



CONTROLLED SUBSTANCES BOARD

Contact: Chad Zadrazil (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison
November 15, 2016

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a 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. **9:30 A.M.: Public Hearing on Emergency Rule 1626 and Clearinghouse Rule 16-059 Relating to Scheduling Furanyl Fentanyl (4-11)**
 - 1) Review and Respond to Clearinghouse Report and Public Hearing Comments
- C. **9:30 A.M.: Public Hearing on Clearinghouse Rule 16-060 Relating to Scheduling [¹²³I]ioflupane (12-19)**
 - 1) Review and Respond to Clearinghouse Report and Public Hearing Comments
- D. **Legislation and Rule Matters – Discussion and Consideration (20-61)**
 - 1) Draft Creating CSB 2.41 Relating to Butyryl Entanyl and Beta-Hydroxythiofentanyl
 - 2) Scope for Creating CSB 2.43 Relating to Scheduling Brivaracetam
 - 3) Scope for Creating CSB 2.44 Relating to Scheduling Thiafentanyl
 - 4) Scope for Creating CSB 2.45 Relating to Scheduling AB-FUBINACA and ADB-PINACA
 - 5) Scheduling Acetyl Fentanyl
 - 6) Scheduling of AH-7921
 - 7) Scheduling pf Eluxadoline
 - 8) Scheduling of U-47700
 - 9) Update on Pending or Possible Rule-Making Projects
- E. **APPEARANCE: Assistant Special Agent in Charge Robert Bell, Drug Enforcement Administration (DEA) Milwaukee Division – DEA Collaboration – Discussion and Consideration (62)**
- F. **APPEARANCE: Dave Hannon, Wisconsin Department of Justice - Wisconsin Crime Lab Update – Discussion and Consideration (63)**

- G. **Approval of Minutes of September 20, 2016 (64-67)**
- H. **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. Subhadeep Barman – Psychiatrist
 - f. Jeffrey Miller – Board of Nursing Designee
 - g. Jason Smith – Attorney General Designee
 - h. Wendy Pietz – Dentistry Examining Board Designee
 - i. Timothy Westlake – Medical Examining Board Designee
 - 3) Recusal Information **(68-69)**
- I. **Board Updates on Prescribing Guidelines – Discussion and Consideration (70)**
- J. **Wisconsin State Coalition for Prescription Drug Abuse Reduction Update – Discussion and Consideration (71)**
- K. **Task Force on Opioid Abuse Update – Discussion and Consideration (72-74)**
- L. **District Attorney Outreach – Discussion and Consideration (75)**
- M. **Prescription Drug Monitoring Program (PDMP) Operations – Discussion and Consideration (76-79)**
- N. **ePDMP Development – Discussion and Consideration (80)**
 - 1) Demonstration of System
 - 2) ePDMP-Electronic Health Record (EHR) integration pathways
 - 3) System Text Review
 - 4) Deployment Planning
- O. **Annual and Quarterly Reports – Discussion and Consideration (81-111)**
 - 1) Quarterly PDMP Report: Wis. Stat. 961.385 (5) and (6)
- P. **CBD Letter – Discussion and Consideration (112-115)**
- Q. **Informational Items – Discussion and Consideration (116-120)**
 - 1) DEA Press Release: “DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017”
 - 2) WI DOJ Items: “Saving Lives” and “Maker of Opiate Addiction Treatment Drug, Suboxone, Accused of Conspiring to Keep Monopoly Profits”

R. 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

S. Public Comments

ADJOURNMENT

The next scheduled meeting is January 13, 2017.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 4 November 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 15 November 2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Public Hearing on Emergency Rule EmR 1626 and Clearinghouse Rule CR-059 relating to scheduling furanyl fentanyl Review and respond to Clearinghouse Report and Public Hearing comments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Hold Public Hearing at 9:30 Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.			
11) Authorization			
<i>Sharon Henes</i>		<i>4 November 2016</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

ORDER

An order of the Controlled Substances Board to create CSB 2.42 relating to scheduling furanyl fentanyl.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

Statutory authority: ss. 961.11 (1) and (4m), Stats.

Explanation of agency authority:

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

The controlled substances board, by rule and without regard to the requirements of sub. (1m), may schedule a controlled substance analog as a substance in schedule I regardless of whether the substance is substantially similar to a controlled substance in schedule I or II, if the board finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under 21 USC 355. Upon receipt of notice under s. 961.25, the board shall initiate scheduling of the controlled substance analog on an emergency basis under this subsection. The scheduling of a controlled substance analog under this subsection expires one year after the adoption of the scheduling rule. With respect to the finding of an imminent hazard to the public safety, the board shall consider whether the substance has been scheduled on a temporary basis under federal law or factors under sub. (1m) (d), (e) and (f), and may also consider clandestine importation, manufacture or distribution, and, if available, information concerning the other factors under sub. (1m). The board may not promulgate a rule under this subsection until it initiates a rule-making proceeding under subs. (1), (1m), (1r) and (2) with respect to the controlled substance analog. A rule promulgated under this subsection lapses upon the conclusion of the rule-making proceeding initiated under subs. (1), (1m), (1r) and (2) with respect to the substance. (s. 961.11 (4m), Stats.)

Related statute or rule: s. 961.14, Stats.

Plain language analysis:

This rule schedules furanyl fentanyl as a Schedule I controlled substance.

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

On September 27, 2016, the U.S. Department of Justice, Division of Drug Enforcement published a notice of intent to schedule furanyl fentanyl as a Schedule I.

Comparison with rules in adjacent states:

Illinois: A review of the Illinois Controlled Substances Act does not indicate the scheduling of furanyl fentanyl.

Iowa: A review of the Iowa Controlled Substances Act does not indicate the scheduling of furanyl fentanyl.

Michigan: A review of the Michigan Controlled Substances Act does not indicate the scheduling of furanyl fentanyl.

Minnesota: A review of the Minnesota Controlled Substances Act does not indicate the scheduling of furanyl fentanyl.

Summary of factual data and analytical methodologies:

Based upon the Waupaca County District Attorney’s request for emergency scheduling and the finding of an imminent hazard to the public safety, the Controlled Substances Board decided to schedule furanyl fentanyl. In making the finding of imminent hazard to the public safety, the Board considered the following factors: the history and current pattern of abuse; the scope, duration and significance of abuse; and the risk to the public health.

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

The rule schedules a synthetic opiate as a Schedule I substance controlled substance which will not have any effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@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 DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing on November 15, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.42 is created to read:

CSB 2.42 Scheduling of furanyl fentanyl. Section 961.14 (2) (ne) is created to read:
961.14 (2) (ne) Furanyl fentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide).

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

(END OF TEXT OF RULE)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	
2. Administrative Rule Chapter, Title and Number CSB 2.42	
3. Subject Scheduling furanyl fentanyl as a Schedule I controlled substance	
4. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	5. Chapter 20, Stats. Appropriations Affected
6. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget <input type="checkbox"/> Decrease Cost	
7. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
8. Would Implementation and Compliance Costs Be Greater Than \$20 million? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
9. Policy Problem Addressed by the Rule Waupaca County District Attorney requested emergency scheduling of furanyl fentanyl as required under s. 961.25, Stats. The Controlled Substances Board made a determination of an imminent hazard to the public.	
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.	
11. Identify the local governmental units that participated in the development of this EIA. None	
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 a fiscal or economic impact.	
13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule Currently fentanyl analogs have increased in popularity and prevalence creating an imminent public health hazard. The benefit to scheduling furanyl fentanyl is protection of the public.	
14. Long Range Implications of Implementing the Rule Furanyl fentanyl would be treated as a Schedule I controlled substance.	
15. Compare With Approaches Being Used by Federal Government On September 27, 2016, the Dept. of Justice published a notice of intent to schedule furanyl fentanyl as a Schedule I.	
16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Our surrounding states have not scheduled furanyl fentanyl.	
17. Contact Name Sharon Henes	18. Contact Phone Number (608) 261-2377

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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)

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

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

5. Describe the Rule's Enforcement Provisions

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

- Yes No
-



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

CLEARINGHOUSE RULE 16-059

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.]

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

a. For clarity, the board should add the phrase “controlled substance” to the end of the text in the rule summary’s section titled “Summary of, and comparison with, existing or proposed federal regulation”.

b. The board should remove the first use of the word “substance” in the rule summary’s section titled “Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis”.

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

AGENDA REQUEST FORM

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3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 15 November 2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Public Hearing on Clearinghouse Rule CR-059 relating to scheduling [123]ioflupane. Review and respond to Clearinghouse Report and Public Hearing comments	
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11) Authorization			
<i>Sharon Henes</i>		<i>4 November 2016</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
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STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

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

Explanation of agency authority:

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

Related statute or rule: s. 961.16, Stats.

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

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

Plain language analysis:

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

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

Comparison with rules in adjacent states:

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

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

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

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

Summary of factual data and analytical methodologies:

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

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

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

TEXT OF RULE

SECTION 1. CSB 2.40 is created to read:

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

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

(END OF TEXT OF RULE)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	
2. Administrative Rule Chapter, Title and Number CSB 2.40	
3. Subject Exclusion of [¹²³ I]ioflupane	
4. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	5. Chapter 20, Stats. Appropriations Affected 20.165(1)(g)
6. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget <input type="checkbox"/> Decrease Cost	
7. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
8. Would Implementation and Compliance Costs Be Greater Than \$20 million? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
9. Policy Problem Addressed by the Rule On September 11, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [¹²³ I]ioflupane from schedule II of the federal Controlled Substances Act. The Wisconsin Controlled Substances Board took affirmative action on October 13, 2015 to similarly exclude [¹²³ I]ioflupane under chapter 961, Stats. effective October 19, 2015 to allow for publication in the Administrative Register.	
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.	
11. Identify the local governmental units that participated in the development of this EIA. None	
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) There is no economic or fiscal impact.	
13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is for the federal and state controlled substance acts to be in conformity.	
14. Long Range Implications of Implementing the Rule [¹²³ I]ioflupane will not be treated as a controlled substance.	
15. Compare With Approaches Being Used by Federal Government The federal government removed [¹²³ I]ioflupane from scheduling on September 11, 2015.	
16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Iowa excludes [¹²³ I]ioflupane from scheduling. Illinois, Michigan and Minnesota does not exclude [¹²³ I]ioflupane.	
17. Contact Name Sharon Henes	18. Contact Phone Number (608) 261-2377

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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)

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

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

5. Describe the Rule's Enforcement Provisions

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

- Yes No
-



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 16-060

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

a. In SECTION 1, the reference to s. 961.16 (2) (b), Stats., should include the designation “(intro.)” after “(b)”, in order to more precisely identify the statutory subunit affected by the provision. [s. 1.03 (3), Manual.]

b. In SECTION 1, the new material (“ [123]ioflupane is excluded from this paragraph”), which is to be inserted in s. 961.16 (2) (b) (intro.), Stats., should be underscored. [s. 1.06 (1) (a) and (4), Manual.]

c. In SECTION 1, the period at the end of the text should be changed to a semicolon, to reflect how it appears within s. 961.16 (2) (b), Stats. The language should read “...are included in this paragraph:”.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 3 November 2016 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 15 Nov. 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. Draft Creating CSB 2.41 Relating to Butyrl entanyl and Beta-Hydroxythiofentanyl 2. Scope for Creating CSB 2.43 Relating to Scheduling Brivaracetam 3. Scope for Creating CSB 2.44 Relating to Scheduling Thiafentanil 4. Scope for Creating CSB 2.45 Relating to Scheduling AB-FUBINACA and ADB-PINACA 5. Scheduling Acetyl Fentanyl 6. Scheduling of AH-7921 7. Scheduling of Eluxadoline 8. Scheduling of U-47700 9. Update on Pending and Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>3 November 2016</i>	
<small>Signature of person making this request</small>		<small>Date</small>	
<hr/> <small>Supervisor (if required)</small>		<hr/> <small>Date</small>	
<hr/> <small>Executive Director signature (indicates approval to add post agenda deadline item to agenda)</small>		<hr/> <small>Date</small>	

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.41 relating to scheduling of beta-hydroxythiofentanyl and butyryl fentanyl.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

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

Explanation of agency authority:

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

Related statute or rule: s. 961.14, Stats.

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

On May 12, 2016, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing beta-hydroxythiofentanyl and butyryl fentanyl into Schedule I of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating beta-hydroxythiofentanyl and butyryl fentanyl as a schedule I under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on July 13, 2016 to similarly treat beta-hydroxythiofentanyl and butyryl fentanyl under chapter 961 effective July 18, 2016 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.14 (2) (eu) and (ey), Stats. which adds beta-hydroxythiofentanyl and butyryl fentanyl to schedule I.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled beta-hydroxythiofentanyl and butyryl fentanyl.

Iowa: Iowa has not scheduled beta-hydroxythiofentanyl and butyryl fentanyl

Michigan: Michigan has not scheduled beta-hydroxythiofentanyl and butyryl fentanyl

Minnesota: Minnesota has not scheduled beta-hydroxythiofentanyl and butyryl fentanyl

Summary of factual data and analytical methodologies:

The methodology was to schedule beta-hydroxythiofentanyl and butyryl fentanyl to conform with the federal Controlled Substances Act.

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

This rule schedules two drugs and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

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

TEXT OF RULE

SECTION 1. CSB 2.41 is created to read:

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

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

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

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

(END OF TEXT OF RULE)

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.43

Relating to: Scheduling of brivaracetam

Rule Type: Permanent

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

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

The objective of the rule is to schedule brivaracetam as a Schedule V controlled substance.

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

On May 12, 2016, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing brivaracetam into Schedule V of the federal Controlled Substances Act. The scheduling action was effective May 12, 2016. The Controlled Substances Board did not receive an objection to similarly treat brivaracetam as a Schedule V controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating brivaracetam as a controlled substance.

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

CSB 2.43 Addition of brivaracetam to schedule V. Section 961.22(6), Stats., is created to read: *961.22(6) BRIVARACETAM. Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide), including its salts, isomers or salts of isomers.*

The Affirmative Action order, dated September 22, 2016, took effect on September 26, 2016 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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

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

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

Rev. 3/6/2012

substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

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

25 hours

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

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

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

On May 12, 2016, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing brivaracetam into Schedule V of the federal Controlled Substances Act. The scheduling action was effective on May 12, 2016.

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

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

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

Authorized Signature

Date Submitted

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.44

Relating to: Scheduling of thiafentanil

Rule Type: Permanent

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

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

The objective of the rule is to schedule thiafentanil as a Schedule II controlled substance.

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

On August 26, 2016, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing thiafentanil into Schedule II of the federal Controlled Substances Act. The scheduling action was effective August 26, 2016. The Controlled Substances Board did not receive an objection to similarly treat thiafentanil as a Schedule II controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating thiafentanil as a controlled substance.

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

CSB 2.44 Addition of thiafentanil to schedule II. Section 961.16(3)(zx), Stats., is created to read: 961.16(3)(zx) Thiafentanil.

The Affirmative Action Order took effect on October 3, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

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

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

961.11(4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final
Rev. 3/6/2012

unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

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

25 hours

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

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

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

On August 26, 2016, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing thiafentanil into Schedule II of the federal Controlled Substances Act. The scheduling action was effective on August 26, 2016.

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

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

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

Authorized Signature

Date Submitted

STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.45

Relating to: Scheduling of AB-FUBINACA and ADB-PINACA

Rule Type: Permanent

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

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

The objective of the rule is to schedule AB-FUBINACA and ADB-PINACA as Schedule I substances.

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

On September 6, 2016, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing AB-FUBINACA and ADB-PINACA into Schedule I of the federal Controlled Substances Act. The scheduling action was effective September 6, 2016. The Controlled Substances Board did not receive an objection to similarly treat AB-FUBINACA and ADB-PINACA as Schedule I controlled substances under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating AB-FUBINACA and ADB-PINACA as controlled substances.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats AB-FUBINACA and ADB-PINACA under chapter 961, Stats. by creating the following:

CSB 2.45 Addition of AB-FUBINACA and ADB-PINACA to schedule I. Section 961.14 (4) (tb) 32. and 33., Stats., is created to read:

961.14 (4) (tb) 32. *N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, commonly known as AB-FUBINACA.*

33. *N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, commonly known as ADB-PINACA.*

The Affirmative Action order, dated October 6, 2016, took effect on October 10, 2016 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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

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

961.11(4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final Rev. 3/6/2012

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

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

25 hours

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

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

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

On September 6, 2016, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing AB-FUBINACA and ADB-PINACA into Schedule I of the federal Controlled Substances Act. The scheduling action was effective on September 6, 2016.

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

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

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

Authorized Signature

Date Submitted

untreated wood components. Therefore this rule would be expected to impact only a small number of manufacturers and importers or at most, a small portion of the toys in the market.

Second, manufacturers of toys containing unfinished and untreated wood components still would be required to test to other aspects of the ASTM toy standard, so the impact of this rule relative to production costs for most firms should be small. Due to the small number of entities affected and the limited scope of the impact, the Commission certifies that this rule will not have a significant impact on a substantial number of small entities pursuant to section 605(b) of the RFA, 5 U.S.C. 605(b).

G. Environmental Considerations

The Commission's regulations provide a categorical exclusion for Commission rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required. The Commission's regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

List of Subjects

Business and industry, Infants and children, Consumer protection, Imports, Product testing and certification, Toys.

Accordingly, 16 CFR part 1251 is added to read as follows:

PART 1251—TOYS: DETERMINATIONS REGARDING HEAVY ELEMENTS LIMITS FOR CERTAIN MATERIALS

- Sec.
- 1251.1 The toy standard and testing requirements.
- 1251.2 Wood.

Authority: Sec. 3, Pub. L. 110-314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

§ 1251.1 The toy standard and testing requirements.

The Consumer Product Safety Improvement Act of 2008 ("CPSIA") made provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety ("toy standard"), a mandatory consumer product safety standard. Among the mandated provisions is section 4.3.5 of ASTM F963 which requires that surface coating materials and accessible substrates of toys that can be sucked, mouthed, or

ingested, must comply with solubility limits that the toy standard establishes for eight heavy elements. Materials used in toys subject to section 4.3.5 of the toy standard must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act ("CPSA"), unless listed in § 1251.2.

§ 1251.2 Wood.

(a) Unfinished and untreated wood does not exceed the limits for the heavy elements established in section 4.3.5 of the toy standard with a high degree of assurance as that term is defined in 16 CFR part 1107, provided that the material has been neither treated nor adulterated with materials that could result in the addition of any of the heavy elements listed in the toy standard at levels above their respective solubility limits.

(b) For purposes of this section, unfinished and untreated wood means wood harvested from the trunks of trees with no added surface coatings (such as, varnish, paint, shellac, or polyurethane) and no materials added to the wood substrate (such as, stains, dyes, preservatives, antifungals, or insecticides). Unfinished and untreated wood does not include manufactured or engineered woods (such as pressed wood, plywood, particle board, or fiberboard).

Dated: July 13, 2015.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. 2015-17413 Filed 7-16-15; 8:45 am]
BILLING CODE 6355-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-413F]

Schedules of Controlled Substances: Temporary Placement of Acetyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), and its optical, positional, and geometric isomers, salts and salts of isomers, into schedule I pursuant to the temporary scheduling provisions of the Controlled

Substances Act. This action is based on a finding by the Administrator that the placement of this opioid substance into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, import, export, engage in research, or possess), or propose to handle, acetyl fentanyl.

