Missouri Board Of Pharmacy

"Lunch with the Chief Inspector"

2016 Legislative Update

August 25, 2016

Kimberly Grinston, J.D.
Executive Director

Tom Glenski, R.Ph.
Chief Inspector

Webinar Design

- All participants are muted, "listen only" mode
- Listen by telephone option

Continuing Education

- Board-approved for one hour (0.1 CEU) of live pharmacist continuing education
- Must be officially signed up and logged on via your computer
- CE credit will not be issued to those listening via the phone only
- Complete post survey within 48 hours of the webinar
- Instructions at the end of webinar
- CE credit is not submitted to CPE Monitor

Handouts and Recordings

- ❑Handouts posted on Board's website
- ❑Recording of webinar
  - Videos/Webinars under "Publications/Resources" on the Board's website

  - No CE credit for watching recording.

How to Ask a Question

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Webinar Objectives

- Discuss 2016 legislative session outcomes
- Provide 2015 inspection violation summary
- Answer questions

DISCLAIMER

****This webinar summarizes key legislation and does not include all legislation that may impact licensees. This presentation is provided for informational purposes only and does not constitute legal advice or a binding rule/opinion. In the event of a conflict, statutory language will control. Licensees should review the legislation referenced in their entirety to ensure compliance*****

What Passed?

- **SB 579 (Sen. Schaaf)**
- **SB 875 (Sen. Schaefer)**
- **SB 865 (Sen. Sater)**
- **HB 1568 (Rep. Lynch)**
- **Effective 8/28/2016**

SB 579 (Telehealth/Telemedicine)

- **Allows Missouri health care providers to provide "telehealth" or "telemedicine" services**
- **Contains requirements for prescriptions issued based on a "telehealth" or "telemedicine" examination**

SB 579 (Telehealth/Telemedicine)

- **"Telehealth" or "Telemedicine" defined as:**
  - The delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while such patient is at the originating site and the health care provider is at the distant site. Telehealth or telemedicine shall also include the use of asynchronous store-and-forward technology.

SB 579 (Telehealth/Telemedicine)

- **Definition does not include prescribing based solely on an internet questionnaire or prescribing based on a telephone examination without an ongoing and previous prescriber-patient relationship.**

SB 579 (Telehealth/Telemedicine)

- Includes other healthcare practitioners authorized to prescribe
- Includes APRNs & PAs acting within their licensed scope of practice
- Must still comply with all prescribing & collaborative practice requirements

Cam Missouri Pharmacies Fill A Telemedicine Prescription?

- YES, IF….
  1. The services are "within the [prescriber's] scope of practice"
  2. "Provided with the same standard of care as services provided in person"
  3. Cannot be based on an internet questionnaire
  4. Cannot be based on a telephone examination without a previously established and ongoing physician-patient relationship

Cam Missouri Pharmacies Fill A Telemedicine Prescription?

WHAT DOES THAT MEAN????

Cam Missouri Pharmacies Fill A Telemedicine Prescription?

- YES, IF….
  1. Missouri licensed prescriber
  2. Valid physician-patient relationship
  3. Rx complies with state/federal requirements
  4. Within the prescriber's "scope of practice"
  5. Meet the applicable standard of care

Cam Missouri Pharmacies Fill A Telemedicine Prescription?

- CANNOT Be Filled If….
  - ✓Based solely on an internet questionnaire
  - ✓Based on a telephone examination without a previously established and ongoing prescriber-patient relationship
  - ✓No legitimate practitioner-patient relationship exists.

Do you still need a physical examination?

- Board changed 20 CSR 2220-2.020
- Prescriber must have "performed a medical evaluation of the patient as required by law"
- Telehealth/Telemed prescriptions valid if they comply with the new law

SB 579 (Telehealth/Telemedicine)

- **What about controlled substances?**
- **See Board August Newsletter**
- **Ryan Haight Act**

SB 579 (Telehealth/Telemedicine)

- **What about out-of-state prescribers?**
- **Bd. of Healing Arts may provide additional guidance**
- **20 CSR 2220-2.020(11): "**A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire or without a valid preexisting patient-practitioner relationship."

