

DEA Minneapolis Pharmacy Diversion Awareness Conference

Update from the Minnesota
Board of Pharmacy

July 8 & 9, 2016

Cody Wiberg, PharmD, MS, RPh, Executive Director

Objectives

1. Describe changes in Minnesota state law concerning the Prescription Monitoring Program
2. Understand how pharmacies can legally collect unwanted pharmaceuticals from the public and from long-term care facilities
3. Describe the options pharmacists have for participating in the prescribing of naloxone



Pharmaceutical Waste

– History

– 2010 Legislation (changes to Minn. Stats. 151.37)

- (b) **Nothing in this chapter shall prohibit the following entities from possessing a legend drug for the purpose of disposing** of the legend drug as pharmaceutical waste:
 - (1) **a law enforcement officer;**
 - (2) **a hazardous waste transporter** licensed by the Department of Transportation;
 - (3) **a facility permitted by the Pollution Control Agency** to treat, store, or dispose of hazardous waste, including household hazardous waste;
 - (4) **a facility licensed by the Pollution Control Agency** or a metropolitan county as a very small quantity generator collection program or a minimal generator;
 - (5) **a county** that collects, stores, transports, or disposes of a legend drug pursuant to a program in compliance with applicable federal law or a person authorized by the county to conduct one or more of these activities; or
 - (6) **a sanitary district** organized under chapter 115, or a special law.
- (c) **Nothing in this chapter shall prohibit a person for whom a prescription drug has been dispensed** in accordance with a valid prescription issued by a practitioner **from transferring the legend drug to a county that collects, stores, transports, or disposes of a legend drug** pursuant to a program in compliance with applicable federal law or to a person authorized by the county to conduct one or more of these activities.

Pharmaceutical Waste

– 2016 Legislation

- Minn. Stats. 151.01. Subd. 39. **Ultimate user. "Ultimate user" means a natural person who possesses a legend drug that was lawfully obtained for personal use or for the use of a household member or for the use of an animal owned by the natural person or by a household member.**
- (b) **Nothing in this chapter shall prohibit an employee of the following entities, while acting in the course of employment, from possessing a legend drug for the purpose of disposing of the legend drug as pharmaceutical waste, provided that controlled substances listed in section 152.02, subdivisions 3 to 6, may only be collected and disposed of as allowed under section 152.105:**
 - (1) **a law enforcement officer agency;**
 - (2) **a hazardous waste transporter licensed by the Department of Transportation that has notified the Pollution Control Agency of its activity;**
 - (3) **a facility permitted by the Pollution Control Agency to treat, store, or dispose of hazardous waste, including household hazardous waste;**
 - (4) **a facility licensed by the Pollution Control Agency or a metropolitan county, as defined in section 473.121, as a very small quantity generator collection program or a minimal generator or household hazardous waste collection program; or**
 - (5) **a county that collects, stores, transports, or disposes of a legend drug pursuant to a program in compliance with applicable federal law or a person authorized by the county to conduct one or more of these activities; or**
 - (6) **a sanitary district organized under chapter 115, or a special law.**

Pharmaceutical Waste

– 2016 Legislation

- Minn. Stats. 151.37. Subd. 6a. **Collection of legend drugs by pharmacies. A pharmacy licensed under section 151.19 may collect a legend drug from an ultimate user, or from a long-term care facility on behalf of an ultimate user who resides or resided at the long-term care facility, for the purpose of disposing of the legend drug as pharmaceutical waste, provided that:**
 - (1) **a pharmacy may collect and dispose of controlled substances listed in section 152.02, subdivision 3 to 6, only as allowed under section 152.105; and**
 - (2) **a pharmacy that has established a controlled substance disposal program pursuant to section 152.105 may also collect and dispose of noncontrolled substance legend and nonlegend drugs, but only in the same manner in which it collects and disposes of controlled substances.**
- (c) **Nothing in this chapter shall prohibit a person for whom a ~~prescription~~ legend drug has been dispensed in accordance with a valid prescription issued by a practitioner from transferring the legend drug to a county that collects, stores, transports, or disposes of a legend drug pursuant to a program in compliance with applicable federal law or to a person authorized by the county to conduct one or more of these activities. an entity identified in subdivision 6.** Controlled substances listed in section 152.02, subdivision 3 to 6, may only be collected, stored, transported, and disposed of as allowed under section 152.105.