DATES: This final order is effective on July 17, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

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

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

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a

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

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

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of the Administrator's intention to temporarily place a substance into schedule I of the CSA.¹ The Administrator transmitted the notice of intent to place acetyl fentanyl into schedule I on a temporary basis to the Assistant Secretary by letter dated April 7, 2015. The Assistant Secretary responded to this notice by letter dated April 29, 2015 (received by the DEA on May 05, 2015), and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for acetyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of acetyl fentanyl into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). Acetyl fentanyl is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for acetyl fentanyl under section 505 of the FDCA,

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

21 U.S.C. 355. The DEA has found that the scheduling of acetyl fentanyl in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule acetyl fentanyl was published in the **Federal Register** on May 21, 2015. 80 FR 29227.

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

A substance meeting the statutory requirements for temporary scheduling may only be placed into schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for acetyl fentanyl, summarized below, indicate that this synthetic opioid has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA analysis is available in its entirety under the tab "Supporting and Related Material" of the public docket of this action at www.regulations.gov under Docket Number DEA-413F.

Factor 4. History and Current Pattern of Abuse

Clandestinely produced substances structurally related to the schedule II opioid analgesic fentanyl were trafficked and abused on the West Coast in the late 1970s and 1980s. These clandestinely produced fentanyl-like substances were commonly known as designer drugs, and recently, there has been a reemergence in the trafficking and abuse of designer drug substances, including fentanyl-like substances. Alpha-methylfentanyl, the first fentanyl analogue identified in California, was placed into schedule I of the CSA in September 1981. Following the control of alpha-methylfentanyl, the DEA identified several other fentanyl analogues (3-methylthiofentanyl, acetyl-

alpha-methylfentanyl, beta-hydroxy-3-methylfentanyl, alpha-methylthiofentanyl, thiofentanyl, beta-hydroxyfentanyl, para-fluorofentanyl and 3-methylfentanyl) in submissions to forensic laboratories. These substances were temporarily controlled under schedule I of the CSA after finding that they posed an imminent hazard to public safety and were subsequently permanently placed into schedule I of the CSA.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories across the country. The first laboratory submission of acetyl fentanyl was recorded in Maine in April 2013 according to NFLIS. NFLIS registered eight reports containing acetyl fentanyl in 2013 in Louisiana, Maine, and North Dakota; and 30 reports in 2014 in Florida, Illinois, Louisiana, Maine, New Jersey, Ohio, Oregon, Pennsylvania, and Virginia.

The System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from this database are from the DEA, other Federal agencies, and some local law enforcement agencies. Acetyl fentanyl was first reported to STRIDE in September 2013 from exhibits obtained through a controlled purchase in Louisiana. In October 2013, an exhibit collected from a controlled purchase of suspected oxycodone tablets in Rhode Island contained acetyl fentanyl as the primary substance. In 2014, STARLIMS (a Web-based, commercial laboratory information management system that is in transition to replace STRIDE) and STRIDE reported eight additional seizures in Colorado, Florida, Georgia, and Washington.

In August 2013, the Centers for Disease Control and Prevention published an article in its *Morbidity and Mortality Weekly Report* documenting a series of 14 fatalities related to acetyl fentanyl that occurred between March and May 2013. In December 2013, another fatality associated with acetyl fentanyl was reported in Rhode Island for a total of 15 fatalities. In February 2014, the North Carolina Department of Health and Human Services issued a health advisory related to acetyl fentanyl following at least three deaths related to this synthetic drug. Toxicologists at the North Carolina Office of the Chief Medical Examiner detected acetyl fentanyl in specimens associated with deaths that occurred in January 2014 in Sampson, Person, and

Transylvania counties. In July and August 2014, four additional fatalities involving acetyl fentanyl were reported for a total of seven fatalities in North Carolina. Deaths involving acetyl fentanyl have also been reported in California (1), Louisiana (14), Oregon (1) and Pennsylvania (1).

A significant seizure of acetyl fentanyl occurred in April 2013 during a law enforcement investigation in Montreal, Canada. Approximately three kilograms of acetyl fentanyl in powder form and approximately 11,000 tablets containing acetyl fentanyl were seized. Given that a typical dose of acetyl fentanyl is in the microgram range, a three kilogram quantity could potentially produce millions of dosage units. In the United States, tablets that mimic pharmaceutical opioid products have been reported in multiple states, including Colorado, Florida, Georgia, Rhode Island, and Washington. Recent reports indicate that acetyl fentanyl in powder form is available over the Internet and has been imported to addresses within the United States.

Evidence also suggests that the pattern of abuse of fentanyl analogues, including acetyl fentanyl, parallels that of heroin and prescription opioid analgesics. For example, seizures of acetyl fentanyl have been encountered both in powder and in tablet form. It is also known to have caused many fatal overdoses, in which intravenous routes of administration and histories of drug abuse are documented.

Factor 5. Scope, Duration and Significance of Abuse

The DEA is currently aware of at least 39 fatalities associated with acetyl fentanyl. These deaths occurred in 2013 and 2014 from six states including California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. STARLiMS and STRIDE, databases capturing drug evidence information from DEA forensic laboratories, have a total of 10 drug reports in which acetyl fentanyl was identified in six cases for analyzed drugs submitted from January 2010—December 2014 from Colorado, Florida, Georgia, Louisiana, Rhode Island, and Washington. It is likely that the prevalence of acetyl fentanyl in opioid analgesic-related emergency room admissions and deaths is underreported since standard immunoassays cannot differentiate acetyl fentanyl from fentanyl.

The population likely to abuse acetyl fentanyl overlaps with the populations abusing prescription opioid analgesics and heroin. This is evidenced by the routes of administration and drug use

history documented in acetyl fentanyl fatal overdose cases. Because abusers of acetyl fentanyl are likely to obtain the drug through illicit sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to its abusers. This risk is particularly heightened by the fact that acetyl fentanyl is a highly potent opioid (15.7 fold more potent than that of morphine as tested in mice using an acetic acid writhing method). Thus small changes in the amount and purity of the substance could potentially lead to overdose and death.

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

Acetyl fentanyl exhibits a pharmacological profile similar to that of fentanyl and other opioid analgesic compounds, and it is a potent opioid analgesic reported to be 1/3 as potent as fentanyl and 15.7 times as potent as morphine in mice tested in an acetic acid writhing method. In addition, studies also showed that the range between the effective dose (ED50) and the lethal dose (LD50) of acetyl fentanyl is narrower than that of morphine and fentanyl, increasing the risk of fatal overdose. Thus, its abuse is likely to pose quantitatively greater risks to the public health and safety than abuse of traditional opioid analgesics such as morphine.

Based on the above pharmacological data, the abuse of acetyl fentanyl at least leads to the same qualitative public health risks as heroin, fentanyl, and other opioid analgesic compounds. The public health risks attendant to the abuse of heroin and opioid analgesics are well established. The abuse of opioid analgesics has resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

Acetyl fentanyl has been associated with numerous fatalities. At least 39 overdose deaths due to acetyl fentanyl abuse have been reported in six states in 2013 and 2014, California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. This indicates that acetyl fentanyl poses an imminent hazard to public safety.

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

Based on the data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of acetyl fentanyl poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the

United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed into schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for acetyl fentanyl indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 7, 2015, notified the Assistant Secretary of the DEA's intention to temporarily place this substance into schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl), into schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Because the Administrator hereby finds it necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, this final order temporarily scheduling acetyl fentanyl will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary

scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, acetyl fentanyl will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, research, conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities with, or possesses), or who desires to handle, acetyl fentanyl must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of July 17, 2015. Any person who currently handles acetyl fentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle acetyl fentanyl as of July 17, 2015, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after July 17, 2015 is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Security.* Acetyl fentanyl is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of July 17, 2015.

3. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of acetyl fentanyl must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of July 17, 2015. Current DEA registrants shall have 30 calendar days from July 17, 2015, to comply with all labeling and packaging requirements.

4. *Inventory.* Every DEA registrant who possesses any quantity of acetyl fentanyl on the effective date of this order must take an inventory of all stocks of this substance on hand as of July 17, 2015, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with

all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including acetyl fentanyl) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. *Records.* All DEA registrants must maintain records with respect to acetyl fentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1307, and 1312 as of July 17, 2015. Current DEA registrants authorized to handle acetyl fentanyl shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

6. *Reports.* All DEA registrants who manufacture or distribute acetyl fentanyl must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1307, and 1312 as of July 17, 2015.

7. *Order Forms.* All DEA registrants who distribute acetyl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 17, 2015.

8. *Importation and Exportation.* All importation and exportation of acetyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of July 17, 2015.

9. *Quota.* Only DEA registered manufacturers may manufacture acetyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of July 17, 2015.

10. *Liability.* Any activity involving acetyl fentanyl not authorized by, or in violation of the CSA, occurring as of July 17, 2015, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

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

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

Further, the DEA believes that this temporary scheduling action final order is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

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

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

Pursuant to the Congressional Review Act, “any rule for which an agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order

from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place this substance into schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with 5 U.S.C. 808(2), this order shall take effect immediately upon its publication.

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Amend § 1308.11 by adding paragraph (h)(24) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(24) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: acetyl fentanyl) (9821).

* * * * *

Dated: July 13, 2015.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2015-17563 Filed 7-16-15; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG-2014-0863]

RIN 1625-AA00

Safety Zone; Big Foot TLP, Walker Ridge 29, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Interim rule and request for comments.

SUMMARY: The Coast Guard is establishing a safety zone around the

Big Foot Tension Leg Platform construction site, located in Walker Ridge Block 29 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. The purpose of this interim rule is to include the construction area and protect the facility and all operations during the construction phase from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Placing a safety zone around the facility while under construction that includes the construction site will significantly reduce the threat of allisions, collisions, security breaches, oil spills, releases of natural gas, and thereby protect the safety of life, property, and the environment.

DATES: This rule is effective without actual notice July 17, 2015. For the purposes of enforcement, actual notice will be used from June 3, 2015 until July 17, 2015. Comments and related material must be received by the Coast Guard on or before August 3, 2015.

ADDRESSES: Documents mentioned in this preamble are part of Docket Number USCG-2014-0863. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on "Open Docket Folder" on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may submit comments, identified by docket number, using any one of the following methods:

(1) *Federal eRulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* (202) 493-2251.

(3) *Mail or Delivery:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202-366-9329.

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or

email Mr. Rusty Wright, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504-671-2138, rusty.h.wright@uscg.mil. If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on "Submit a Comment" on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On July 17, 2015, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing acetyl fentanyl into schedule I of the federal Controlled Substances Act. The scheduling action is effective July 17, 2015.
2. The Controlled Substances Board did not receive an objection to similarly treating acetyl fentanyl as a schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating acetyl fentanyl as a controlled substance.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rule making, designating acetyl fentanyl as a schedule I controlled substance.

ORDER

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

CSB 2.46 Addition of acetyl fentanyl to schedule I. Section 961.14 (2) (ae), Stats., is created to read:

961.14 (2) (ae) Acetyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide).

This order shall take effect on November 21, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebort, Chair
Controlled Substances Board

Rules and Regulations

Federal Register

Vol. 81, No. 72

Thursday, April 14, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-432]

Schedules of Controlled Substances: Placement of AH-7921 Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration places the substance AH-7921 (Systematic IUPAC Name: 3,4-dichloro-*N*-[(1dimethylamino)cyclohexylmethyl]benzamide), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act and is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle, AH-7921.

DATES: Effective May 16, 2016.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the

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

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

Section 201(d)(1) of the CSA (21 U.S.C. 811(d)(1)) states that, if control of a substance is required "by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings and procedures required by section 201(a) and (b) (21 U.S.C. 811(a) and (b)) and section 202(b) (21 U.S.C. 812(b)) of the Act." 21 U.S.C. 811(d)(1), 21 CFR 1308.46. If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs, 1961, then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control that substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C.

811 to the Administrator of the DEA. 28 CFR 0.100.

Background

On May 8, 2015, the Secretary-General of the United Nations advised the Secretary of State of the United States, that during the 58th session of the Commission on Narcotic Drugs, AH-7921 was added to schedule I of the Single Convention on Narcotic Drugs, 1961. This letter was prompted by a decision at the 58th session of the Commission on Narcotic Drugs in March 2015 to schedule AH-7921 under schedule I of the Single Convention on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control AH-7921 under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

AH-7921

AH-7921 is an *N*-substituted cyclohexylmethyl benzamide developed in 1962 by Allen and Hanbury's, Ltd., a pharmaceutical company in the United Kingdom. AH-7921 is a μ -opioid receptor agonist with analgesic activity similar to that of morphine. The DEA is not aware of any commercial or medical uses for this substance. In animals, withdrawal symptoms are observed following repeated administration of AH-7921. Currently, clinical studies evaluating the safety and pharmacological effects of AH-7921 in humans have not been reported in the scientific literature. Usage of AH-7921 for eliciting euphoria and relaxation has been documented. There have been several reports of overdoses and deaths from AH-7921 reported worldwide including at least one published case report of a death resulting from AH-7921 in the United States. Given the increasing abuse of opioid prescription drugs (e.g., oxycodone, hydrocodone and fentanyl) and increased use of heroin in the United States, there are legitimate concerns about an increased potential of abuse of AH-7921.

DEA is not aware of any claims or any medical or scientific literature suggesting that AH-7921 has a currently accepted medical use in treatment in the United States. Accordingly, DEA has not requested that HHS conduct a scientific and medical evaluation of the substance's medical utility.

Furthermore, DEA is not required under 21 U.S.C. 811(d)(1) to make any findings required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). Therefore, consistent with the framework of 21 U.S.C. 811(d), DEA concludes that AH-7921 has no currently accepted medical use in treatment in the United States and is most appropriately placed in schedule I of the CSA.

Conclusion

In order to meet the obligations of the Single Convention on Narcotic Drugs, 1961 and because AH-7921 has no currently accepted medical use in treatment in the United States, the Administrator of the Drug Enforcement Administration has determined that this substance should be placed in schedule I of the Controlled Substances Act.

Requirements for Handling

Upon the effective date of this final order, AH-7921 is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, and conduct of instructional activities with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, AH-7921 must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of May 16, 2016. Any person who currently handles AH-7921, and is not registered with the DEA, must submit an application for registration and may not continue to handle AH-7921 as of May 16, 2016, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration must surrender all quantities of currently held AH-7921, or may transfer all quantities of currently held AH-7921 to a person registered with the DEA on or before May 16, 2016 in accordance with all applicable federal, state, local, and tribal laws. As of May 16, 2016, controlled substances must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* AH-7921 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of May 16, 2016.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of AH-7921 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of May 16, 2016.

5. *Quota.* A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 is required in order to manufacture AH-7921 as of May 16, 2016.

6. *Inventory.* Every DEA registrant who possesses any quantity of AH-7921 on the effective date of this order must take an inventory of all stocks of this substance on hand as of May 16, 2016, pursuant to 21 U.S.C. 827 and 958, and in accordance with §§ 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA after May 16, 2016 must take an initial inventory of all stocks of controlled substances (including AH-7921) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including AH-7921) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with §§ 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to AH-7921 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute AH-7921 must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of May 16, 2016.

9. *Importation and Exportation.* All importation and exportation of AH-7921 must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of May 16, 2016.

10. *Liability.* Any activity involving AH-7921 not authorized by, or in violation of the CSA, occurring as of May 16, 2016, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute "rule making" under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)'s requirement that such action be taken to comply with the United States obligations under the specified international agreements.

Executive Order 12866

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

Executive Order 13132

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

Executive Order 13175

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

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

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

Congressional Review Act

This action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). However, the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

- 2. Amend § 1308.11 by redesignating paragraphs (b)(3) through (55) as (b)(4) through (56) and adding a new (b)(3) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

- (3) AH-7921 (3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide 9551

* * * * *

Dated: April 8, 2016

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016–08566 Filed 4–13–16; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–HQ–OAR–2016–0098; FRL–9944–88–OAR]

Findings of Failure To Submit State Implementation Plans Required for Attainment of the 2010 1-Hour Primary Sulfur Dioxide National Ambient Air Quality Standard (NAAQS); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule that appeared in the **Federal Register** on March 18, 2016 (81 FR 14736). The document included a listing of areas for which states had not submitted State Implementation Plans (SIPs) addressing nonattainment area SIP requirements for the 2010 1-hour primary sulfur dioxide (SO₂) NAAQS. This action corrects that listing to clarify that the Indiana, Pennsylvania nonattainment area for the 2010 SO₂ NAAQS consists of the entirety of Indiana County and part of Armstrong County.

DATES: The effective date of this document is April 18, 2016.

FOR FURTHER INFORMATION CONTACT: For questions regarding this correction, contact Dr. Larry Wallace, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Mail Code C539–01, Research Triangle Park, NC 27711, phone number (919) 541-0906 or by email at wallace.larry@epa.gov.

SUPPLEMENTARY INFORMATION:**Background**

The EPA issued the final rule, in FR Doc 2016–06063 on March 18, 2016 (81 FR 14736). That final rule establishes certain Clean Air Act deadlines for the EPA to impose sanctions if a state does not submit a SIP addressing nonattainment area SIP requirements to bring the affected areas into attainment of the 2010 1-hour primary SO₂ NAAQS and for the EPA to promulgate a Federal Implementation Plan to address any outstanding SIP requirements.

Need for Correction

As published, the final preamble contains an error in a table identifying areas subject to the findings of failure to submit related to the Indiana, Pennsylvania nonattainment area. The Indiana, Pennsylvania nonattainment area consists of the entirety of Indiana County and part of Armstrong County. See 78 FR 47191, August 5, 2013 codified at 40 CFR part 81, subpart C. The preamble table mistakenly lists Indiana County as a “partial” county that is part of the Indiana, Pennsylvania nonattainment area subject to a finding of failure to submit, when the full county should have been listed as subject to the finding. Additional notice and comment for this minor technical correction is unnecessary under 5 U.S.C. 553(b)(3)(B), and the EPA finds that good cause exists for this minor technical correction to become effective at the same time as the final rule. Accordingly, this correction is incorporated into the final rule and also becomes effective on April 18, 2016.

Correction of Publication

In FR Doc 2016–06063 appearing on page 14736 in the **Federal Register** of Friday, March 18, 2016, the following correction is made:

On page 14737, table entitled “STATES AND SO₂ NONATTAINMENT AREAS AFFECTED BY THESE FINDINGS OF FAILURE TO SUBMIT,” remove from the end of the fourth entry, under the column titled “Nonattainment area” the text “(p)”.

Dated: April 4, 2016.

Janet G. McCabe,

Acting Assistant Administrator.

[FR Doc. 2016–08509 Filed 4–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R09–OAR–2015–0204; FRL–9944–16–Region 9]

Partial Approval and Partial Disapproval of Air Quality State Implementation Plans; California; South Coast; Moderate Area Plan for the 2006 PM_{2.5} NAAQS

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving in part and disapproving in part State implementation plan (SIP) revisions

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On April 14, 2016, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing AH-7921 into schedule I of the federal Controlled Substances Act. The scheduling action is effective May 16, 2016.
2. The Controlled Substances Board did not receive an objection to similarly treating AH-7921 as a schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating AH-7921 as a controlled substance.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rule making, designating AH-7921 as a schedule I controlled substance.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats AH-7921 under chapter 961, Stats. by creating the following:

CSB 2.47 Addition of AH-7921 to schedule I. Section 961.14 (2) (aj), Stats., is created to read:
961.14 (2) (aj) AH-7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide).

This order shall take effect on November 21, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebert, Chair
Controlled Substances Board

Dated: November 5, 2015.

Kevin J. Wolf,
Assistant Secretary for Export
Administration.

[FR Doc. 2015-28552 Filed 11-10-15; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-419F]

Schedules of Controlled Substances: Placement of Eluxadoline Into Schedule IV

AGENCY: Drug Enforcement
Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration places the substance 5-[[[(2*S*)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1*S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle eluxadoline.

DATES: *Effective date:* December 17, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

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

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

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

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

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated

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

at the request of the Assistant Secretary of the HHS and imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle or propose to handle eluxadoline.