SB 875 (Interchangeable Biosimilars)

- **Allows a pharmacist to substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber.**

SB 875 (Interchangeable Biosimilars)

- RPh must inform the patient that an interchangeable biological product has been substituted either verbally or in writing.
- Notify the prescriber of the product name and manufacturer either electronically, verbally or in writing within five (5) days of dispensing.
- Prescriber notification is not required if there is no FDA approved interchangeable biological product for the product prescribed or the prescription is a refill and no changes have been made from the prior filling.

SB 875 (Interchangeable Biosimilars)

- Substitution of interchangeable biological products must comply with all other Board rules applicable to generic substitutions, including, all labeling and recordkeeping requirements.

SB 875 (Mandatory Reporting)

- Have to report:
  - Final adverse action taken by another licensing state, jurisdiction or governmental agency against any license that is also issued by the Board
  - Voluntary surrender while under disciplinary investigation
  - Exclusion from any state or federally funded health care program
  - Board will do rules. Reports within seven (7) days. Form online.

SB 875 (Consolidating Refills)

- **§ 338.202, RSMo**
  - **Allows a pharmacist to consolidate refills of maintenance medication in a single fill**
  - **"Maintenance medication": A medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.**

SB 875 (Consolidating Refills)

- Pharmacists may dispense up to the total number of authorized dosage units, however, no more than a **90-day supply** can be dispensed at one time
- Patient must have **previously been prescribed** the "maintenance medication" for at least a **three-month period**
  - Statute doesn't require consecutive months
  - Doesn't require prior fills from the same pharmacy
  - Document eligibility

SB 875 (Consolidating Refills)

- **Consolidation not allowed if the prescriber indicates on the Rx that dispensing the initial amount followed by periodic refills is medically necessary**
- **Controlled substances cannot be consolidated.**
- **RPh should exercise professional judgment**
- **The Board suggests advising patients of any additional costs/insurance requirements.**

HB 1568 (Naloxone Dispensing)

- Authorizes Missouri licensed pharmacists to sell and dispense an "emergency opioid antagonist" without a prescription under protocol with an authorizing physician
- No additional Board license or certification required.
- No purchase restrictions (age, quantity, relationship)
  May be restricted in the protocol

HB 1568 (Naloxone Dispensing)

- No specific protocol requirements
- Sample protocol on the Board's website
- Protocol can be stricter than statute

HB 1568 (Naloxone Dispensing)

- Document all sales/dispensing
- Should include:
  - Transaction date
  - Product name, strength and dosage form;
  - Quantity; and
  - The names of the parties/entities (if known)

HB 1568 (Naloxone Dispensing)

- **First Responder Agencies**
- **Section 190.255 (2014)**
- "Any state or local law enforcement agency, fire department or ambulance service that provides documented training to its staff related to the administration of naloxone"
- **Sell to a "first responder agency" without a protocol**

HB 1568 (Pharmacist/Patient Education)

- **Naloxone Resource Center**
  - **Patient Brochure**
  - **Sample Protocol**
  - **Other state/federal resources**
  - **http://pr.mo.gov/pharmacists-naloxone.asp**

Who is at Risk of Overdosing?

People who:

- Mix opioids with other medications, illicit drugs, and/or alcohol
- Take more medication than prescribed
- Are new to using opioids
- Take opioid medication over a long time period
- Use opioids without doctor supervision
- People with a history of chemical addiction[1]

Heroin users are also at risk.

Signs of an Overdose

- Cold, clammy skin
- Slow, loud breathing or no breathing
- Low blood pressure
- Sleepiness, stupor or coma
- Small, constricted or "pinpoint" pupils[2]

Call 911 immediately if you suspect an overdose.