Pharmaceutical Waste

– 2016 Legislation

- **[152.105] DISPOSAL.** Controlled substances listed in section 152.02, subdivisions 3 to 6, may be collected and disposed of only pursuant to the provisions of Code of Federal Regulations, Title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, that are applicable to the disposal of controlled substances. Disposal of controlled substances and legend and nonlegend drugs must also comply with the requirements of section 116.07 governing the disposal of hazardous waste, and the rules promulgated thereunder.

Pharmaceutical Waste

– Summary

- “Ultimate users” are basically patients or their representatives
- Ultimate users now have several options for disposing of unwanted pharmaceuticals, including controlled substances:
 - Dropping them off at a permanent collection site operated by a law enforcement agency
 - Approximately 215 sites in Minnesota
 - Locations are available on the following Web site:
<http://search.earth911.com/?what=Medications&where=MN>
 - The Minnesota Pollution Control Agency has additional information at:
<https://www.pca.state.mn.us/living-green/managing-unwanted-medications>
 - Dropping them off during one-day special collection events managed by law enforcement agencies
 - Dropping them off at pharmacies with DEA-compliant collection receptacles
- Ultimate users that reside in long-term care facilities can have unused drugs disposed of in DEA-compliant collection receptacles that are placed in the LTCF. By a pharmacy.
- MPCA and the Board will be issuing a guidance document for pharmacies in the near future

Naloxone

– History

- Steven’s Law (Passed in 2014). Contains a couple of provisions:
 - (a) **A licensed physician, a licensed advanced practice registered nurse** authorized to prescribe drugs pursuant to section 148.235, **or a licensed physician's assistant** authorized to prescribe drugs pursuant to section 147A.18, **may authorize the following individuals to administer opiate antagonists**, as defined in section 604A.04, subdivision 1 (provided certain conditions are met):
 - **(1) an emergency medical responder** registered pursuant to section 144E.27;
 - **(2) a peace officer** as defined in section 626.84, subdivision 1, paragraphs (c) and (d); and
 - **(3) staff of community-based health disease prevention or social service programs.**
 - **A licensed health care professional who is permitted by law to prescribe an opiate antagonist, if acting in good faith, may directly or by standing order prescribe, dispense, distribute, or administer an opiate antagonist to a person without being subject to civil liability or criminal prosecution for the act.** This immunity applies even when the opiate antagonist is eventually administered in either or both of the following instances: (1) by someone other than the person to whom it is prescribed; or (2) to someone other than the person to whom it is prescribed.
 - Provides immunity to individuals who are not licensed health care professionals when, in good faith, they administer naloxone and when they seek medical assistance for someone who is experiencing an opiate overdose.

Naloxone

– History

- Pharmacists have been able to initiate, manage, modify and discontinue therapy while working under a protocol issued by a practitioner for over a decade.
- In 2009, pharmacists were added to this language found in Minn. Stats. 151.37:
 - **A licensed practitioner may prescribe a legend drug**, without reference to a specific patient, **by directing a** licensed dietitian or licensed nutritionist, pursuant to section 148.634; a nurse, pursuant to section 148.235, subdivisions 8 and 9; physician assistant; medical student or resident; or **pharmacist** according to section 151.01, subdivision 27, **to adhere to a particular practice guideline or protocol** when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered.
- That means that a pharmacist can issue a legally valid prescription without having the practitioner counter-sign the prescription. I would sign a prescription:
 - Cody Wiberg, R.Ph. Per naloxone protocol with Ingrid Anderson, MD. Note that Dr. Anderson would be considered the legal prescriber.

Naloxone

– 2016 Session

- Board of Pharmacy proposed language that would have allowed pharmacists to directly prescribe naloxone, without having to work under a protocol.
- Vigorously opposed by the Minnesota Medical Association.
- Alternative language was passed that:
 - Adds the following to the definition of “practice of pharmacy”
 - (10) participation in the initiation, management, modification, and discontinuation of therapy with opiate antagonists, as defined in section 604A.04, subdivision 1, pursuant to:
 - (i) a written protocol as allowed under clause (6); or
 - (ii) a written protocol with a community health board medical consultant or a practitioner designated by the commissioner of health, as allowed under section 151.37, subdivision 13.
 - Requires the Board of Pharmacy to develop a naloxone protocol
 - Requires the MN Department of Health to provide the following items to medical consultants of community based health boards:
 - (1) educational materials concerning the need for, and opportunities to provide, greater access to opiate antagonists;
 - (2) the opiate antagonist protocol developed by the board under paragraph ; and
 - (3) a notice of the liability protections under section 604A.04, subdivision 3, that are extended to cover the use of the opiate antagonist protocol developed under this subdivision.
 - Allows, but does not require, those medical consultants to enter into arrangements with pharmacists to use the Board-developed protocol and provides them immunity when they do so
 - Allows, but does not require, community based health boards to ask MDH to have one of its practitioners enter into the protocol with pharmacists
- If a community-based health board does neither, the pharmacists in that area are on their own – they would need to find some other practitioner willing to enter into a protocol