Background

Eluxadoline (5-[[[(2*S*)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1*S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid), is a new molecular entity with central nervous system opioid properties. Eluxadoline has mixed mu opioid receptor (MOR) and kappa opioid receptor (KOR) agonist and delta opioid receptor (DOR) antagonist properties. The Food and Drug Administration (FDA) approved eluxadoline (brand name "VIBERZI") as a prescription drug for the treatment of irritable bowel syndrome with diarrhea (IBS-D) on May 27, 2015.

DEA and HHS Eight Factor Analyses

On May 5, 2015, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled "Basis for the Recommendation to Place Eluxadoline in Schedule IV of the Controlled Substances Act." After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that eluxadoline be controlled in schedule IV of the CSA. In response, the DEA completed its own eight-factor analysis of eluxadoline. Both the DEA and HHS analyses and other relevant documents are available in their entirety in the public docket of this rule (Docket Number DEA-419) at <http://www.regulations.gov> under "Supporting Documents."²

Determination to Schedule Eluxadoline

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Administrator of the DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled "Schedules of Controlled Substances: Placement of Eluxadoline into Schedule

² Although the published notice of proposed rulemaking stated that such items had been placed into the docket on [regulations.gov](http://www.regulations.gov), the Administration discovered in preparing this final rule that the HHS analysis had in fact not been posted. However, that document was available for review at DEA. The DEA posted the cited analysis to [regulations.gov](http://www.regulations.gov) upon discovery of the error.

IV" which proposed placement of eluxadoline in schedule IV of the CSA. 80 FR 48044, August 11, 2015. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations by September 10, 2015. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before September 10, 2015.

Comments Received

The DEA received two comments on the proposed rule to schedule eluxadoline. One commenter supported controlling eluxadoline as a schedule IV controlled substance. One commenter opposed the control of eluxadoline as a schedule IV substance, and suggested it be controlled as a schedule V substance instead.

Support for the Proposed Rule. One commenter agreed with the DEA's proposal to control eluxadoline as a schedule IV controlled substance, and stated that the public health (specifically, an unmet medical need) necessitates an immediate effective date for the final order controlling eluxadoline.

DEA Response. The DEA appreciates the comment in support of this rulemaking. Generally, DEA scheduling actions are effective 30 days from the date of publication of the final rule in the **Federal Register**. 21 CFR 1308.45; see also 5 U.S.C. 553(d). The DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to comply with regulatory requirements for handling Schedule IV controlled substances. Both the HHS' and the DEA's scientific and medical analyses, the data collectively suggest that eluxadoline does have sufficient abuse potential and the DEA does not agree that eluxadoline's effective date should be the date of publication of the final rule.

Opposition to the Proposed Rule. One commenter opposed the proposal to control eluxadoline as a schedule IV controlled substance, stating "I do not think that eluxadoline meets the factor [5] requirements for scheduling under schedule IV due to there being no general widespread use throughout other countries." The commenter also stated that the best approach would be to place eluxadoline in schedule V, rather than schedule IV.

DEA Response. Although eluxadoline is a new chemical entity and information on actual abuse is not currently available, there is a sufficient

factual basis to meet the requirements of Factor 5 (the scope, duration, and significance of abuse). The legislative history of the CSA provides guidance regarding the assessment of a new drug's potential for abuse. The legislative history of the CSA provides that a substance may have a potential for abuse if: "The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community." Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444 (1970); as reprinted in 1970 U.S.C.C.A.N. 4566, 4601. As discussed in the HHS and the DEA eight-factor analyses, both pre-clinical and clinical studies indicate eluxadoline shares pharmacological similarities with schedule IV drugs such as butorphanol and pentazocine and has similar abuse potential.

In addition, the HHS and DEA eight-factor analyses support the finding that the overall abuse potential of eluxadoline is comparable to schedule IV substances such as pentazocine and butorphanol. This indicates that placement in schedule IV is appropriate rather than schedule V.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and the DEA's consideration of its own eight-factor analysis, the Administrator finds that these facts and all relevant data demonstrate substantial evidence of potential for abuse of eluxadoline. As such, the DEA is scheduling eluxadoline as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) 5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline) has a low potential for abuse relative to the drugs or other substances in schedule III. The overall abuse potential of eluxadoline is comparable to schedule IV substances such as pentazocine and butorphanol;

(2) 5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline) has a currently accepted medical use in treatment in the United States. Recently, the FDA approved eluxadoline as a prescription drug for the treatment of IBS-D. Therefore, eluxadoline has a currently accepted medical use in treatment in the United States; and

(3) Abuse of 5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline) may lead to limited psychological dependence similar to that of schedule IV drugs, but less than that of schedule III drugs.

Based on these findings, the Administrator of the DEA concludes that eluxadoline, including its salts, isomers, and salts of isomers, warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Eluxadoline

Upon the effective date of this final rule, any person who handles eluxadoline is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research, and conduct of instructional activities, of schedule IV controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) eluxadoline, or who desires to handle eluxadoline, must be registered with the DEA to conduct such activities, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312 as of December 14, 2015. Any person who currently handles eluxadoline and is not registered with the DEA must submit an application for registration and may not continue to handle eluxadoline as of December 14, 2015 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and

in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* Eluxadoline is subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.93, as of December 14, 2015.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of eluxadoline must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302, as of December 14, 2015.

4. *Inventory.* Every DEA registrant who possesses any quantity of eluxadoline on the effective date of this final rule must take an inventory of all stocks of eluxadoline on hand as of December 14, 2015, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a), (d), and (e).

Any person who becomes registered with the DEA after November 12, 2015 must take an initial inventory of all stocks of controlled substances (including eluxadoline) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a), (b), and (e).

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

5. *Records.* All DEA registrants must maintain records with respect to eluxadoline pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312 and § 1307.11, as of December 14, 2015.

6. *Prescriptions.* All prescriptions for eluxadoline or products containing eluxadoline must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of December 14, 2015.

7. *Importation and Exportation.* All importation and exportation of eluxadoline must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312 as of December 14, 2015.

8. *Liability.* Any activity involving eluxadoline not authorized by, or in violation of, the CSA, occurring as of December 14, 2015 is unlawful, and may subject the person to administrative, civil, and/or criminal proceedings.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

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

Executive Order 13132

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

Executive Order 13175

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

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place eluxadoline, including its salts, isomers, and salts of isomers, into schedule IV of the CSA. No less restrictive measures (*i.e.*, non-control, or control in schedule V) enable the DEA to meet its statutory obligations under the CSA. In preparing this certification, the DEA has assessed economic impact by size category and has considered costs with respect to the

various DEA registrant business activity classes.

Eluxadoline is a new molecular entity which has not yet been marketed in the United States or any other country. The DEA has no basis to determine the level of contracted or outsourced manufacturing activities or the breadth of the distribution network. Furthermore, due to the wide variety of unidentifiable and unquantifiable variables that could potentially influence the dispensing and distribution rates of new pharmaceutical drugs, the DEA is unable to determine the number of potential small entities that might handle eluxadoline. However, the DEA estimates that all persons who would handle, or propose to handle, eluxadoline are currently registered with the DEA to handle schedule IV controlled substances, because it is a pharmaceutical controlled substance intended for medical treatment. Accordingly, the number of DEA registrations authorized to handle schedule IV controlled substances is a reasonable estimate for the maximum number of eluxadoline handlers. Therefore, the DEA estimates that 1.6 million (1,554,254 as of June 2015) controlled substance registrations, representing approximately 427,584 entities, would be the maximum number of entities affected by this final rule. The DEA estimates that 418,141 (97.8%) of 427,584 affected entities are “small entities” in accordance with the RFA and SBA size standards.

The DEA anticipates that prospective eluxadoline handlers already handle other schedule IV controlled substances and that the cost impact as a result of placing eluxadoline in schedule IV would be nominal. As the anticipated eluxadoline handlers already handle other schedule IV controlled substances, they already have DEA registrations and the required security and recordkeeping processes, equipment, and facilities in place, and would only require a nominal increase in security, inventory, recordkeeping and labeling costs.

As discussed above, while the DEA does not have a basis to estimate the number of affected entities, the DEA estimates that the maximum number of affected entities is 427,584 of which 418,141 are estimated to be small entities. Since the affected entities are expected to handle other schedule IV controlled substances and maintain security and recordkeeping facilities and processes consistent with schedule IV controlled substances, the DEA estimates any economic impact will be nominal.

Because of these facts, this final rule will not result in a significant economic

impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

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

Paperwork Reduction Act of 1995

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

Congressional Review Act

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

Administrative Procedure Act

The APA requires the publication of a substantive rule to be made not less than 30 days before its effective date. 5 U.S.C. 553(d). However, one exception is "as otherwise provided by the agency for good cause found and published with the rule." As fully discussed above in response to the comment suggesting an immediate effective date, an immediate effective date is necessary in this case because there are limited therapeutic options currently available

to patients with IBS-D and the eluxadoline NDA received priority review with FDA. Therefore, it is unnecessary to delay the effective date of this final rule by 30 days, and this rule shall take effect immediately upon publication.

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Amend § 1308.14 by adding paragraph (g)(3) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(g) * * *

(3) Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers (9725).

Dated: November 5, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015-28718 Filed 11-10-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 91 and 570

[Docket No. FR 5797-I-01]

RIN 2506-AC39

Changes to Accounting Requirements for the Community Development Block Grants (CDBG) Program

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Interim final rule.

SUMMARY: This rule makes several changes to the existing Community Development Block Grant (CDBG) program regulations in order to better track the use of grant funds and improve accounting procedures in the program. Through this rule, HUD requires grantees to commence tracking the

obligations and expenditures of funds for each specific fiscal year grant, rather than track such information cumulatively. In order to effectively implement this accounting change, changes are needed to the regulations applicable to affected grants, such as the program-specific regulations, consolidated plan regulations, and methods to calculate the cap on administrative and planning expenses. While amending these regulations to conform to and support this accounting practice in applicable regulations, HUD is also making certain grammatical and other technical corrections in those regulations.

DATES: *Effective date:* December 14, 2015.

Comment due date: January 11, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this interim rule. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410-0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at www.regulations.gov. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the www.regulations.gov Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m., weekdays, at the

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On November 12, 2015, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing eluxadoline into schedule IV of the federal Controlled Substances Act. The scheduling action is effective December 17, 2015.
2. The Controlled Substances Board did not receive an objection to similarly treating eluxadoline as a schedule IV under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating eluxadoline as a controlled substance.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rule making, designating eluxadoline as a schedule IV controlled substance.

ORDER

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

CSB 2.48 Addition of eluxadoline to schedule IV. Section 961.20 (4) (cm), Stats., is created to read:

961.20 (4) (cm) Eluxadoline, including any of its isomers, and salts of isomers.

This order shall take effect on November 21, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebert, Chair
Controlled Substances Board



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-440]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, 3,4-dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide (also known as U-47700), and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of U-47700 into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, U-47700.

DATES: This final order is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION:

Legal Authority

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

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress

are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

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

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

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.¹ The Administrator transmitted the notice of intent to place U-47700 into schedule I on a

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

temporary basis to the Assistant Secretary by letter dated April 18, 2016. The Assistant Secretary responded to this notice by letter dated April 28, 2016, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for U-47700. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of U-47700 into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). U-47700 is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for U-47700 under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of U-47700 in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule U-47700 was published in the *Federal Register* on September 7, 2016. 81 FR 61636.

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

A substance meeting the statutory requirements for temporary scheduling may only be placed into schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the

United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for U-47700, summarized below, indicate that this synthetic opioid has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's updated three-factor analysis, and the Assistant Secretary's April 28, 2016, letter, are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under FDMS Docket ID: DEA-2016-0016 (Docket Number DEA-440).

Factor 4. History and Current Pattern of Abuse

The recreational abuse of novel opioids continues to be a significant concern. These substances are distributed to users with often unpredictable outcomes. The novel synthetic opioid U-47700 has recently been encountered by law enforcement and public health officials and the adverse health effects and outcomes are documented in the scientific literature. Self-reporting by users describes the effects of U-47700 to be similar to other opioids. The negative effects documented in the scientific literature are also consistent with other opioids. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by participating Federal, State, and local forensic laboratories across the country. The DEA utilizes NFLIS to monitor for drug trends. The first laboratory submission of U-47700 was recorded in October 2015; a total of 88 records were reported from State and local forensic laboratories between October 2015 – September 2016 according to NFLIS (query date: October 24, 2016).

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are repositied in STARLiMS; data from STARLiMS were queried on November 1, 2016. STARLiMS registered 45 reports containing U-47700 in 2016 from California, Connecticut, Florida, Maryland, Montana, North Dakota, New Jersey, New York, Tennessee, Texas, Virginia, West Virginia, and the District of Columbia. Through information collected from NFLIS, law enforcement reports, and email communications, the DEA is aware of the identification of U-47700 from toxicology reports and submitted evidence to forensic laboratories in several states, including Arkansas, California, Colorado, Connecticut, Florida, Georgia, Iowa, Kentucky, Missouri, Montana, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, and Wisconsin. These identifications occurred in 2015 and 2016.

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

The scientific literature and information collected by DEA demonstrate U-47700 is being abused for its opioid properties. The distribution of U-47700 and the increased prevalence of abuse remain deeply concerning to the DEA.

Factor 5. Scope, Duration and Significance of Abuse

The scientific literature and reports collected by the DEA demonstrate U-47700 is being abused for its opioid properties. This abuse of U-47700 has resulted in morbidity and mortality (see updated DEA 3-Factor Analysis for full discussion). The DEA has received reports for at least 46 confirmed fatalities² associated with U-47700. The information on these deaths occurring in 2015 and 2016 was collected from email communications and toxicology and medical examiner reports and was reported from New Hampshire (1), New York (31), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). The scientific literature notes additional fatal overdoses connected to U-47700. The population likely to abuse U-47700 appears to overlap with the populations abusing prescription opioid analgesics, other “designer opioids,” and heroin, as evidenced by drug use history documented in U-47700 fatal overdose cases. This observation is further supported by U-47700 being sold on the illicit market in glassine bags, some of which are marked with stamped logos, imitating the sale of heroin. Additionally, U-47700 has been found in counterfeit pills. Because abusers of U-47700 are likely to obtain this substance through non-regulated sources (i.e. on-line purchases or drug dealers), the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (i.e. use a drug

² Due to a proofreading error, the number of fatalities listed in the U-47700 NOI, which was 15, is incorrect. The correct number, 46, has been added to this Final Order.

for the first time) U-47700 abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.).

STARLiMS contains 45 reports in which U-47700 was identified in drug exhibits submitted in 2016. A query of NFLIS returned 88 records of U-47700 being identified in exhibits submitted to State and local forensic laboratories between October 2015 – September 2016. The DEA is not aware of any laboratory analyses of drug evidence identifying U-47700 prior to 2015, indicating that this synthetic opioid only recently became available as a replacement for other opioids that are commonly abused (i.e. oxycodone, heroin, fentanyl). U-47700 is available over the Internet and is marketed as a “research chemical.” The on-line sale and marketing of U-47700 are similar to other new psychoactive substances that have rapidly appeared on the recreational drug market and also resulted in negative consequences for the user.

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

U-47700 exhibits pharmacological profiles similar to that of morphine and other mu-opioid receptor agonists. Cases of intoxication are reported in the literature with morbidity and mortality associated with U-47700 use. The toxic effects of U-47700 in humans are demonstrated by overdoses and overdose fatalities associated with this substance, as reported in the scientific literature. Abusers of U-47700 may not know the origin, identity, or purity of this substance, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone. Additionally, the potent opioid U-47700 may serve as a precursor to problematic opioid use and dependence.

Based on reports in the scientific literature and information received by the DEA, the abuse of U-47700 leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are great. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

U-47700 has been associated with a number of fatalities and non-fatal overdoses as detailed in the scientific literature. The DEA has received information connecting U-47700 to at least 46 confirmed overdose deaths, occurring in 2015 and 2016 in New Hampshire (1), New York (31), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1).

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

In accordance with 21 U.S.C. 811(h)(3), based on the data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of U-47700 pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed into schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for U-47700 indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of

the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 18, 2016, notified the Assistant Secretary of the DEA's intention to temporarily place this substance into schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule U-47700 into schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Because the Administrator hereby finds it necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, this final order temporarily scheduling U-47700 will be effective on the date of publication in the *Federal Register*, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h) (1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, U-47700 will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, U-47700 must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles U-47700, and is not registered with the DEA, must submit an application for registration and may not continue to handle U-47700 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle U-47700, must surrender all quantities of currently held U-47700.

3. *Security.* U-47700 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of U-47700 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of U-47700 on the effective date of this order must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including U-47700) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to U-47700 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 1312,

1317 and §1307.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute U-47700 must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Order Forms.* All DEA registrants who distribute U-47700 must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Importation and Exportation.* All importation and exportation of U-47700 must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

10. *Quota.* Only DEA registered manufacturers may manufacture U-47700 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

11. *Liability.* Any activity involving U-47700 not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration

of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

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

Further, the DEA believes that this temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

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

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the Congressional Review Act, “any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to schedule this substance immediately because it poses a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA’s need to move quickly to place this substance into schedule I because it poses an imminent hazard to the public safety and it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808, because, as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, the DEA amends 21 CFR Part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Amend § 1308.11 by adding paragraph (h)(18) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(18) 3,4-Dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: U-47700).....(9547)

* * * * *

Dated: November 7, 2016

Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2016-27357 Filed: 11/10/2016 8:45 am; Publication Date: 11/14/2016]

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

FINDINGS

1. On November 14, 2016, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing U-47700 into schedule I of the federal Controlled Substances Act. The scheduling action is effective November 14, 2016.
2. The Controlled Substances Board did not receive an objection to similarly treating U-47700 as a schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating U-47700 as a controlled substance.
3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rule making, designating U-47700 as a schedule I controlled substance.

ORDER

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

CSB 2.49 Addition of U-47700 to schedule I. Section 961.14 (2) (z), Stats., is created to read: *961.14 (2) (z) U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide).*

This order shall take effect on December 19, 2016 to allow for publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____

Doug Englebert, Chair
Controlled Substances Board

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil		2) Date When Request Submitted: 11/8/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Drug Enforcement Administration Update – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Introduction of Assistant Special Agent in Charge Robert Bell from the Milwaukee Division Office of the DEA, US Department of Justice. The Board may discuss and consider the information provided by Mr. Bell.			

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil		2) Date When Request Submitted: 11/8/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? WI Crime Lab Update – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Introduction of Dave Hannon from the Wisconsin Crime Lab Bureau, Wisconsin Department of Justice. The Board may discuss and consider the information provided by Mr. Hannon.			

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
SEPTEMBER 20, 2016**

PRESENT: Alan Bloom (*joined the meeting at 9:32 a.m.*), Yvonne Bellay, Doug Englebert, Franklin LaDien (*via GoToMeeting*), Jeffrey Miller, Jason Smith, Timothy Westlake

EXCUSED: Gunnar Larson, Wendy Pietz

STAFF: Dan Williams – Executive 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: Jeffrey Miller moved, seconded by Timothy Westlake, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES

MOTION: Timothy Westlake moved, seconded by Jeffrey Miller, to approve the minutes of July 13, 2016 as published. Motion carried unanimously.

Alan Bloom joined the meeting at 9:32 a.m.