Tell them if the person is not responding or has stopped breathing and give a clear address and/or a description of your location.[2]

After calling 911, consider administering naloxone. An overdose-related death can be prevented if naloxone is given in a timely manner.[2]

[1] "When Pain Medications Become a Problem", Missouri Dept. of Mental Health, Division, of Behavioral Health (March 2016)
[2] Substance Abuse and Mental Health Services Administration, SAMHSA, Opioid Overdose Prevention Toolkit, HHS Publication No. (SMA) 16-4742, Rockville, MD: Substance Abuse and Mental Health Services Administration, 2016.

Common Opioids	Brand Name
Codeine	Tylenol with Codeine®, TyCo®, Tylenol #3®
Buprenorphine	Suboxone®, Suboxone®, Buraval®, Butrans®, Zubsolv®
Fentanyl	Duragesic®
Hydrocodone	Vicodin®, Lorcet®, Lortab®, Norco®
Hydromorphone	Dilaudid®
Meperidine	Demerol®
Methadone	Dolophine®, Methadose®
Morphine	MSContin®, Kadian®, Embeda®, Avinza®
Oxycodone	Oxycontin®, Percodan®, Percocet®, Roxicodone®

Need Help?

The Missouri Department of Mental Health, Division of Behavioral Health, has programs around the state to help people with alcohol and drug problems. There are programs for children, teenagers and adults. For more information, call the **Division of Behavioral Health** at (800) 575-7480 or (573) 751-4942 or e-mail them at dbhmail@dmh.mo.gov.

Missouri's Suicide Hotline can be reached at 1-800-273-TALK (1-800-273-8255)

Want More Information?

For patient education, videos and additional materials, please visit the **Board of Pharmacy's Naloxone Resource Center** at www.pr.mo.gov/pharmacists.asp. Additional information is also available at:

- www.endfcmisuse.org
- www.prescribetoprevent.org
- www.StopOverdose.org

OPIOID SAFETY AND NALOXONE

A Guide For Missouri Patients and Caregivers

State of Missouri Board of Pharmacy

pr.mo.gov/pharmacists

What are opioids?

Opioids are drugs that decrease the body's perception of pain. Because opioids can limit breathing, there is a risk of overdose. Opioids include illegal drugs like heroin as well as prescription drugs.

How to Avoid an Opioid Overdose

1. Take medicine only if it has been prescribed to you by your doctor
2. Do not take more medicine or take it more often than instructed
3. Call a doctor if your pain gets worse
4. Never mix pain medicines with alcohol, sleeping pills, or any illicit substance
5. Store your medicine in a safe place where children or pets cannot reach it
6. Learn the signs of overdose and how to use naloxone to keep it from being fatal
7. Teach your family and friends how to respond to an overdose
8. Dispose of unused medication properly[1]

[1] "When Pain Medications Become a Problem", Missouri Dept. of Mental Health, Division, of Behavioral Health (March 2016)

What is Naloxone?

Naloxone is a medication approved by the Food and Drug Administration (FDA) to prevent an opioid overdose. When administered during an overdose, naloxone can block the effects of opioids on the brain and restore breathing.

Naloxone Side Effects

The U.S. Substance Abuse and Mental Health Services Administration has issued the following caution:

"Get emergency medical help if you or someone has any signs of an allergic reaction after taking naloxone, such as hives, difficulty breathing or swelling of your face, lips, tongue or throat.

Call your doctor or 911 at once if you have a serious side effect such as:

- Chest pain or fast or irregular heartbeats
- Dry cough, wheezing or feeling short of breath
- Sweating, severe nausea or vomiting
- Severe headache, agitation, anxiety, confusion or ringing in your ears
- Seizures (convulsions)
- Feeling that you may pass out
- Slow heart rate, weak pulse, fainting or slowed breathing

This is not a complete list of side effects and others may occur. Talk to your doctor about side effects and how to deal with them."

How to Give Naloxone

Make sure you know how to administer naloxone in an emergency. Each naloxone kit comes with instructions that you should follow. Talk with your pharmacist if you have any questions.

After giving naloxone, stay with the person until emergency help arrives.