Past Efforts

– 2008 Session – Justin’s Law

- Meant to crack down on illicit Internet Web sites posing as “pharmacies”
- (c) A prescription or drug order for a legend drug the following drugs is not valid if it is based solely on an online questionnaire, unless it can be established that the prescription or order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:
 - (1) controlled substance drugs listed in section 152.02, subdivisions 3 to 5;
 - (2) drugs defined by the Board of Pharmacy as controlled substances under section 152.02, subdivisions 7, 8, and 12;
 - (3) muscle relaxants;
 - (4) centrally acting analgesics with opioid activity;
 - (5) drugs containing butalbital; or
 - (6) phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.
- Makes it illegal for a pharmacy licensed by the Board to knowingly fill prescriptions for these drugs when a legitimate examination hasn’t occurred
 - Explains how requirement for in-person examination can be met
- Worked with the National Association of Boards of Pharmacy and LegitScripts to shut down 6,000 Web sites that were falsely claiming to be licensed by our Board.



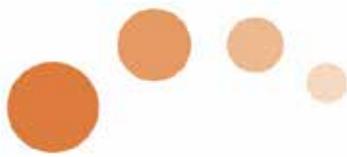
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Executive Director

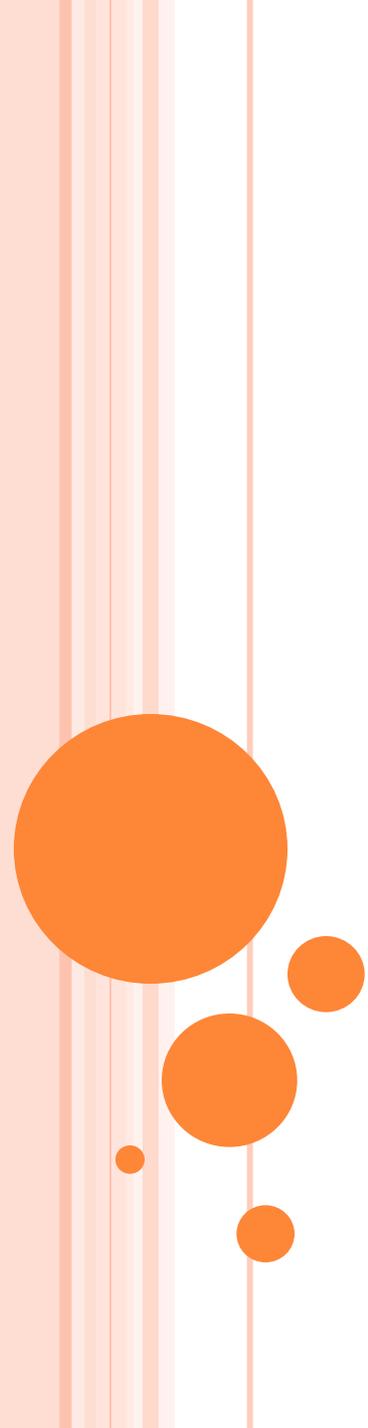
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MINPMP

MINNESOTA
PRESCRIPTION
MONITORING
PROGRAM



Barbara A Carter
Program Manager

UPDATES TO MN STATUTES, SECTION 152.126

- Effective 8.1.2016
 - ⌚ Reporting Requirement Changes
 - ⌚ Delayed until 9/1/16
 - Gabapentin
 - ASAP 4.2 data reporting format
 - ⌚ Update PMP customer notice
 - ⌚ Required Registration for PMP Account
 - ⌚ No later than 7/1/2017
 - MN licensed pharmacists
 - Practicing in MN
 - ⌚ Must maintain
 - Passwords expire every 120 days
 - Annual account profile update

PERMISSIBLE USE OF PMP DATA

- ⌄ Pharmacist or their delegate
 - ⌄ Dispensing or considering dispensing for a current patient.
- ⌄ Pharmacist only
 - ⌄ Providing pharmaceutical care and is being consulted by a prescriber. As long as the prescriber is requesting data in accordance with the law.
 - ⌄ Providing pharmaceutical care but **only with patient consent.**
- ⌄ Prescriber or their delegate
 - ⌄ Prescribing or considering prescribing for a current patient.
 - ⌄ Providing emergency medical treatment.
 - ⌄ Providing care and has reason to believe patient is abusing.
 - ⌄ Providing other medical care **but only with patient consent.**