LEGISLATION AND RULE MATTERS

CSB 4 Relating to Prescription Drug Monitoring Program

MOTION: Jeffrey Miller moved, seconded by Alan Bloom, to authorize Chair to approve the emergency rule draft of CSB 4 relating to Prescription Drug Monitoring Program for submission to the Governor's Office and Publication and the corresponding preliminary rule draft for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.40 Relating to Exclusion of [¹²³I]ioflupane

MOTION: Alan Bloom moved, seconded by Yvonne Bellay, to approve the creation of CSB 2.40 relating to exclusion of [¹²³I]ioflupane for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CSB 2.42 Relating to Furanyl Fentanyl

MOTION: Yvonne Bellay moved, seconded by Jeffrey Miller, to approve the creation of CSB 2.42 relating to creating CSB 2.42 relating to scheduling furanyl fentanyl for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Scope for CSB 2.41 Relating to Butyrl Fentanyl and Beta-Hydroxythiofentanyl

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to request DSPS staff draft a letter providing information to District Attorneys to meet requirements under Wis. Stats. § 961.25. The letter will be provided to DOJ DCI for distribution once approved by the Chair. Motion carried unanimously.

MOTION: Jeffrey Miller moved, seconded by Timothy Westlake, to approve the Scope Statement on CSB 2.41 relating to scheduling butyrl fentanyl and Beta-Hydroxythiofentanyl for submission to the Governor's Office and publication and to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

Affirmative Action Relating to Scheduling to Brivaracetam

MOTION: Timothy Westlake moved, seconded by Jeffrey Miller, to affirm the scheduling of Brivaracetam to Schedule V to take effect on September 26, 2016 to allow for publication in the Administrative Register. Motion carried unanimously.

Scheduling of Thiafentanil (Schedule II)

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to affirm the scheduling of Thiafentanil to Schedule II after the expiration of 30 days from the date of publication of a federal final order. Motion carried unanimously.

Scheduling of PB-22, SF-PB-22, AB-FUBINACA and ADB-PINACA

MOTION: Timothy Westlake moved, seconded by Jeffrey Miller, to affirm the scheduling of PB-22, SF-PB-22, AB-FUBINACA and ADB-PINACA to Schedule I after the expiration of 30 days from the date of publication of a federal final order. Motion carried unanimously.

MOTION: Jeffrey Miller moved, seconded by Yvonne Bellay, to request DSPS staff draft a Scope Statement scheduling substances derived from a 3-carboxamideindazole structure and to authorize the Chair to approve the Scope Statement for submission to the Governor's Office and publication and to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

Scheduling of U-47700

MOTION: Alan Bloom moved, seconded by Jason Smith, to affirm the scheduling of U-47700 to Schedule I after the expiration of 30 days from the date of publication of a federal final order. Motion carried unanimously.

PRESCRIPTION DRUG MONITORING PROGRAM OPERATIONS

PDMP Account Suspension Proposed Process Diagram

MOTION: Timothy Westlake moved, seconded by Yvonne Bellay, to implement the proposed PDMP Account Suspension Process. Motion carried unanimously.

Implementation of CSB 4.09 for Integration Purposes

MOTION: Jeffrey Miller moved, seconded by Timothy Westlake, to designate the PDMP liaison/DSPS Staff to approve or reject entities for electronic health record integration with PDMP as it relates to Wis. Admin. Code CSB § 4.09. Motion carried unanimously.

ANNUAL AND QUARTERLY REPORTS

Quarterly PDMP Report: Wis. Stat. 961.385 (5) and (6)

MOTION: Jeffrey Miller moved, seconded by Timothy Westlake, to designate the Chair to review and approve the Quarterly PDMP Report for submission to DSPS. Motion carried unanimously.

CLOSED SESSION

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

The Board convened into Closed Session at 11:30 a.m.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 11:49 a.m.

ADJOURNMENT

MOTION: Timothy Westlake moved, seconded by Jeffrey Miller, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:50 a.m.

DRAFT

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Amber Cardenas, Board Counsel		2) Date When Request Submitted: 10.4.2016 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections:			
4) Meeting Date:	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Board Member Recusal	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Review information regarding ethical and legal obligations to recuse on certain matters at meetings.			
11) Authorization			
Signature of person making this request		Date	
s/Amber Cardenas		10.4.2016	
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.			

Recusal

Board members are charged with making decisions that objectively represent the voice of the public, members of the profession, and those seeking entry into the profession. This means that as a board member you are not an advocate for a private interest group or professional association. As a public official, you are held to the highest standards of ethical and professional conduct, and should strive to avoid any relationship, activity or position that may influence the performance of your official duties as a board member.

It follows that you must recuse yourself from any conflict of interest that would compromise your neutrality in making decisions on the board. Ask yourself, “can I decide the issue, fairly and without bias, prejudice, or the impression or appearance of impropriety?” If not, you should recuse from the matter.

A conflict of interest is a type of interest that would result in some benefit, perceived benefit to you, or a bias or perceived bias in favor of or against a particular matter. Under any of the above circumstances, you may have an ethical duty to recuse. Factors to consider in deciding whether to recuse are whether the issue at hand involves a colleague, friend, family member or someone with a close business or social relationship. If yes, then it may be proper to recuse yourself from the matter. The more remote the relationship, professional association, or knowledge becomes, the further you may be removed from bias. You must consider whether you can render an impartial and unbiased decision.

Finally, when acting as a case advisor, you have a legal duty to recuse when the case involves a **contested matter** which is being deliberated and voted upon.

Examples include:

- Reviews of Administrative Warnings
- Petitions for Summary Suspension
- Complaints for Probable Cause (Med Board)
- Administrative Law Judge Proposed Decision and Orders (ALJ PDOs).

The Case Advisor **must** recuse him or herself and leave the room for any contested matter. Board Counsel should be present for contested cases to answer any legal questions and to provide information to the prosecutor should the case be remanded.

The Department of Safety and Professional Services greatly appreciates your willingness to serve the public and those in your profession. If there are any questions about whether a Board member should recuse, please contact Board Legal Counsel.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: 11/4/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Board Updates on Prescribing Guidelines-Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Update on prescribing guidelines from Medical Examining Board, Dentistry Examining Board and Board of Nursing.			

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

AGENDA REQUEST FORM

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3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? State Coalition Update - Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Update on WI State Coalition for Prescription Drug Abuse Reduction			

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

AGENDA REQUEST FORM

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4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Task Force on Opioid Abuse Update - Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Update about the Task Force on Opioid Abuse			



SCOTT WALKER

OFFICE OF THE GOVERNOR

FOR IMMEDIATE RELEASE

October 25, 2016

Contact: Julie Lund, Dept. of Health Services (608) 266-1683

Governor Walker Announces Members of the Task Force on Opioid Abuse

Group to hold its first meeting on October 28 in Green Bay

Madison – In response to Wisconsin's opioid overdose epidemic, Governor Scott Walker today announced the members of the Task Force on [Opioid Abuse](#) that was created under [Executive Order #214](#).

"I appreciate the commitment task force members are making to help Wisconsin end this public health crisis, which is claiming lives and hurting families in our state," Governor Walker said. "Each member of the task force brings a unique perspective and will work together to help Wisconsin solve this serious issue."

The Task Force members include:

- Lieutenant Governor Rebecca Kleefisch, Co-Chair
- Representative John Nygren, Co-Chair
- Attorney General Brad Schimel
- Secretary Jon Litscher, Department of Corrections
- Secretary Dave Ross, Department of Safety and Professional Services
- Deputy Secretary Tom Engels, Department of Health Services
- Deputy Commissioner J.P. Wieske, Office of the Commissioner of Insurance
- Senator Leah Vukmir
- Senator Janet Bewley
- Representative Jill Billings
- Sheriff Reg Gill, Lafayette County Sheriff's Department
- Judge William Domina, Waukesha County Circuit Court
- John Weitekamp, R.P.H., Pharmacy Society of Wisconsin
- Joan Coffman, Wisconsin Hospital Association
- Dr. Nameeta Dookeran, Wisconsin Medical Society
- Dr. Tim Westlake, Wisconsin State Coalition for Prescription Drug Abuse Reduction
- Joan Mack, R.N., Director, C.A.R.E
- Jesse Heffernan, Helios Addiction Recovery Services

- Heather VanZanile, Forest County Potowatomi
- □Jen Rombalski, La Crosse County Health Department

In 2014, more Wisconsin residents died from drug overdoses than from motor vehicle crashes, and the number of drug overdose deaths in the state doubled from 2004 to 2014. Prescription opioid pain relievers contributed to 47 percent of the 843 drug overdose deaths in 2014, while heroin contributed to 32 percent.

"While we've made great strides to combat opioid abuse in Wisconsin, this task force is a unified effort to help end opioid abuse and overdoses in our state," Governor Walker said.

The Task Force will hold its first meeting on Friday, October 28 from 1:00PM - 4:00PM at the Aurora BayCare Sports Medicine Center in Green Bay.

###

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

AGENDA REQUEST FORM

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3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? District Attorney Outreach – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p>Discussion and consideration of the outreach plan and draft letter pursuant to the Board’s motion on September 20, 2016:</p> <p>Yvonne Bellay moved, seconded by Alan Bloom, to request DSPS staff draft a letter providing information to District Attorneys to meet requirements under Wis. Stats. § 961.25. The letter will be provided to DOJ DCI for distribution once approved by the Chair. Motion carried unanimously.</p>			

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

AGENDA REQUEST FORM

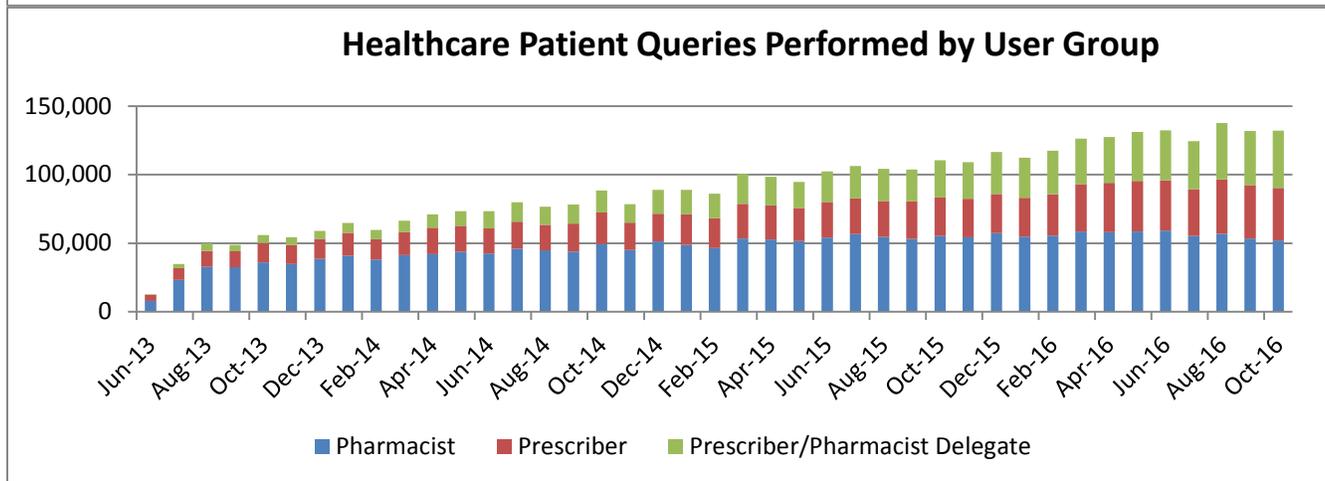
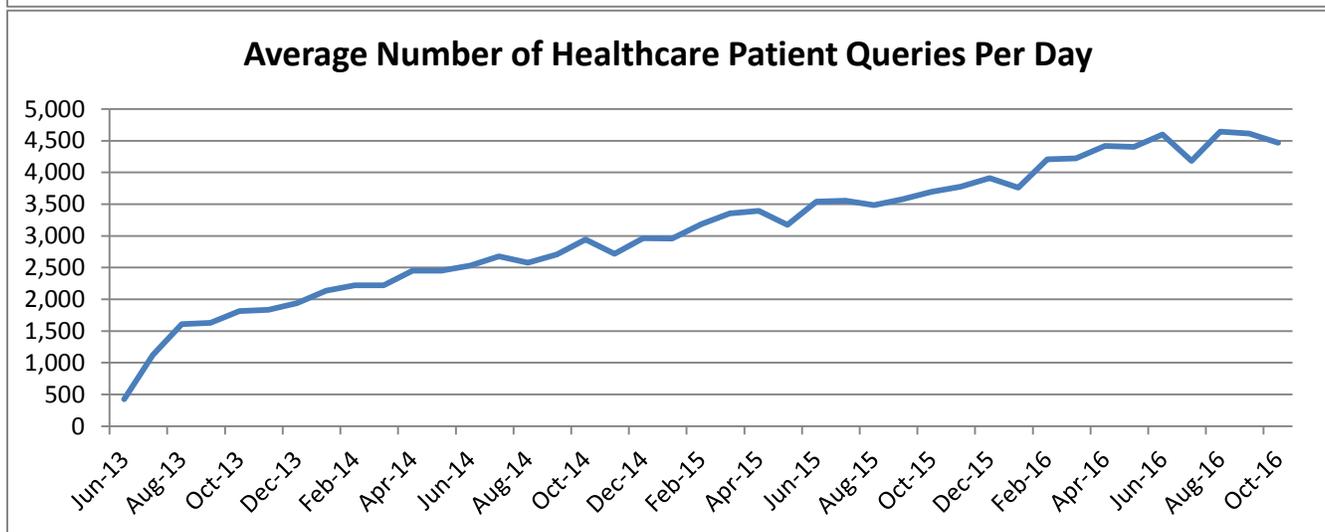
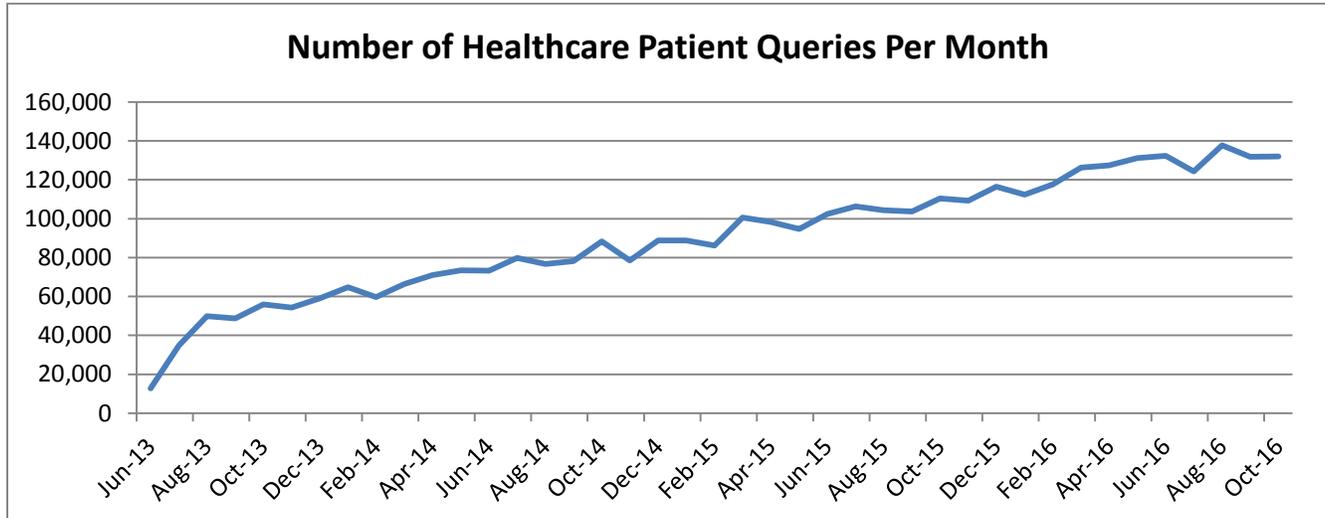
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4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Operations Statistics-Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the current operations of the PDMP.			



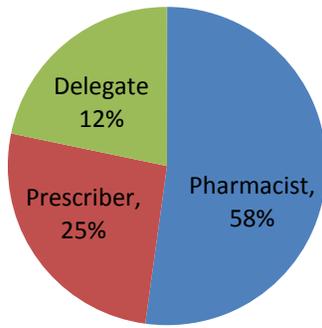
Scott Walker, Governor
Dave Ross, Secretary

Operational Statistics of the WI PDMP

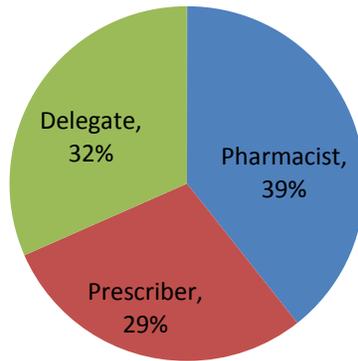
Compiled on October 8, 2016



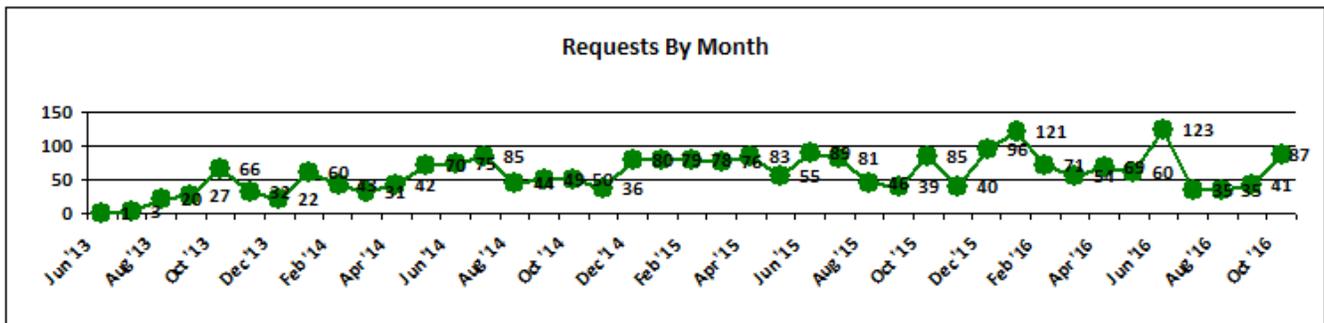
Healthcare Patient Queries Performed by User Group



Healthcare Patient Queries Performed by User Group, October 2016



- Law enforcement and government requests:

