MISSOURI BOARD OF PHARMACY

NEWSLETTER

AUGUST 2016

CONTENTS

2016 LEGISLATIVE UPDATE

The 2016 legislative season has come to a close! A number of legislative bills were passed this year that will affect pharmacy. The following summary of key legislation is being provided for informational purposes. The summary does not include a comprehensive review of all legislative provisions passed this year. Licensees should independently review the recent legislative changes to ensure compliance. Copies of the legislation discussed below are available on the Board's website:

THE FOLLOWING LEGISLATION WILL BE EFFECTIVE ON AUGUST 28, 2016

TELEHEALTH/TELEMEDICINE

The Missouri General Assembly enacted **Senate Bill 579** which allows Missouri health care providers to provide "telehealth" or "telemedicine" services and also contains requirements for prescriptions issued based on a "telehealth" or "telemedicine" examination.

SB 579 defines "telehealth" or "telemedicine" 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.

Significantly, telehealth/telemedicine does not include prescribing based solely on an internet questionnaire or prescribing based on a telephone examination without a valid prescriber-patient relationship. [1]

Can Missouri pharmacies fill a telemedicine prescription?

Yes, a pharmacy may fill a prescription that was issued based on a "telehealth" or "telemedicine" exam if the prescriber/prescription complies with **SB 579**. The prescription must also comply with Chapter 338, RSMo, and all other state/federal law (including controlled substance laws).

Does the Board's rule still require a "physical" examination?

In anticipation of the telemedicine changes, the Board changed 20 CSR 2220-2.020 in 2016 to allow Missouri pharmacies to fill an otherwise valid prescription from an authorized prescriber "who has performed a medical evaluation of the patient as required by law." **SB 579** establishes the requirements for a qualifying medical evaluation.

Licensees should note that the rule still prohibits pharmacies from filling prescriptions based solely on an internet questionnaire or from filling a prescription issued without a valid prescriber-patient relationship. **[20 CSR 2220-2.020(11)]**

[1] SB 579 uses "telehealth" and "telemedicine" synonymously. For simplicity, this document references "telemedicine" which also includes "telehealth" as defined by SB 579.

Does SB 579 only apply to physicians?

No. Section 191.1145.2, RSMo, of the legislation provides:

> Any licensed health care provider shall be authorized to provide telehealth services if such services are within the scope of practice for which the health care provider is licensed and are provided with the same standard of care as services provided in person.

This allowance would include advanced practice registered nurses and physician assistants acting within their licensed scope of practice. The healthcare provider must comply with all applicable prescribing and collaborative practice requirements. Note: Only authorized prescribers may prescribe.

What about controlled substances?

The **Ryan Haight Act** and federal controlled substance laws include specific requirements for telemedicine and controlled substances. Licensees should consult with legal counsel, the DEA and BNDD to ensure compliance with any applicable federal law; the Board cannot give legal advice.

The DEA has issued the following caution regarding controlled substances:

> "The pharmacist who deliberately ignores a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense which may result in the loss of one's business or professional license."

BNDD has also issued the following excerpted statement regarding telemedicine and controlled substance activities:

> *The Missouri BNDD has reviewed the telemedicine statutes and discussed them with the Drug Enforcement Administration (DEA). The statutes provide definitions and make determinations on the delivery of telemedicine. As always, a state licensing board would make determinations regarding proper clinical care. For controlled substance prescribing and dispensing, the following issues are relevant:*
>
> - *The controlled substance activity must be by an authorized and registered professional who is acting within their scope of professional practice and within the guidelines of Chapter 195, RSMo and its regulations.*
> - *For Missouri practitioners who will be prescribing, the prescribers must have a professional Missouri license, a Missouri BNDD registration and a Missouri DEA registration. This registration must be at their primary practice location where they spend the most time.*
> - *According to the DEA, pursuant to 21 USC 802(54), if the telemedicine is taking place across state lines, the prescriber must be licensed and also have DEA registrations in both states; the state they are prescribing from and also the state where the patient is. If the patient is an in-patient admitted to a hospital, the hospital may have one of their local practitioners issue the drug orders or the hospital may allow that out of state consulting physician to use the hospital's DEA number pursuant to 21 CFR 1301.22(c).*

What is a valid telemedicine prescription?

To be valid, a telemedicine prescription from a Missouri prescriber must meet the following requirements:

- The prescriber must be licensed to practice in Missouri, and
- The prescription must be based on a valid physician-patient relationship, and
- The prescription must comply with all other state/federal prescription requirements, including, **20 CSR 2220-2.018** and **§ 338.056, RSMo** (two-line format), and
- The telemedicine services must be within the provider's "scope of practice" and meet the applicable standard of care.

A telemedicine prescription CANNOT be filled if:

- The prescription was issued based solely on an internet request or an internet questionnaire, or
- No legitimate practitioner-patient relationship exists, or
- The prescription was based solely on a telephone evaluation unless a previously established and ongoing prescriber-patient relationship exists.