PERMISSIBLE USE OF PMP DATA (CONTINUED)

Health Related Licensing Boards

&

Emergency Medical Services Regulatory Board (EMSRB)

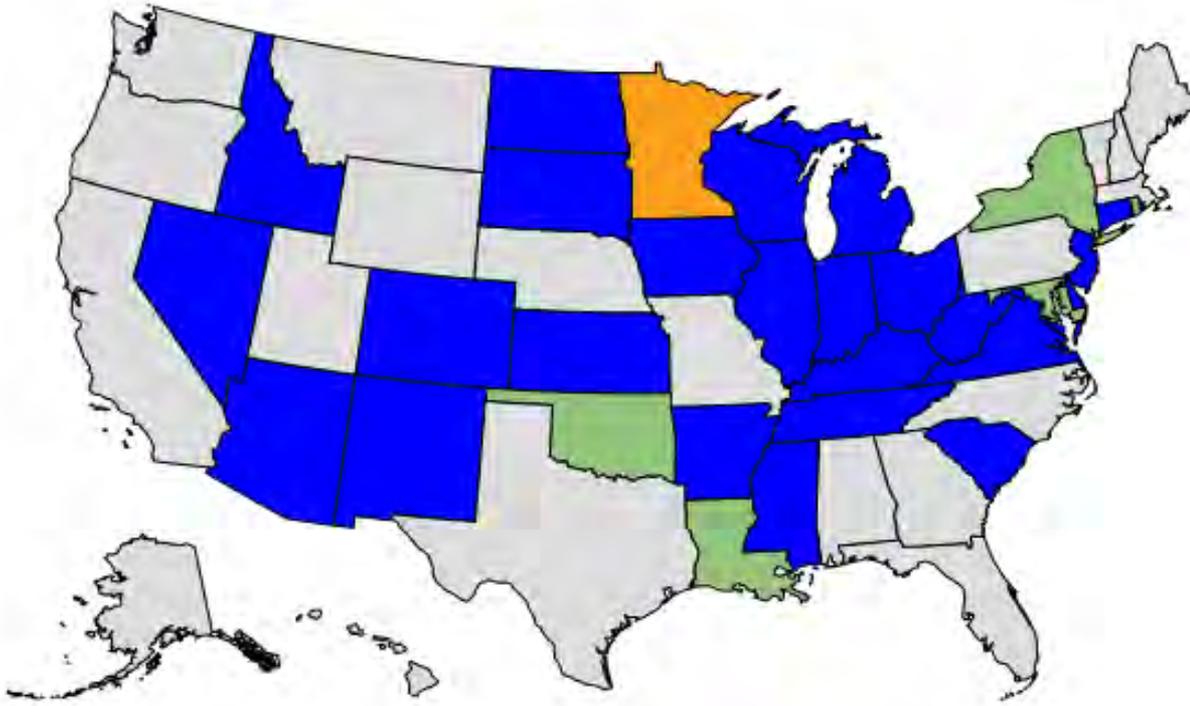
- Conducting bona fide investigation
- Alleging
 - ⌘ Impaired by use of a drug (controlled substances schedules II-V, butalbital and gabapentin)
 - ⌘ Engaged in activity that constitutes a crime defined in 152.025. (CS crimes in the 5th degree)
 - ⌘ Engaged in doctor shopping or presenting forged or otherwise false prescriptions.

PERMISSIBLE USE OF PMP DATA (CONTINUED)

Health Related Licensing Boards

- Conducting bona fide investigation
 - ⌘ Licensed prescriber
- Alleging
 - ⌘ Inappropriate prescribing a controlled substance (schedules II-V, butalbital and gabapentin)

STATES CONNECTED WITH MN (VIA PMP INTERCONNECT)



- | | |
|--------------|----------------|
| Arkansas | Mississippi* |
| Arizona* | Nevada* |
| Colorado | New Jersey* |
| Connecticut* | New Mexico |
| Delaware | North Dakota |
| Idaho | Ohio |
| Illinois* | South Carolina |
| Indiana | South Dakota |
| Iowa* | Tennessee |
| Kansas* | Virginia |
| Kentucky | West Virginia |
| Michigan* | Wisconsin |

*Delegates may not be permitted to access data in this state

★ LA,MD,NY,OK,RI
Coming soon!



Thank you!

www.pmp.pharmacy.state.mn.us