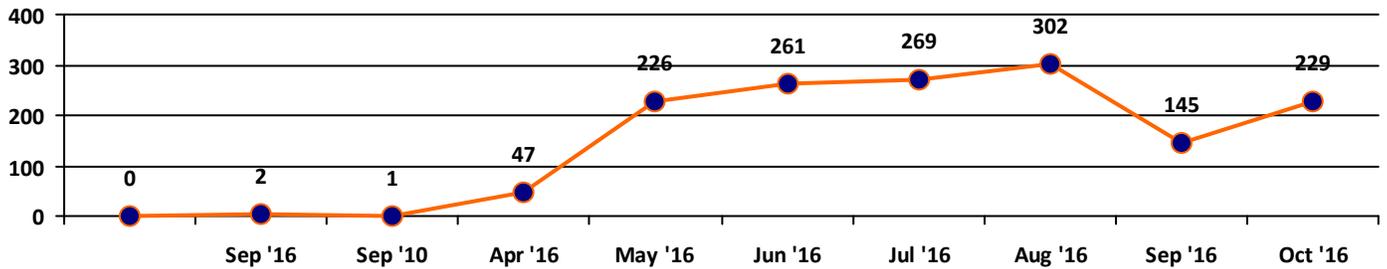




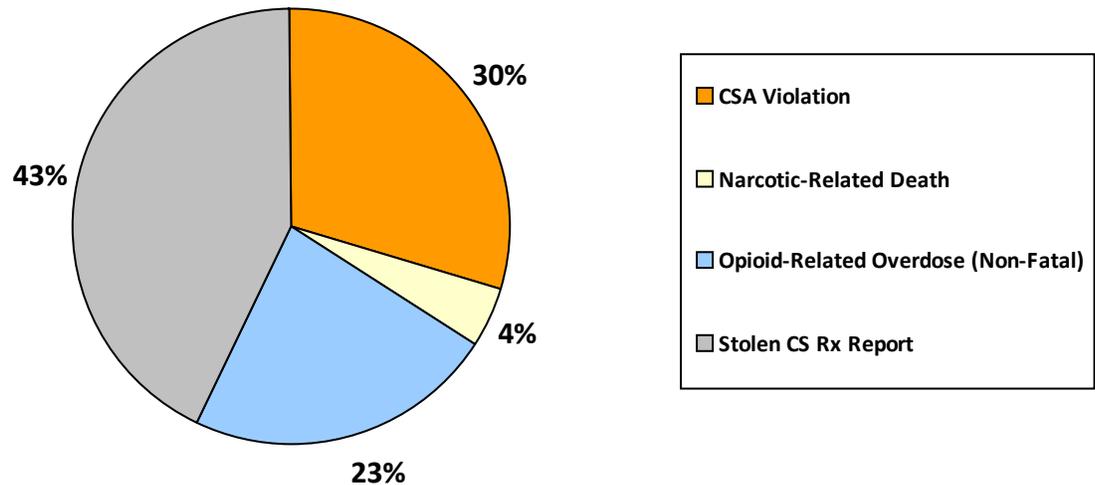
Act 268 Reports

Total Act 268 Reports Submitted: **1489** as of: 11/8/2016

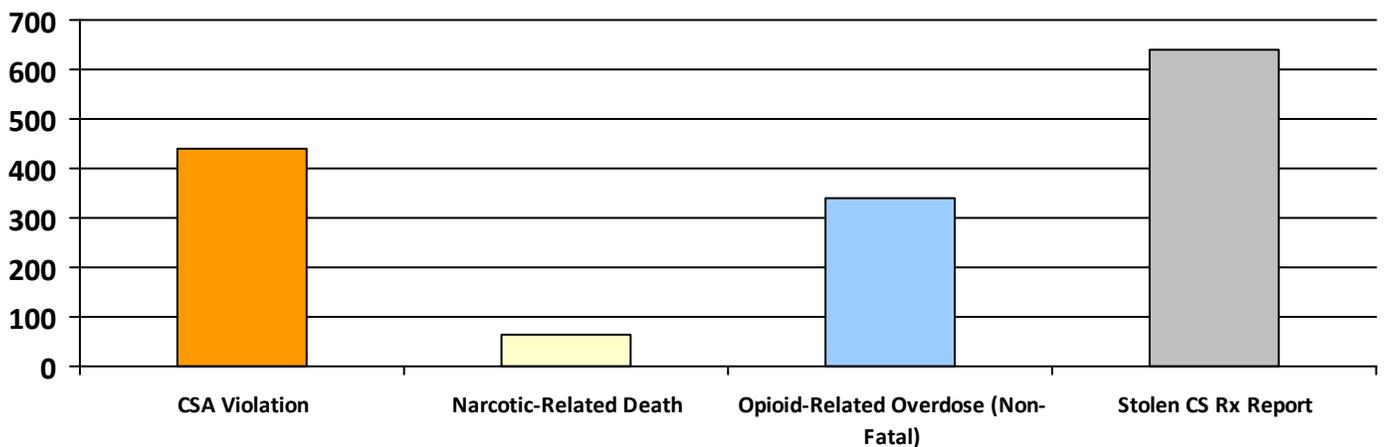
Act 268 Reports per Month



Act 268 Reports By Type



Act 268 Reports By Type



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

AGENDA REQUEST FORM

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3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? ePDMP Status and Integration Pathways -Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the development status of the Enhanced Prescription Drug Monitoring Program (ePDMP) and ePDMP-Electronic Health Record (EHR) integration pathways. - Demonstration of System - System Text Review - Deployment Planning			

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

AGENDA REQUEST FORM

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4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Annual and Quarterly Reports-Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration of the quarterly PDMP report requirements of 961.385 (5) and (6)			

Doug Englebert
Chairperson

Alan Bloom
Vice Chairperson

Yvonne Bellay
Secretary

CONTROLLED SUBSTANCES BOARD



1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935

Email: dsps@wisconsin.gov
Voice: 608-266-2112
FAX: 608-267-3816

October 24, 2016

The Honorable Dave Ross
Secretary, Department of Safety and Professional Services
State of Wisconsin
Department of Safety and Professional Services
PO Box 8935
Madison, WI 53708-8935

Dear Secretary Ross,

On March 17, 2016, 2015 Wisconsin Act 267 was enacted providing reporting requirements for the Prescription Drug Monitoring Program (PDMP). On behalf of the Controlled Substance Board, I am pleased to provide you and the Department with a copy of the first quarterly report.

The Controlled Substance Board expects the report to continue to improve, especially as we move to the new enhanced PDMP and have greater functionality for reporting. On behalf of the Controlled Substance Board, I would like to thank Department staff for their extensive work to create the current report and look forward to working with staff as we continue to improve the PDMP functionality and reporting.

This report will be a valuable tool for those around the state who are interested in promoting the health, safety and well-being of Wisconsin residents. If you receive any questions or comments about the report please forward them to the Controlled Substance Board so we can improve the report as necessary.

Sincerely,

A handwritten signature in black ink, appearing to read "Doug Englebert", with a large, sweeping flourish extending to the right.

Doug Englebert
Chair, Wisconsin Controlled Substance Board



Controlled Substances Board



Report 1

July 1 – September 30, 2016

Contact Information

Wisconsin Controlled Substances Board

Chairperson: Doug Englebert

Members:

Englebert, Doug, Chairperson
Bloom, Alan, Vice Chairperson
Bellay, Yvonne M., Secretary
LaDien, Franklin "Rocky"
Larson, Gunnar
Miller, Jeffrey G.
Pietz, Wendy M.
Smith, Jason
Westlake, Timothy W.

DHS Designated Member
Pharmacologist
DATCP Designated Member
Pharmacy Board Representative
Psychiatrist
Board of Nursing Representative
Dentistry Board Representative
Attorney General Designee
Medical Board Representative

Wisconsin Department of Safety and Professional Services

1400 E Washington Ave
Madison, WI 53703
608-266-2112
DSPS@wisconsin.gov

Wisconsin Prescription Drug Monitoring Program

PDMP@wisconsin.gov

Table of Contents

Introduction	4
User Satisfaction	6
Impact on Referrals for Investigation	11
Monitored Prescription Drug Use Trend	12
Data Submissions	14
Law Enforcement Reports.....	15
Disclosure of PDMP Data	17
Doctor Shopping and Pharmacy Hopping.....	20
Morphine Milligram Equivalent (MME).....	21
Opioid-Benzodiazepine Overlap	22
Attachment	23

Introduction

The Wisconsin Prescription Drug Monitoring Program (PDMP) was deployed in June 2013. It is administered by the Wisconsin Department of Safety and Professional Services (DSPS) pursuant to the regulations and policies established by the Wisconsin Controlled Substances Board (CSB). Since being deployed, the PDMP primarily has been a tool to help healthcare professionals make more informed decisions about prescribing and dispensing controlled substance prescription drugs to patients. It also discloses data as authorized by law to governmental and law enforcement agencies.

The PDMP currently stores over 40 million prescription records submitted by over 2,000 pharmacies and dispensing practitioners. Over 15,000 prescribers, pharmacists, and their delegates have performed over 3 million queries for patient prescription reports. The number of queries performed by healthcare users per day has steadily risen, with an average of over 4,500 queries performed each day.

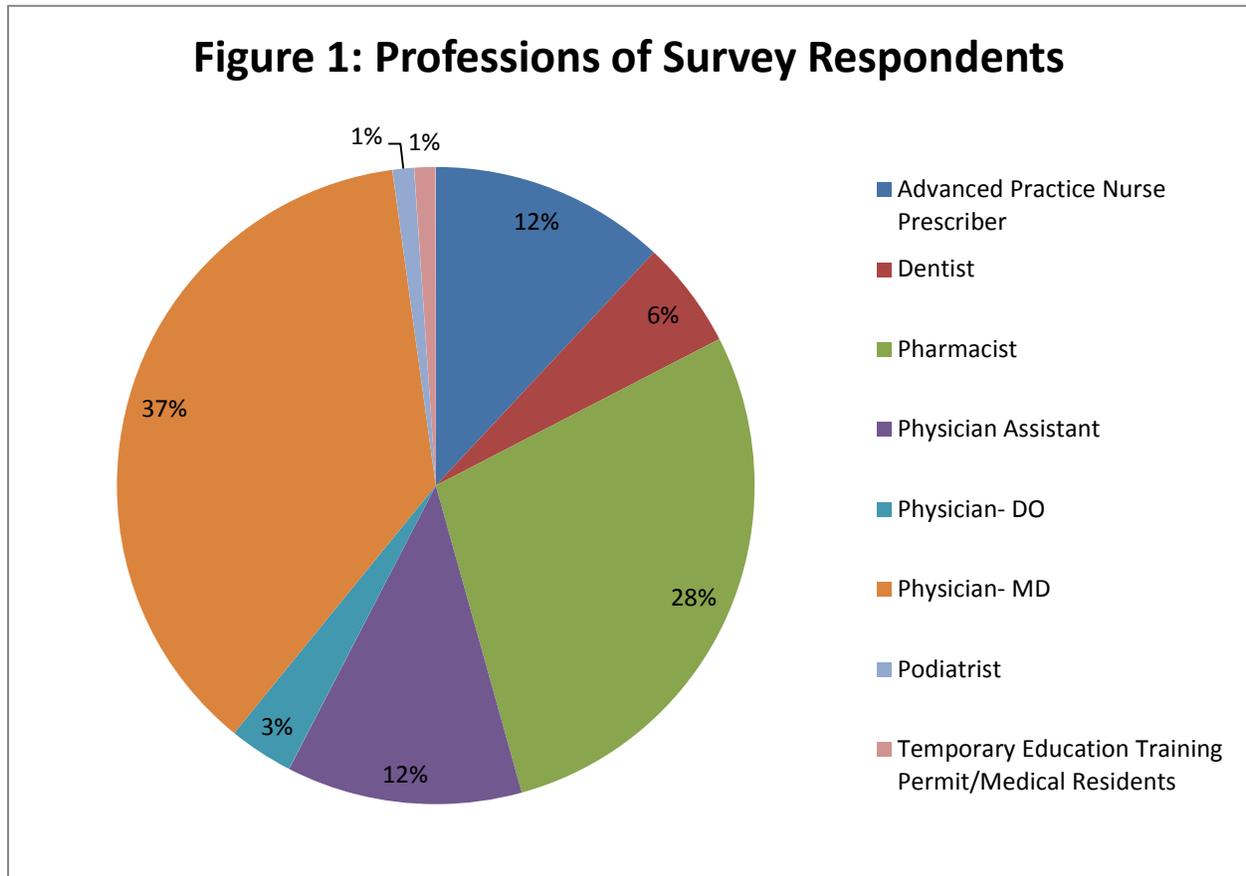
Pursuant to ss. 961.385 (5) – (6), Wis. Stats., the CSB is required to submit a report to DSPS about the PDMP. This report is the first report intended to satisfy that requirement. It includes information related to each of the following topics identified in the law:

- The satisfaction with the program of pharmacists, pharmacies, practitioners, and other users of the program.
- The program's impact on referrals of pharmacists, pharmacies, and practitioners to licensing or regulatory boards for discipline and to law enforcement agencies for investigation and possible prosecution.
- An assessment of the trends and changes in the use of monitored prescription drugs in this state.
- The number of practitioners, by profession, and pharmacies submitting records to the board under the program in the previous quarter.
- A description of the number, frequency, and nature of submissions by law enforcement agencies under s. 961.37 (3) (a) in the previous quarter.
- A description of the number, frequency, and nature of requests made in the previous quarter for disclosure of records generated under the program.
- The number of individuals receiving prescription orders from 5 or more practitioners or having monitored prescription drugs dispensed by 5 or more pharmacies within the same 90-day period at any time over the course of the program.
- The number of individuals receiving daily morphine milligram equivalents of 1 to 19 milligrams, 20 to 49 milligrams, 50 to 99 milligrams, and 100 or more milligrams in the previous quarter.
- The number of individuals to whom both opioids and benzodiazepines were dispensed within the same 90-day period at any time over the course of the program.

Currently, DSPS is developing an enhanced PDMP (ePDMP) system that will be deployed no later than the first quarter of 2017. The primary emphasis of the new system's design is value-added clinical workflow integration, improved data quality capabilities for both searching and reporting, and maximized public health and public safety use. It will also be capable of compiling all of the data required for future reports.

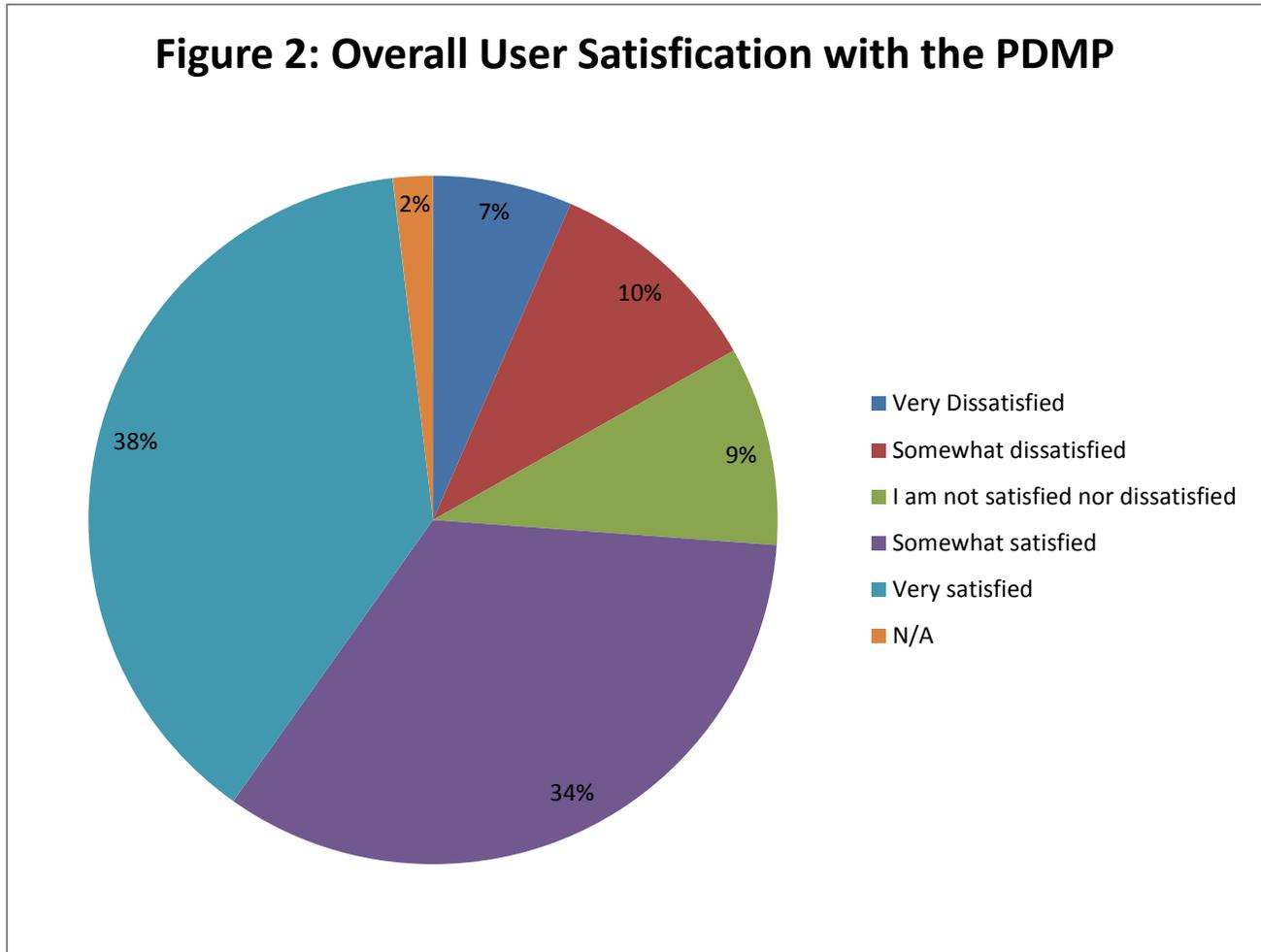
User Satisfaction

DSPS conducted an online survey between August 22 and September 14, 2016. During that time, DSPS emailed the user satisfaction survey attached to this report to 398 random current users of the PDMP. During the survey period, 109 current users of the PDMP completed the survey. Figure 1 shows the profession of the survey respondents.



While 109 users responded to the survey, only 92 users indicated their profession. The most common profession with 34 individuals is physician – MD. The second most common profession of survey respondents is pharmacist with 26 individuals. Besides optometrists, very few of whom are current PDMP users, and anesthesiologist assistants, none of whom are current PDMP users, all professions granted access to the PDMP are represented in the survey results.

Overall, current users of the PDMP are satisfied with the PDMP system. In fact, 72% of current users surveyed describe their satisfaction with the PDMP as “somewhat satisfied” or “very satisfied.” For the purposes of the survey, current users were defined as users who had registered with the PDMP and had an active PDMP account at the time the survey began. Figure 2 shows the 107 responses collected as part of the survey from current users about their satisfaction with the PDMP system.

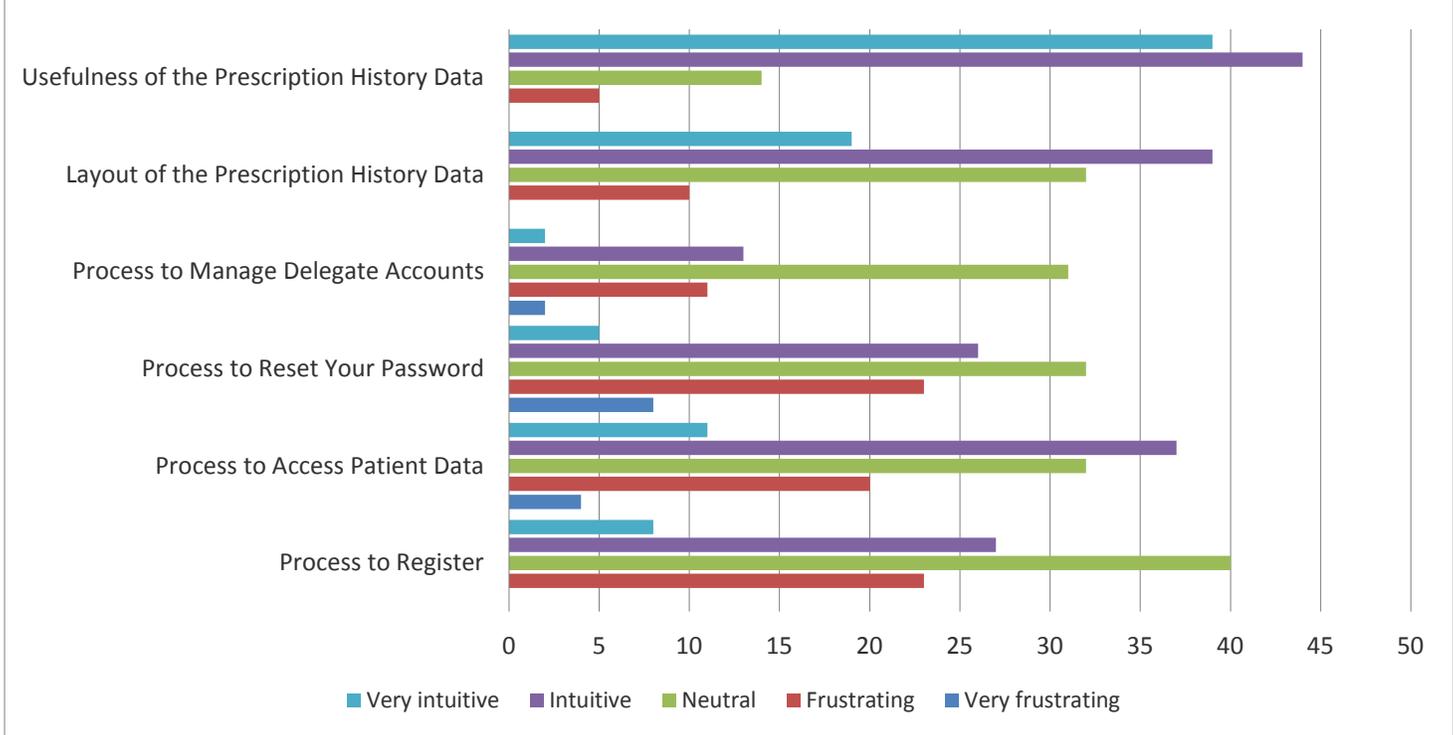


The survey also asked users to rate specific qualities of the PDMP system. The qualities of the PDMP in the survey are:

- Process to Register
- Process to Access Patient Data
- Process to Reset Your Password
- Process to Manage Delegate Accounts
- Layout of the Prescription History Data
- Usefulness of the Prescription History Data

Figure 3 shows the results from the survey.

