD</b>			
4) Meeting Date:  <b>12/1/15</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Narcan Nasal Spray Approval Article – Informational Only</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? 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:  FYI.			

# FDA Approves *Narcan* Nasal Spray to Treat Opioid Overdose

Troy Brown, RN | November 18, 2015

An intranasal form of naloxone hydrochloride (*Narcan*, Adapt Pharma, Inc), a drug that stops or reverses opioid overdose, has been approved by the US Food and Drug Administration (FDA) under a fast-track approval process.

Naloxone hydrochloride has long been given by intramuscular injection to stop or reverse the effects of opioid overdose, in particular respiratory depression. It usually works within 2 minutes but must be given quickly to prevent death.

The nasal form will be easier for first responders and others to deliver, and will eliminate the threat of contaminated needle sticks. Until now, unapproved naloxone kits have combined the injectable form of naloxone with an atomizer to administer the drug nasally.

No assembly is required for the approved nasal product, and anyone can administer it, even those without medical training. The product can be given to adults and children. It is sprayed into one nostril while the patient lies on his or her back, and can be repeated if needed. The FDA cautions that the person administering the drug should still seek immediate medical attention for the patient.

Drug overdose deaths have risen steadily for the past decade and now surpass motor vehicle crashes as the leading cause of injury death in the United States. The increase is due in large part to prescription drug overdoses, as well as a rise in heroin use.

"Combating the opioid abuse epidemic is a top priority for the FDA," Stephen Ostroff, MD, acting FDA commissioner, said in an FDA [news release](#). "We cannot stand by while Americans are dying. While naloxone will not solve the underlying problems of the opioid epidemic, we are speeding to review new formulations that will ultimately save lives that might otherwise be lost to drug addiction and overdose."

The approval follows an expedited review of data from clinical trials in which nasal administration achieved the same or higher levels of naloxone as those obtained with intramuscular injection, and in about the same amount of time.

The FDA's priority review program facilitates approval of drugs that are expected to significantly improve the safety or effectiveness of the prevention, treatment, or diagnosis of a serious medical condition. The FDA approved the nasal spray in less than 4 months.

"We heard the public call for this new route of administration, and we are happy to have been able to move so quickly on a product we are confident will deliver consistently adequate levels of the medication — a critical attribute for this emergency life-saving drug," Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research, said in the FDA news release.

The National Institute on Drug Abuse (NIDA) designed and conducted clinical trials to determine that the intranasal formulation worked as quickly and effectively as the injectable form. NIDA then worked with its partners in the private sector to obtain approval from the FDA.

"This easy-to-use intranasal formulation will no doubt save many lives," Nora Volkow, MD, director, National Institute on Drug Abuse at the National Institutes of Health, explained in the news release. "While prevention is the ultimate goal, the drug's successful development illustrates how public/private scientific partnerships can play an important role in responding to a national crisis right now."

Health and Human Services Secretary Sylvia M. Burwell proposed a targeted strategy for addressing the opioid epidemic that includes increasing access to and use of naloxone in March. In July the FDA sponsored a [public](#)

[workshop](#) at which addiction and advocacy groups demanded expanded availability of the lifesaving drug.

Naloxone nasal spray can cause severe opioid withdrawal in patients who are opioid dependent.

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