How can I determine if there is a valid prescriber or physician-patient relationship?

SB 579 provides:

> (2) Prior to providing treatment, including issuing prescriptions, a physician who uses telemedicine shall interview the patient, collect or review relevant medical history, and perform an examination sufficient for the diagnosis and treatment of the patient. A questionnaire completed by the patient, whether via the internet or

telephone, does not constitute an acceptable medical interview and examination for the provision of treatment by telehealth.

Pharmacists should use their professional discretion when verifying that a valid physician-patient relationship exists. Once again, a prescription cannot be filled if the patient only completed an internet/telephone questionnaire.

How can I determine the provider's "scope of practice" or the "applicable standard of care"?

This would depend on the health care provider's licensing regulations and applicable medical standards. The Board cannot give additional guidance here. However, licensees should be attentive to prescriptions that appear to be outside of the prescriber's scope of practice.

What about internet questionnaires?

Under **SB 579**, pharmacies cannot fill a prescription that was issued based solely on an internet request or an internet questionnaire completed by the patient. Section 334.108.4 of the bill specifically provides:

> No health care provider shall prescribe any drug, controlled substance, or other treatment to a patient based solely on an internet request or an internet questionnaire.

What about telephone questionnaires?

SB 579 also prohibits pharmacies from filling a prescription that is based solely on a telephone questionnaire or on a telephone evaluation (see below).

The Board is aware that prescribers frequently issue prescriptions after consulting with a patient over the phone. SB 579 allows this practice and provides a prescription may be issued based on a telephone evaluation if "a previously ongoing physician-patient relationship exists" between the prescriber and the patient being treated. [Sec. 334.108.3]. This exception would allow prescribers to continue their current practice of consulting with patients over the phone if the provider and patient have a previously established ongoing relationship.

What about out-of-state prescribers?

The Board understands that the Missouri Board of Registration for the Healing Arts will be reviewing the applicability of SB 579 to out-of-state prescribers. In the interim, licensees are reminded that Board rule **20 CSR 2220-2.020(11)** provides:

> 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.

Prescriptions based solely on an internet-based questionnaire or that are issued without a valid preexisting patient-practitioner relationship are not valid in Missouri and cannot be filled, regardless of the location of the prescriber.

Pharmacists play a vital role in preventing prescription fraud and abuse. Licensees are reminded of their corresponding responsibility and should exercise sound professional judgment when determining if a prescription is legitimate. Once again, licensees should consult with DEA and BNDD for controlled substances.

INTERCHANGEABLE BIOSIMILARS

SB 875 revised Chapter 338, RSMo, to allow a pharmacist to substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber. An "interchangeable biological product" is defined as a biological product that the Food and Drug Administration:

a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or

b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

The pharmacist must inform the patient that an interchangeable biological product has been substituted either verbally or in writing. Additionally, pharmacists must 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.

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

MANDATORY REPORTING

SB 865 enacted § 338.075, RSMo, which requires all Board licensees, registrants and permit holders to report to the Board:

- Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug

distributor, drug manufacturer or drug outsourcing facility;

- Any surrender of a license or authorization to practice as a pharmacist, pharmacy, drug distributor, technician, intern pharmacist or drug outsourcer; and
- Any exclusion to participate in any state or federal funded health care program such as Medicare, Medicaid or MoHealthNet for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement.

An electronic reporting form is available on the Board's website. Pending final rulemaking, licensees should report a required action/exclusion to the Board within seven (7) days.

CONSOLIDATING REFILLS

SB 865 enacted § 338.202, RSMo, which allows a pharmacist to consolidate refills of maintenance medication in a single filling. "Maintenance medication" is defined as a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

- Pharmacists may dispense up to the total number of authorized dosage units, however, no more than a 90-day supply may be dispensed at one time.
- Controlled substances cannot be consolidated.
- The patient must have been previously prescribed the "maintenance medication" for at least a three-month period. The Board office has been asked if the required 3-month period has to be consecutive. The Board has also been asked if prior fills/refills must have been dispensed by the same pharmacy. The new statute is silent on both of these questions. Absent further statutory clarification, it appears licensees may consolidate refills for patients prescribed a maintenance medication for any 3-month period even if prior fills/refills were dispensed by another pharmacy.

Consolidation is not allowed if the prescriber indicates on the prescription that dispensing the initial amount followed by periodic refills is medically necessary.

Pharmacists should exercise their professional judgment when consolidating refills as consolidation may not be appropriate for all patients. The Board suggests advising patients of any additional costs/insurance requirements.

NON-RESIDENT DRUG DISTRIBUTOR LICENSING

Section 338.347, RSMo, has been revised to provide that non-resident drug distributors must be similarly licensed in their home state in order to renew their Missouri license. [**SB 865**]

NALOXONE DISPENSING WITHOUT A PRESCRIPTION

HB 1568 was passed which authorizes Missouri licensed pharmacists to sell and dispense an "emergency opioid antagonist" without a prescription under protocol with an authorizing physician. 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.