Figure 3: Rating Qualities of the PDMP System

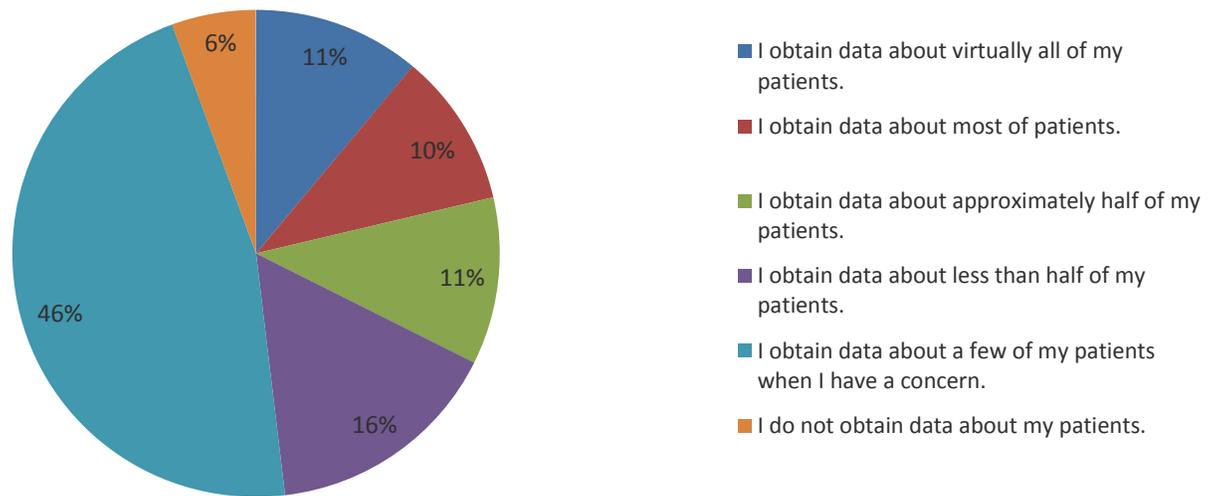


The most positive responses related to the usefulness of the prescription history data. Almost 80% of current users highly rated the usefulness of the data as intuitive or very intuitive. However, only 55% of current users describe the layout of the prescription history data as intuitive or very intuitive. So, while current users find the data useful, less find it laid out in an intuitive manner.

There is significantly more variation in the responses to the ratings for the processes. The most negative ratings regard the process to reset a password in the PDMP system. While approximately 29% of current users rate the process to reset their passwords as intuitive or very intuitive, an equal percentage of current users, 29%, rate the process as frustrating or very frustrating.

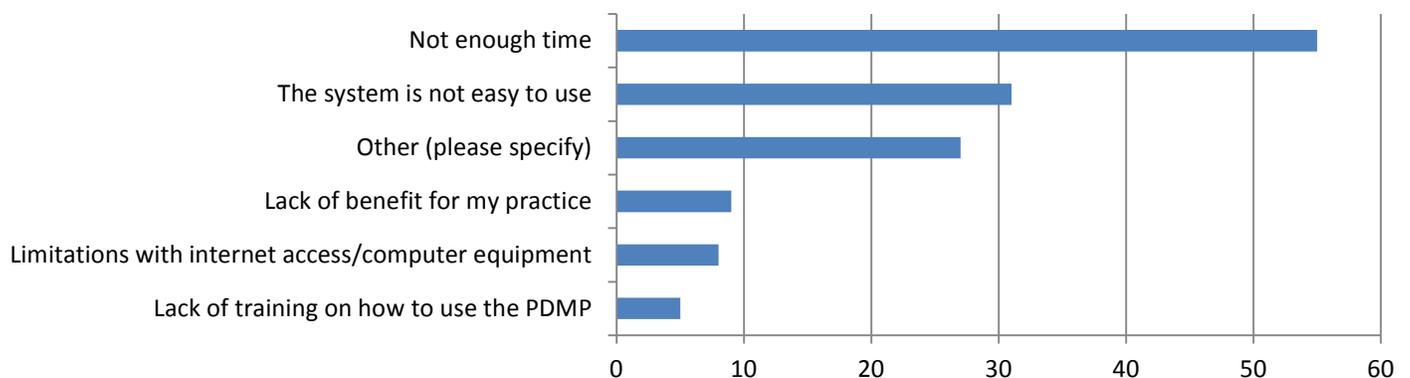
In addition to asking about satisfaction with the PDMP, the survey asked users about how often the current users or someone to whom they have delegated their authority to access PDMP data actually access PDMP data about a patient. Approximately 46% of the survey respondents only access PDMP data about “a few of my patients when I have a concern.” Nearly 28% of survey respondents accessed data about half of their patients or less. Over 5% of survey respondents do not access PDMP data about their patients. Taken together, almost 79% of current users only access data about half of their patients or less. Figure 4 shows the results from the survey.

Figure 4: Frequency of Accessing PDMP Data About Patients



Current users most often cited not having enough time to access PDMP data as a barrier to using the PDMP more. In fact, approximately 55% of current users identified it as a barrier in the survey. The second most cited barrier, identified by 31% of current users, is that the current users do not find the PDMP system easy to use. Figure 5 shows the results of the survey.

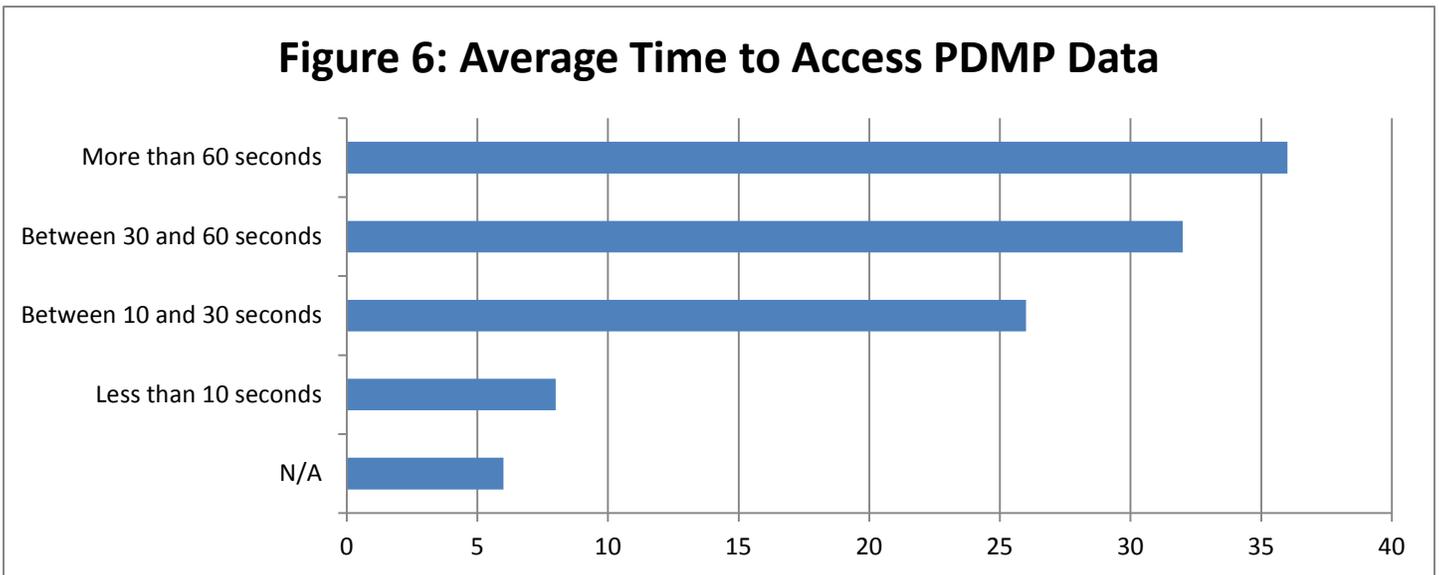
Figure 5: Barriers to Using the PDMP More



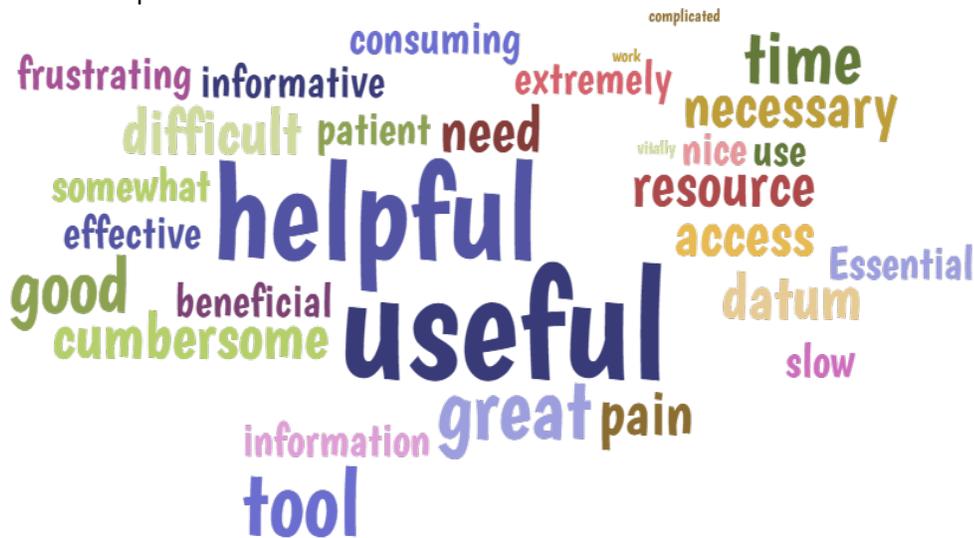
In the survey, 27% of the current users said that other barriers prevent them from using the PDMP more. There were two prevailing themes in the responses: passwords expire too often and are difficult to remember, and the PDMP system is cumbersome and requires too many clicks to access PDMP data. One response succinctly summed up the frustrations with both commonly cited barriers:

“frequent cumbersome [sic] passwords that change frequently resulting in forgotten password; a MILLION clicks to finally get to the screen to look someone up.”

The survey also asked the current users to judge the average amount of time it takes them to access PDMP data about a patient. The results are in Figure 6.



Finally, the survey asked current users to describe the PDMP in three or fewer words. The below word cloud was built using WordSift.org. It visualizes the cumulative responses. Words that appear larger in the word cloud were used in more responses than the words that appear smaller. The words most commonly used were “helpful” and “useful.”



Impact on Referrals for Investigation

Between July 1 and September 30, 2016, the Controlled Substances Board referred two pharmacists to the Pharmacy Examining Board for possible investigation and disciplinary action pursuant to s. 961.385 (2) (f), Wis. Stats. The referrals were made for suspected improper use of the PDMP. Prior to referring the pharmacists, the Controlled Substances Board suspended the pharmacists' access to PDMP data pursuant to s. CSB 4.09 (3) (a), Wis. Admin. Code.

Monitored Prescription Drug Use Trend¹

The amount of monitored prescription drugs, and opioids in particular, dispensed between July 1 and September 30, 2016 is less than the amount dispensed during the same period in 2015. During the third quarter 2016, the total number of prescriptions dispensed was 2,494,577, and the number of doses dispensed was 146,531,257. During the third quarter 2015, the total number of prescriptions dispensed was 2,657,001, and the number of doses dispensed was 157,555,903. The number of dispensed prescriptions for a monitored prescription drug this quarter is approximately 6% less than the same quarter in 2015. Similarly, the number of dispensed doses for a monitored prescription drug this quarter is approximately 7% less than the same period in 2015.

While there was a reduction in the volume of monitored prescription drugs dispensed, there has been little change in the 15 most dispensed monitored prescription drugs. The tables below show the top 15 most dispensed monitored prescription drugs between July 1 and September 30, 2016 and the top 15 most dispensed monitored prescription drugs during the same period in 2015.

Top 15 Monitored Prescription Drugs Dispensed Between July and September 2016		
Drug Name	Prescriptions	Quantity Dispensed
HYDROCODONE/ACETAMINOPHEN	389,632	22,269,636
DEXTROAMPHETAMINE/AMPHETAMINE	208,954	10,100,647
TRAMADOL HCL	198,362	15,095,871
OXYCODONE HCL	190,063	16,472,754
ALPRAZOLAM	173,583	10,199,304
LORAZEPAM	172,093	8,348,298
CLONAZEPAM	141,305	8,434,444
OXYCODONE HCL/ACETAMINOPHEN	140,847	9,457,861
ZOLPIDEM TARTRATE	139,336	4,615,915
METHYLPHENIDATE HCL	94,914	4,862,880
LISDEXAMFETAMINE DIMESYLATE	73,736	2,337,536
MORPHINE SULFATE	72,890	4,389,732
DIAZEPAM	67,557	2,969,951
PREGABALIN	58,234	4,369,183
ACETAMINOPHEN WITH CODEINE	51,001	2,386,879

The top 15 dispensed monitored prescription drugs accounted for over 86% of all monitored prescription drug doses dispensed between July 1 and September 30, 2016.

¹ The data presented in this section are from the records of the PDMP as of October 28, 2016. Because the PDMP is an accumulation of records submitted to it by pharmacies and other dispensers, the data are subject to correction and revision as the PDMP receives new data.

Top 15 Monitored Prescription Drugs Dispensed Between July and September 2015		
Drug Name	Prescriptions	Quantity Dispensed
HYDROCODONE/ACETAMINOPHEN	451,804	25,678,901
DEXTROAMPHETAMINE/AMPHETAMINE	214,635	10,307,051
TRAMADOL HCL	204,911	15,746,469
OXYCODONE HCL	203,196	17,820,075
ALPRAZOLAM	181,426	10,851,074
LORAZEPAM	180,710	8,825,318
OXYCODONE HCL/ACETAMINOPHEN	163,026	10,770,720
ZOLPIDEM TARTRATE	151,835	4,982,872
CLONAZEPAM	148,402	8,779,629
METHYLPHENIDATE HCL	95,324	4,915,617
MORPHINE SULFATE	78,574	4,832,945
DIAZEPAM	73,420	3,302,828
LISDEXAMFETAMINE DIMESYLATE	60,295	1,931,833
ACETAMINOPHEN WITH CODEINE	56,616	2,705,064
PREGABALIN	56,500	4,226,453

The top 15 dispensed monitored prescription drugs accounted for over 86% of all monitored prescription drug doses dispensed between July 1 and September 30, 2015.

Additionally, there was a nearly 10% reduction in the number of opioid prescriptions issued and opioid doses dispensed when comparing the data of the third quarter 2015 and third quarter 2016.

Amount of Opioid Prescriptions and Opioid Doses Dispensed		
Period	Opioid Prescription Orders	Quantity Dispensed
2015 Q3	1,280,367	83,223,662
2016 Q3	1,157,102	74,993,240
Difference	(123,265)	(8,230,422)
Percent Decrease	9.63%	9.89%

The current PDMP system identified the classes of prescriptions using the following AHFS Pharmacologic-Therapeutic Classifications:

Opioids:

- 280808: Opiate Agonists
- 280812: Opiate Partial Agonist

Data Submissions

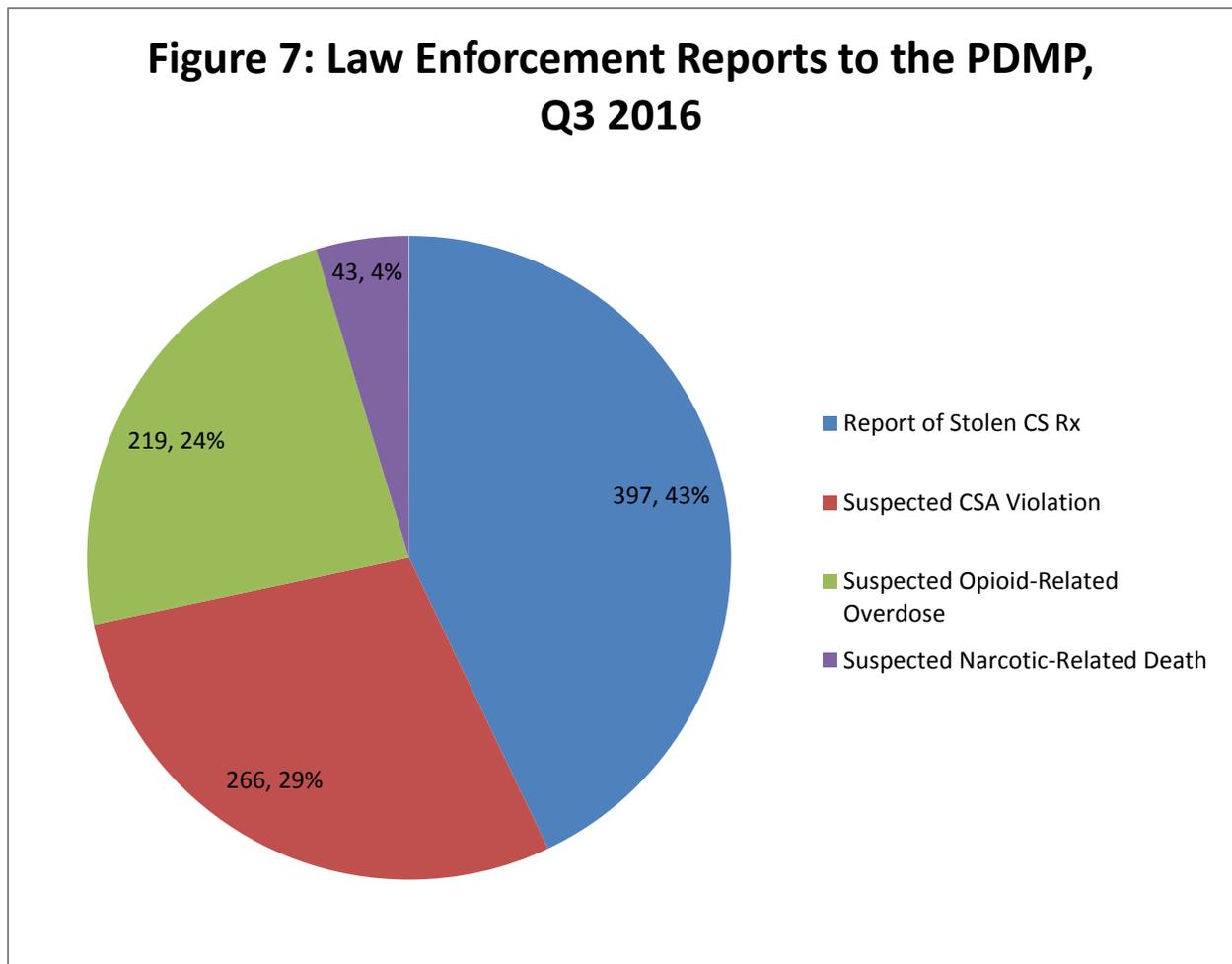
Between July 1 and September 30, 2016, 1,691 dispensers submitted 2,494,577 records to the PDMP. Of those dispensers, approximately 83% were located in Wisconsin, while 17% were located outside of Wisconsin. Approximately 89% of the dispensers were pharmacies, while the remaining 11% of the dispensers were dispensing practitioners. The profession of the dispensing practitioners is not currently reported in a consistent manner but will be available in future reports based on the enhancements being made to the PDMP application.