You could save a life!

SAMPLE MISSOURI PROTOCOL TEMPLATE FOR PHARMACIST NALOXONE DISPENSING

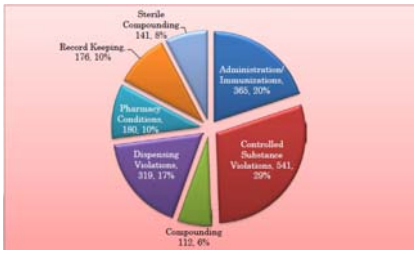
(This sample template can be used to build a pharmacist/physician naloxone protocol. This template is not mandatory and is provided by the Missouri Board of Pharmacy for informational purposes only. Pharmacist should independently determine applicable protocol terms/requirements in conjunction with their protocol physician.)

1. Pursuant to § 195.206, RSMo, this protocol authorizes the undersigned pharmacist(s) to dispense an emergency opioid antagonist without a prescription subject to the terms included herein. For purposes of the protocol, an "emergency opioid antagonist" is defined as naloxone hydrochloride that blocks the effects of an opioid overdose that is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering (also referred to herein as naloxone).
2. The undersigned pharmacist(s) may dispense any of the following formulations of naloxone and the applicable drug delivery devices without a prescription *(check all that apply)*:
   - ☐ Intramuscular naloxone
   - ☐ Intranasal naloxone
   - ☐ Auto-Injector
3. Pursuant to the pharmacist's professional judgment, the undersigned pharmacist(s) may dispense or distribute naloxone without a prescription to the following *(check all that apply)*:
   - ☐ Any individual or entity upon request
   - ☐ Patients of the physician
   - ☐ Any individual experiencing or at risk of experiencing an opioid-related overdose
   - ☐ Any person that may assist an individual who has experienced or may be at risk of experiencing an opioid-related overdose (e.g., family members, caregivers, associates)
   - ☐ Other: _____ *(Any age or other restrictions can be identified in this section)*

BOP Protocol Template (2016) **THIS DOCUMENT CONTAINS SUGGESTED PROVISIONS ONLY** Page 1

2015 Inspection Violation Summary

2015 Inspection Violation Summary



Administration/Immunization

- Notifications missing, late, or incomplete (36%)
- Protocol issues (19%)
- Administration prescription incomplete (10%)

Controlled Substance

- Annual inventory issues (39%)
- Prescription violations (incomplete, unsigned, not authorized, or electronic rx converted to fax) (18%)
- Improper security (12%)

General Compounding

- Compounding log inaccurate/incomplete (35%)
- Beyond-use date greater than ingredient's expiration date (29%)
- Compounding commercially-available products (14%)

Dispensing

- Dispensing errors (32%)
- Labeling errors (16%)
- Failure to verify source of faxed/photocopied rx (12.5%)

Pharmacy Conditions

- Improper drug storage (18%)
- Unsanitary conditions (15%)
- Permit issues (11%)
- Improper refrigeration /temperature controls (11%)

Record Keeping

- Policies & procedures missing/incomplete (65%)
- Prescription records incomplete, inaccurate, or missing (23%)
- Policies and procedures unavailable (4.5%)

Sterile Compounding

- Cleaning/unsanitary conditions (35%)
- Aseptic technique validation not conducted/documented annually (15%)
- Policies and procedures incomplete, missing, or not annually reviewed (14%)

Questions

Next *Lunch with the Chief* Webinar

- Tuesday, October 25, 2016
- Watch e-mail alerts

Continuing Education

- **Post Webinar Survey**
  - **Do not close web browser window**
  - **Click Close on *"The webinar has ended"* screen**
  - **Survey will then open**
  - **Phones and tablets may not receive survey**
- **Survey must be submitted within 48 hours of the webinar to receive CE credit**
- **Certificates will be mailed in 30 days**
- **Questions: compliance@pr.mo.gov**

A link to a recording of this webinar for viewing will be available on the Board's website within 30 days.