Law Enforcement Reports

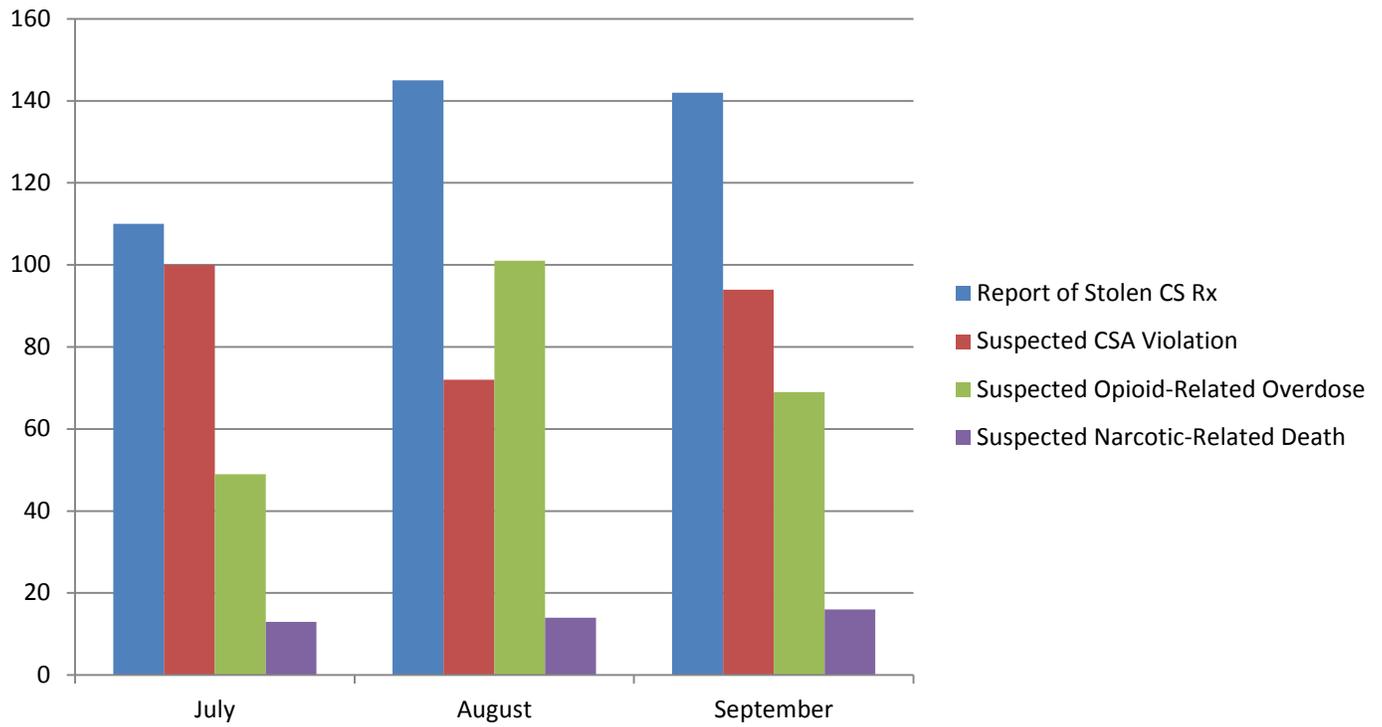
Between July 1, 2016, and September 30, 2016, 141 different Wisconsin law enforcement agencies submitted 925 reports to the PDMP as required by s. 961.37 (3) (a), Wis. Stat. The law requires the agencies to submit a report in each of the following situations:

1. When a law enforcement officer receives a report of a stolen controlled substance prescription.
2. When a law enforcement officer reasonably suspects that a violation of the Controlled Substances Act involving a prescribed drug is occurring or has occurred.
3. When a law enforcement officer believes someone is undergoing or has immediately prior experienced an opioid-related drug overdose.
4. When a law enforcement officer believes someone died as a result of using a narcotic drug.

Figures 7-8 show the breakdown of the reports submitted to the PDMP by type and by month.

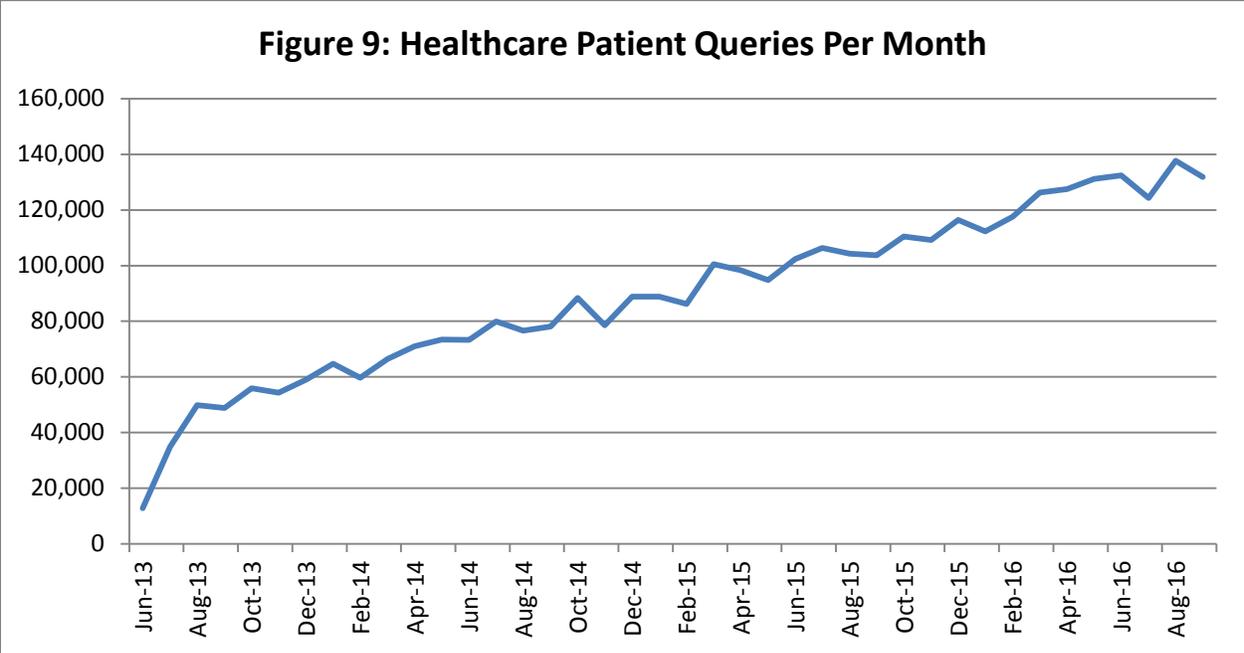


**Figure 8: Law Enforcement Reports to the PDMP,
Q3 2016**

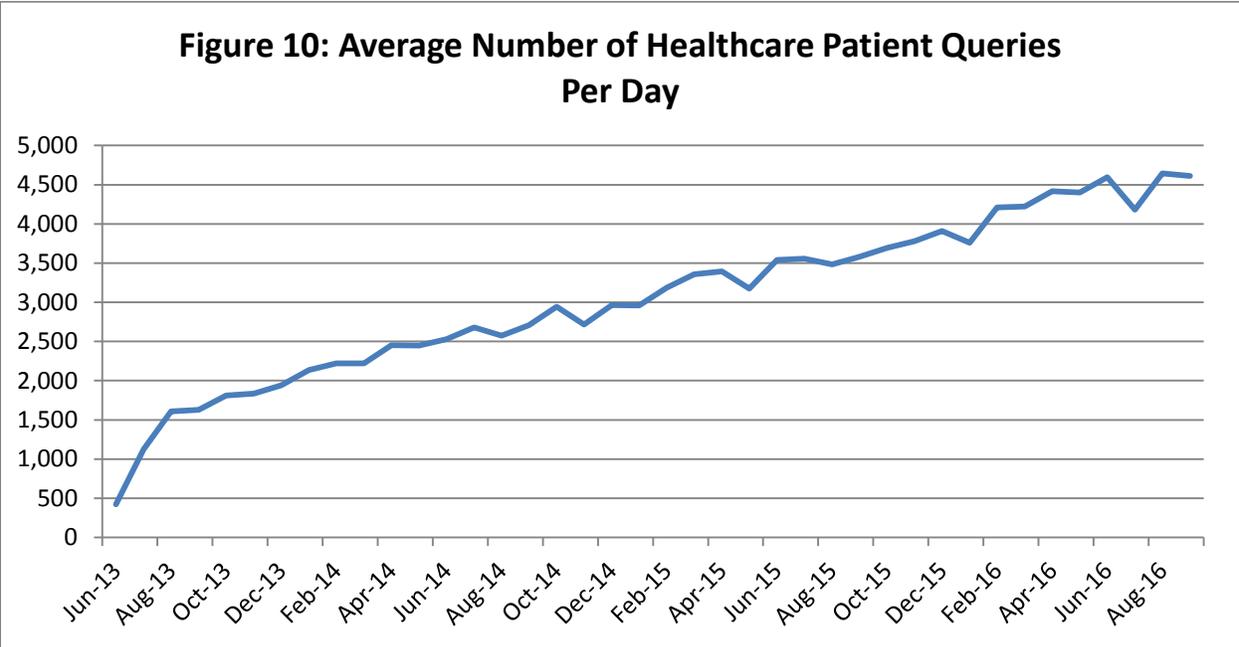


Disclosure of PDMP Data

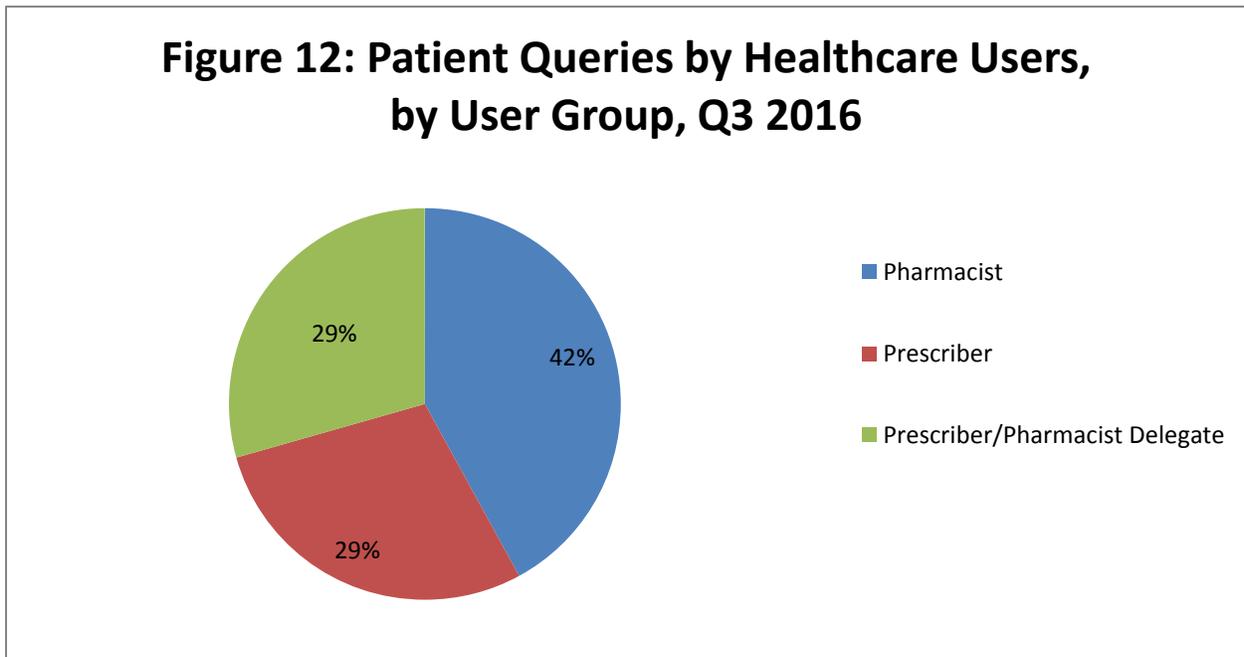
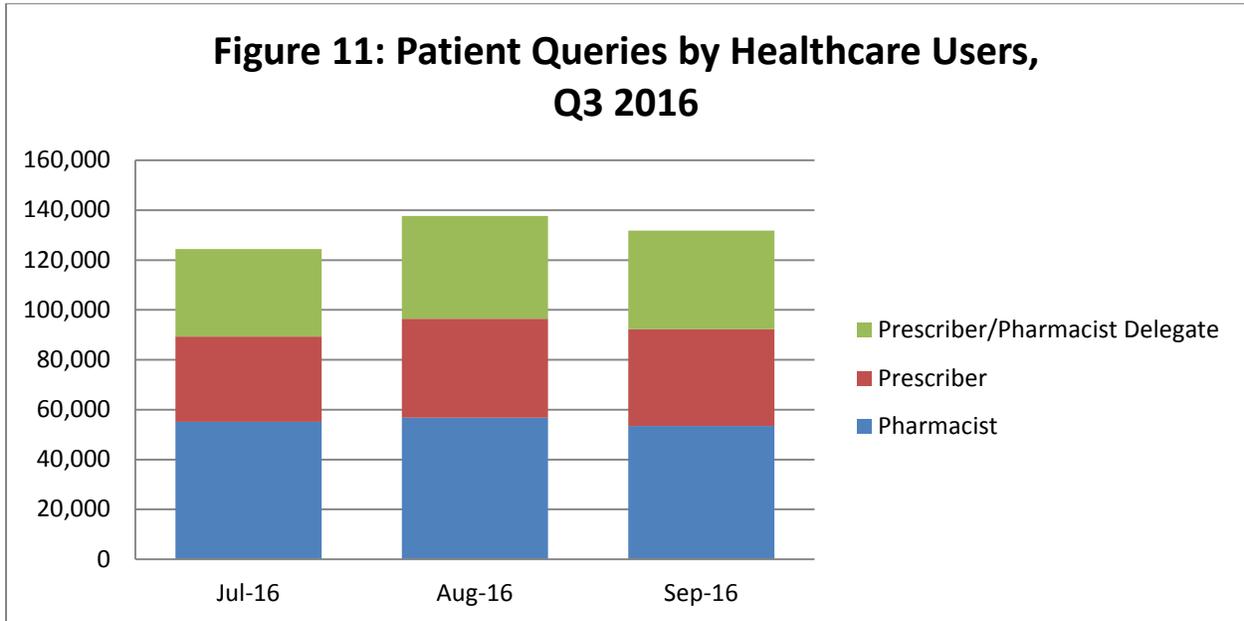
Between July 1, 2016, and September 30, 2016, healthcare users made 411,852 patient queries. The total number of patient queries by healthcare users has steadily increased since the program became operational in June of 2013, as seen in Figure 9.



The daily average of queries by healthcare users also reflects a steady increase, as seen in Figure 10.

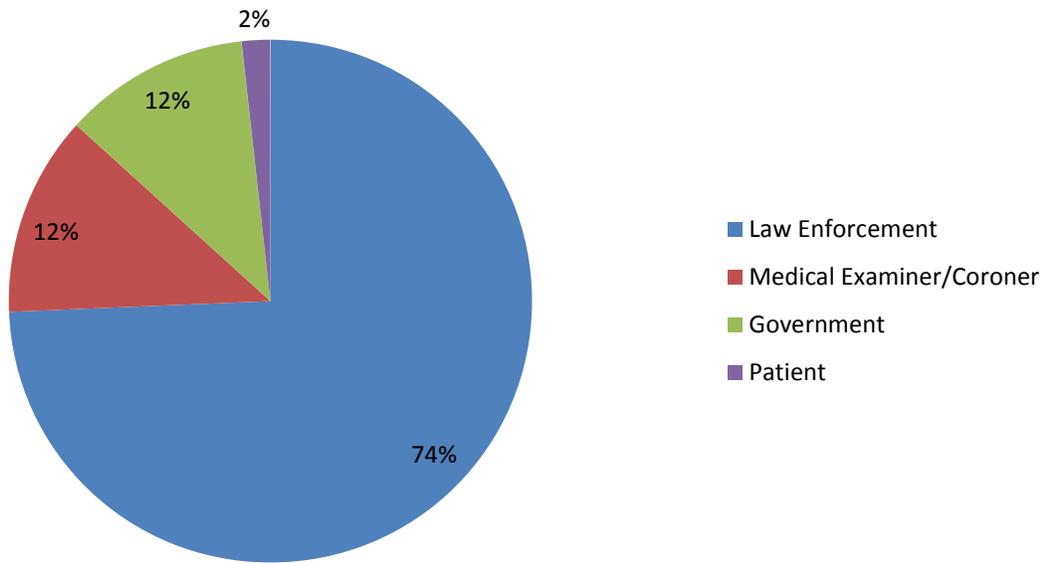


Figures 11 and 12 show the breakdown by profession of patient queries by prescribers, pharmacists, and prescriber/pharmacist delegates for this quarter.



Authorized individuals from non-healthcare groups made 113 requests for PDMP data this quarter. The breakdown among authorized non-healthcare groups can be seen in Figure 13.

Figure 13: Other Authorized Requests, Q3 2016



Doctor Shopping and Pharmacy Hopping

The current PDMP system is capable of calculating the number of individuals who received prescription orders from five or more prescribers and had those prescriptions dispensed by five or more pharmacies between July 1 and September 30, 2016.

According to the records submitted to the PDMP by pharmacies and other dispensers, 368 individuals obtained five or more prescription orders for a monitored prescription drug and had those drugs dispensed by five or more pharmacies this quarter.

Two individuals obtained prescription orders from 16 different prescribers between July 1 and September 30, 2016. One individual obtained monitored prescription drugs at 12 different pharmacies.

Based on its improved data-quality capabilities and analytics, the forthcoming ePDMP application will be able to alert providers about patients that meet doctor-shopping and pharmacy-hopping thresholds in real-time.

Morphine Milligram Equivalent (MME)

The current PDMP system is not capable of calculating morphine milligram equivalent doses of opioid drugs. However, pursuant to the authority provided in 2015 Act 267, DSPS included advanced data analytic functionalities in the scope and design of the new Enhanced Prescription Drug Monitoring Program (ePDMP) system. The ePDMP is currently under development. Once the ePDMP is deployed, DSPS will use it to fulfill the requirements of this section in retrospect and in all new reports.

Opioid-Benzodiazepine Overlap

The current PDMP system is capable of identifying the number of individuals to whom at least one opioid prescription and at least one benzodiazepine prescription were dispensed between July 1 and September 30, 2016. This does not necessarily mean that the prescriptions overlapped. It only means that at some point in the quarter the patient received an opioid prescription and that at some point in the quarter the same patient received a benzodiazepine prescription.

The current PDMP system identified the classes of prescriptions using the following AHFS Pharmacologic-Therapeutic Classifications:

Opioids:

- 280808: Opiate Agonists
- 280812: Opiate Partial Agonists

Benzodiazepines:

- 281208: Benzodiazepines (Anticonvulsants)
- 282408: Benzodiazepines (Anxiolytics, Sedatives, and Hypnotics)

According to the records submitted to the PDMP by pharmacies and other dispensers, 488,137 individuals received an opioid prescription and 283,439 individuals received a benzodiazepine prescription this quarter. Approximately 98,792 individuals received both an opioid prescription and a benzodiazepine prescription between July 1 and September 30, 2016.

Based on its improved data-quality capabilities and analytics, the forthcoming ePDMP application will be able to alert providers about patients that have overlapping benzodiazepine and opioid prescriptions as a standard function of the patient report.

Attachment

Wisconsin Prescription Drug Monitoring Program (PDMP) User Survey

1. What is your profession?

2. Are you registered to use the PDMP?

Yes

No

3. Overall, how satisfied are you with the PDMP?

Very Dissatisfied	Somewhat dissatisfied	I am not satisfied nor dissatisfied	Somewhat satisfied	Very satisfied	N/A
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. How often do you or your delegate obtain data about a patient from the PDMP?

- I obtain data about virtually all of my patients.
- I obtain data about most of patients.
- I obtain data about approximately half of my patients.
- I obtain data about less than half of my patients.
- I obtain data about a few of my patients when I have a concern.
- I do not obtain data about my patients.

5. Which of the following barriers prevent you from using the PDMP more?

- Limitations with internet access/computer equipment
- Not enough time
- Lack of benefit for my practice
- Lack of training on how to use the PDMP
- The system is not easy to use
- Other (please specify)

6. How many seconds does it normally take you or your delegate to log into and access data in the PDMP?

- Less than 10 seconds
- Between 10 and 30 seconds
- Between 30 and 60 seconds
- More than 60 seconds
- N/A

7. Rate the following qualities of the PDMP

	Very frustrating	frustrating	Neutral	Intuitive	Very intuitive	N/A
Process to Register	<input type="radio"/>					
Process to Access Patient Data	<input type="radio"/>					
Process to Reset Your Password	<input type="radio"/>					
Process to Manage Delegate Accounts	<input type="radio"/>					
Layout of the Prescription History Data	<input type="radio"/>					
Usefulness of the Prescription History Data	<input type="radio"/>					

8. Which of the following actions have you taken as a result of using the PDMP? *check all that apply*

- spoken with a patient about controlled substance use
- contacted prescribers or other pharmacies
- confirmed patient not misusing prescriptions
- confirmed patient was doctor shopping
- denied prescription for a patient
- reduced or eliminated prescriptions for a patient
- dismissed patient from practice
- referred or recommended for substance abuse treatment
- referred or recommended for pain management
- referred or recommended for anxiety (or other psychiatric disorder) management
- Other (please specify)

9. How would you describe the PDMP in three or fewer words?

10. Do you have any other comments, questions, or concerns?



SCOTT WALKER

OFFICE OF THE GOVERNOR

FOR IMMEDIATE RELEASE

November 1, 2016

Contact: Tom Evenson, (608) 266-2839

Governor Walker Highlights Efforts to End Drug Abuse in Wisconsin, Applauds Findings of First Report by the Controlled Substances Board

Number of opioid prescription doses dispensed decreases by 8.2 million

Madison – Governor Walker joins the Department of Safety and Professional Services (DSPS) in announcing the findings of the first report from the Controlled Substances Board, which highlights the success of the Wisconsin Prescription Drug Monitoring Program (PDMP). The report indicates that between July 1 and September 30, 2016, the number of opioid prescriptions dispensed decreased by 8.2 million as compared to the same time period in 2015.

"We continue to take steps to fight the opioid epidemic in Wisconsin," Governor Walker said. "The statistics released in this report are very encouraging and indicate the efforts we're putting forth to combat prescription drug abuse and misuse are steps in the right direction. This decrease of 8.2 million fewer doses dispensed means there are fewer doses that may sit in medicine cabinets with the potential of being misused."

The number of opioid prescriptions dispensed in Wisconsin between July 1 and September 30, 2015 was 1,280,367, which is equivalent to 83,233,662 drug doses. Numbers released in the Controlled Substances Board report show that between July 1 and September 30 of this year, there was a 9.63 percent reduction in opioid prescriptions and a 9.89 percent reduction in drug doses when compared to the same time period in 2015.

Additional information in the report includes the number of requests for data about their patients made by health care professionals, the number of law enforcement reports submitted to the PDMP, and the quantity of prescriptions dispensed by Wisconsin dispensers located in Wisconsin versus out-of-state dispensers. It also provides data on doctor shopping, pharmacy hopping, and the number of individuals receiving both opioids and benzodiazepine prescriptions.

"We are proud that this program is making inroads in our fight against opioid abuse," said DSPS Secretary Dave Ross. "We expect the report will continue to provide improved results, especially given our upcoming rollout of the enhanced program, which will launch in early 2017."

The Wisconsin PDMP was deployed in June 2013 and is administered by DSPS. Since its inception, the PDMP has been a tool to help health care professionals make more informed decisions about prescribing and dispensing controlled substance prescriptions to patients and discloses data as authorized by law to governmental and law enforcement agencies. It stores over 40 million prescription records submitted by over 2,000 pharmacies and dispensing practitioners.

A copy of the report is attached.

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- [PDMP Report.pdf](#)



Wisconsin Medical Society

FOR IMMEDIATE RELEASE

November 1, 2016

Contact

Kendi Parvin, 608.442.3748

kendi.parvin@wismed.org

Report shows positive steps in opioid epidemic fight

The statement below is attributable to Wisconsin Medical Society Chief Medical Officer Donn Dexter, MD, regarding today's Controlled Substances Board Report showing 8.2 million fewer opioids dispensed in the third quarter of 2016 compared to the previous year:

“Wisconsin’s collaborative effort to fight the opioid epidemic is already showing results in the latest data. With a nearly 10 percent drop in both the number of opioid prescriptions written and the amount of opioids dispensed to patients over a three-month period, Wisconsin physicians have stepped up their scrutiny in what’s best for patient care. Our partnership with state government, law enforcement and other health care groups is showing how Wisconsin can win this fight.

“The Report also shows there is important work still to be done. There is frustration over the difficulties physicians encounter when using the current Prescription Drug Monitoring Program – we continue to look forward to the roll-out of the new ‘enhanced’ PDMP. We also have yet to see the effectiveness of next year’s requirement that prescribers check a patient’s PDMP information before prescribing many drugs.

“If we want to keep building upon our initial improvements, we must continue the strong partnership that is unique to Wisconsin. The Wisconsin Medical Society is committed to providing physicians’ expertise into that collaboration on this critical issue.”

(The Controlled Substances Board Report is available [here](#).)

With more than 12,500 members dedicated to the best interests of their patients, the Wisconsin Medical Society is the largest association of medical doctors in the state and a trusted source for health policy leadership since 1841.

###

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil		2) Date When Request Submitted: 11/9/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? CBD Letter – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Discussion and consideration about the scheduling of CBD.			

August 31, 2016

Chad Zadrazil
Executive Director
Wisconsin Department of Safety and Professional Services
1400 East Washington Ave, Room 112
Madison, WI 53703

Dear Mr. Zadrazil,

On behalf of the epilepsy community, we, the undersigned organizations, urge you to support changes to state law to ensure access to Food and Drug Administration (FDA) approved therapies. The changes are necessary for timely access to medications derived from cannabidiol (CBD) once approved by the FDA and scheduled by the Drug Enforcement Agency (DEA).

We are hopeful that CBD derived therapies will help individuals living with rare epilepsies, and urge the Wisconsin Department of Safety and Professional Services to begin to explore changes in state law that may be necessary to ensure access to these promising treatment options once approved by the FDA. Acting now would protect patients and families. If the state fails to act, individuals would not be able to access these newly approved FDA therapies at pharmacies in the state or through their health insurance plan.

Our organizations represent the 3 million Americans living with epilepsy and seizure disorders. Together we foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. We have seen firsthand the devastation that uncontrolled seizures can bring, including developmental delays, medical complications, and even death. This is why, as organizations that represent individuals living with severe forms of epilepsy and uncontrolled seizures, we are committed to exploring and advocating for all potential treatment options for epilepsy, including new and innovative treatments approved by the FDA.

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. There is no “one size fits all” treatment option and about one million people live with uncontrolled or intractable seizures. Uncontrolled seizures can lead to disability, injury, and even death, and many individuals living with uncontrolled seizures suffer from rare epilepsies characterized by seizures that are difficult to treat with existing treatment options. Access to new treatments is particularly important for these individuals, who live with the continual risk of serious injuries and loss of life.

Dravet syndrome is a rare and catastrophic form of intractable epilepsy that begins in infancy and is highly treatment-resistant. It is a debilitating, life-long condition characterized by frequent and prolonged seizures, poor seizure control, and

developmental delays, as well as an increased risk of premature death including sudden unexpected death in epilepsy (SUDEP). There are currently no FDA approved treatments for Dravet, and nearly all patients continue to have uncontrolled seizures and other medical needs throughout their lifetime.

Lennox-Gastaut syndrome is a rare and often debilitating form of childhood-onset epilepsy that is highly treatment-resistant. It is characterized by multiple seizure types, and moderate to severe cognitive impairment. Individuals living with LGS experience an increased risk of serious injury because of frequent falls associated with uncontrolled seizures. Despite the FDA approved treatments for LGS, many individuals living with this rare epilepsy do not achieve seizure control and experience related cognitive impairments that severely limit quality of life.

Tuberous Sclerosis Complex (TSC) is a genetic disorder that causes several types of seizures, and the formation of tumors in many different organs, primarily in the brain, eyes, heart, kidney, skin and lungs. Infants are often diagnosed with TSC after experiencing infantile spasms, which lead to developmental delays, intellectual disability and autism. Older children and adults may develop multiple types of seizures including generalized, complex partial, and other focal seizures. Nearly 90 percent of people living with TSC have epilepsy and experience a variety of seizure types, and more than half don't respond to epilepsy medications.

The FDA is currently reviewing at least one CBD derived therapy (Epidiolex) that shows promise for the treatment of Dravet syndrome, Lennox Gastaut syndrome, Tuberous Sclerosis Complex (TSC), and other rare epilepsies. This potential treatment option has both Orphan Drug Designation and Fast Track Designation from the FDA for Dravet syndrome and also Orphan Drug Designation for LGS and TSC. Given the Fast Track Designation, this potential treatment option could be available as soon as early 2018. Since pure CBD is a Schedule I substance under most state schedules, state action is needed to ensure proper rescheduling of FDA-approved treatments derived from CBD.

Unless the Wisconsin Department of Safety and Professional Services acts to ensure access to new treatments derived from CBD that are approved by the FDA and scheduled by the DEA, these therapies would not be made available to individuals living with uncontrolled seizures in Wisconsin. Therefore, we urge you to begin to explore how the Wisconsin Department of Safety and Professional Services can take steps to ensure access to this potentially lifesaving treatment option if approved by the FDA.

We urge you to support the epilepsy community and begin to explore how Wisconsin can remove barriers that would prevent access to FDA approved medications derived from CBD so that individuals living with uncontrolled seizures can have timely access to innovative and lifesaving treatments. We welcome the opportunity to discuss this issue further with you. Please contact Angela Ostrom, Chief Legal Officer and Vice President of Public Policy at the Epilepsy Foundation, at aostrom@efa.org with any questions or concerns.

Sincerely,

Epilepsy Foundation
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation of Western Wisconsin
Aicardi Syndrome Foundation
Citizens United for Research in Epilepsy (CURE)
Danny Did Foundation
Dravet Syndrome Foundation
DUP15q Alliance
FACES at NYU Langone Medical Center
Gillette Children's Specialty Healthcare
Hope for hypothalamic hamaryomas
ICE Epilepsy Alliance
LGS Foundation
PCDH19 Alliance
Phelan-McDermid Syndrome Foundation
The Brain Recovery Project
Tuberous Sclerosis Alliance

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil		2) Date When Request Submitted: 11/8/16 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 11/15/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Informational Items – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <ul style="list-style-type: none"> - DEA Press Release: "DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017" - WI DOJ Posts: "Saving Lives" and "Maker of Opiate Addiction Treatment Drug, Suboxone, Accused of Conspiring to Keep Monopoly Profits" 			

HEADQUARTERS NEWS

October 04, 2016
Contact: DEA Public Affairs
(202) 307-7977

DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017

OCT 04 (WASHINGTON) - The United States Drug Enforcement Administration (DEA) has reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in 2017 by 25 percent or more, according to a [Final Order](#) being published in the Federal Register tomorrow and available for public inspection today. A handful of medicines were reduced by more, such as hydrocodone, which will be 66 percent of last year's level. Demand for these opioid medicines, represented by prescriptions written by DEA-registered practitioners, has decreased according to sales data obtained by DEA from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in America.

The Aggregate Production Quota (APQ) established by the Final Order is the total amount of a controlled substance necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25 percent buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages.

The 2015 National Survey on Drug Use and Health (NSDUH) released last month found 6.5 million Americans over the age of 12 used controlled prescription medicines non-medically during the past month, second only to marijuana and more than past-month users of cocaine, heroin, and hallucinogens combined.

Earlier this year the CDC issued guidelines to practitioners recommending a reduction in prescribing opioid medications for chronic pain. For years, DEA and others have been educating practitioners, pharmacists, manufacturers, and the public about the potential dangers of the misuse of opioid medications.

When Congress passed the Controlled Substances Act (CSA), the quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling "the quantities of the basic ingredients needed for the manufacture of [controlled substances]." The purpose of quotas are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion. DEA establishes APQs for more than 250 Schedule I and II controlled substances annually.

In setting the APQ, DEA considers data from many sources, including estimates of the legitimate medical need; estimates of retail consumption based on prescriptions dispensed; manufacturers' data on actual production, sales, inventory, exports, product development needs, and manufacturing losses; data from DEA's own internal system for tracking controlled substance transactions; and past quota histories. Once the aggregate quota is set, DEA allocates individual manufacturing and procurement quotas to those companies that apply for it. DEA may revise a company's quota at any time during the year if change is warranted due to increased sales or exports; new manufacturers entering the market; new product development; or product recalls.

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Saving Lives



Tuesday, November 1, 2016

On Friday, in Green Bay, I attended the Governor's first Opioid Task Force meeting. In speaking to the task force, I noted the success of DOJ's prescription drug disposal program and the records that have been set during the last few collections. The Lieutenant Governor thanked DOJ for our efforts, especially in light of this dose of reality: the majority of people (4 out of 5) using heroin started by abusing prescription painkillers. Because of the high turnover rate of prescription drug abuse to heroin use, our *Dose of Reality* campaign has promoted the following message:

1. Only use prescription drugs as they are prescribed to you by your doctor.
2. Store prescription drugs safely and securely.
3. Dispose of unused prescription drugs promptly and properly.

Following these steps will prevent additional prescription painkiller abuse in Wisconsin, make prescription painkillers less likely to fall into the wrong hands, and stop these drugs from entering our water supply.

During our fall Drug Take Back day on October 22, the state collected 58,729 pounds of unwanted medications and prescription painkillers (fentanyl patches, too!). And during my time at the Wisconsin Department of Justice over the last two years, Wisconsin has collected more than 200,000 pounds. That's the equivalent of 10 semi-trucks full of prescription drugs!!

Of course, we wouldn't be this successful without the help of local law enforcement and participation from citizens like you. When this campaign launched, Wisconsin had only 152 permanent medication return boxes registered in the state. Today, there are 295 boxes in law enforcement agencies across our state. And many more permanent drug disposal boxes can be found in pharmacies, hospitals, senior centers, and soon, right here at the Risser Justice Center in downtown Madison. We know, from stories told by law enforcement about drug collection, Wisconsinites are getting into the habit of disposing of their medications regularly at permanent disposal sites, not waiting until the biannual drug take back day.

As Drug Take Back Day has grown, so has the generosity of those who support the event. This fall, Fuchs Trucking provided three semi-trucks to haul the unwanted medications to an incinerator in Indiana. And the incineration was provided, free of charge, by Covanta Energy in Indiana.

Drug Take Back Day support is also provided by the U.S. Drug Enforcement Administration, the Wisconsin Department of Justice Division of Criminal Investigation, Wisconsin State Patrol, Indiana State Police, Wisconsin Department of Natural Resources, Wisconsin Department of Agriculture, Trade and Consumer Protection, Waukesha County, and Waukesha County Sheriff's Office.

The fight against this epidemic isn't over, but with continued effort from citizens, we will save lives.



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

BRAD D. SCHIMEL
ATTORNEY GENERAL

NEWS RELEASE

Maker of Opiate Addiction Treatment Drug, Suboxone, Accused of Conspiring to Keep Monopoly Profits

September 23, 2016

Johnny Koremenos
608-266-1221

MADISON, WI – Wisconsin Attorney General Brad Schimel and a bipartisan group of 35 other attorneys general filed an antitrust lawsuit today against the makers of Suboxone, a prescription drug used to treat opiate addiction. The lawsuit, being led by Wisconsin, alleges the companies engaged in a scheme to block generic competitors and cause purchasers to pay artificially high prices.

Reckitt Benckiser Pharmaceuticals, now known as Indivior, is accused of conspiring with MonoSol Rx to switch Suboxone from a tablet version to a film (that dissolves in the mouth) in order to prevent or delay generic alternatives and maintain monopoly profits.

The companies are accused of violating state and federal antitrust laws.

Suboxone is a brand-name prescription drug used to treat heroin and opioid addictions by easing addiction cravings.

“Wisconsin and the nation are suffering hundreds and thousands of opiate-related deaths each year, and we cannot allow treatment barriers to exist for those suffering from addiction,” said Attorney General Schimel. “We have an obligation to prevent monopolies, like the one the makers of Suboxone engaged in, in order to have an even playing field for the rest of the industry and to prevent artificially increased costs to consumers.”

According to the lawsuit, when Reckitt introduced Suboxone in 2002 (in tablet form), it had exclusivity protection that lasted for seven years, meaning no generic version could enter the market during that time. Before that period ended, however, Reckitt worked with MonoSol to create a new version of Suboxone – a dissolvable film, similar in size to a breath strip. Over time, Reckitt allegedly converted the market away from the tablet to the film through marketing, price adjustments, and other methods. Ultimately, after the majority of Suboxone prescriptions were written for the film, Reckitt removed the tablet from the U.S. market.

--more--

The attorneys general allege this conduct was illegal “product hopping,” where a company makes modest changes to its product to extend patent protections so other companies can’t enter the market and offer cheaper generic alternatives. According to the suit, the Suboxone film provided no real benefit over the tablet and Reckitt continued to sell the tablets in other countries even after removing them from the U.S. market. Reckitt also allegedly expressed unfounded safety concerns about the tablet version and intentionally delayed FDA approval of generic versions of Suboxone.

As a result, the attorneys general allege that consumers and purchasers have paid artificially high monopoly prices since late 2009, when generic alternatives of Suboxone might otherwise have become available. During that time, annual sales of Suboxone topped \$1 billion.

The lawsuit, filed in the U.S. District Court for the Eastern District of Pennsylvania, accuses the companies of violating the federal Sherman Act and state laws. Counts include conspiracy to monopolize and illegal restraint of trade. In the suit, the attorneys general ask the court to stop the companies from engaging in anticompetitive conduct, to restore competition, and to order appropriate relief for consumers and the states, plus costs and fees.

In addition to Wisconsin Attorney General Brad Schimel, attorneys general of the following jurisdictions joined in the lawsuit: Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Washington, D.C.

Wisconsin Assistant Attorney General Gwendolyn J. Cooley is coordinating the lawsuit.

A redacted version of the filed complaint will be available on the DOJ website later today. Redactions have been made pursuant to agreements with other state and federal parties to the litigation.

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