Who Can Dispense/Sell Naloxone?

Under the new law, any Missouri licensed pharmacist may sell and dispense naloxone pursuant to a protocol with a licensed physician. No additional Board license or certification is required.

What has to be included in a protocol?

The Board is in the process of reviewing applicable protocol standards. In the interim, the Board suggests that naloxone protocols include provisions/requirements for:

- Pharmacist education and training
- Emergency notification and documentation
- Patient education and counseling, and
- Protocol review, signatures and timeframe.

A **sample protocol template** is available on the Board's website on the Naloxone Resource page. Licensees should maintain proof of the authorizing physician's licensure in the pharmacy's records.

Who can buy Naloxone?

HB 1568 allows any individual or entity to purchase naloxone from a pharmacist. However, the pharmacist's protocol may include additional restrictions.

First Responder Agencies: Section **190.255, RSMo**, was enacted in 2014 which authorizes any licensed drug distributor or pharmacy to sell naloxone to a "qualified first responder agency". A "qualified first responder agency" is defined by statute as "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 in an apparent narcotic or opiate overdose situation." Pharmacists can sell naloxone to a qualified first responder agency without a protocol.

Is There a Dispensing Limit?

HB 1568 does not include dispensing limits. However, the pharmacist's protocol may include additional restrictions.

Documenting Naloxone Sales and Dispensing

Licensees must document all naloxone sales/dispensing. If naloxone is sold by protocol, the pharmacy must have a record of the sale that should include:

- Transaction date
- Product name, strength and dosage form; and
- Quantity; and
- The names of the parties/entities (if known)

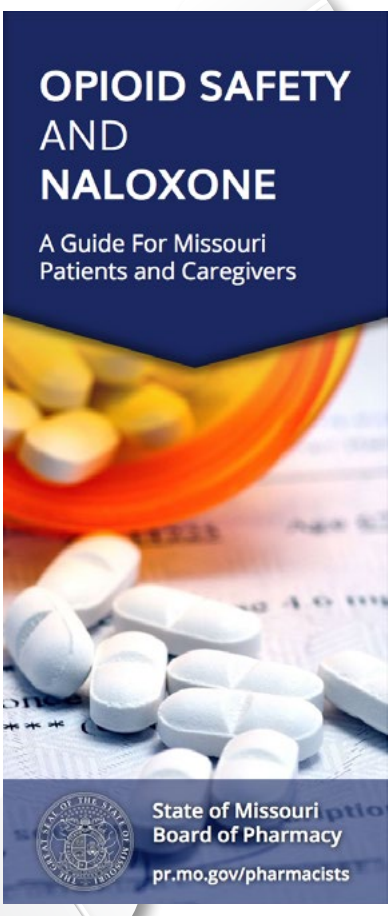
Licensees must comply with all prescription recordkeeping requirements if naloxone is dispensed by prescription.

Pharmacist Education

Pharmacists should educate themselves before dispensing or administering naloxone. To assist licensees, the Board has established a **Naloxone Resource page** on its website that contains a variety of free state and federal naloxone resources for pharmacists.

Patient Education

The Board also suggests that pharmacists educate patients on the proper use and administration of naloxone whenever possible. The Board has drafted a patient educational brochure titled: "Opioid Safety and Naloxone: A Guide for Missouri Patients and Caregivers." The free brochure is available on the Board's website. Copies of the brochure can also be requested online at **http://pr.mo.gov/pharmacists-naloxone.asp** or by contacting the Board office.



Also available on the Board's website is a free Opioid Overdose Prevention Toolkit published by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA). The Toolkit includes the following patient and caregiver resources that can be printed and provided to consumers:

- Safety Advice for Patients & Family Members: **http://store.samhsa.gov/shin/content//SMA16-4742/SafetyAdviceforPatientsAndFamilyMembers.pdf**
- Recovering from Opioid Overdose: **http://store.samhsa.gov/shin/content//SMA16-4742/RecoveringfromOpioidOverdose.pdf**
- Facts for Community Members: **http://store.samhsa.gov/shin/content//SMA16-4742/FactsforCommunityMembers.pdf**

Additional Guidance for Drug Distributors

HB 1568 allows "any person or organization acting under a standing order issued by a health care professional who is authorized to prescribe an opioid antagonist" to store naloxone. Missouri drug distributors may sell naloxone to a qualifying person or organization. Licensees should maintain documentation of the required standing order in their records and document the sale/distribution as otherwise required by law.

2018 RULE REVIEW

In 2012, the Missouri General Assembly enacted § 536.175, RSMo, which requires all state agencies to periodically review its rules for fairness, consistency and appropriateness and to file a report with the Missouri Joint Commission on Administrative Rules. The Board's report must be submitted in 2019.

To allow sufficient time for review, the Board will begin its rule review process in October of 2016. The public is invited to take part in the rulemaking process by submitting comments. A calendar of the review schedule showing when each rule will be reviewed is available **online**.

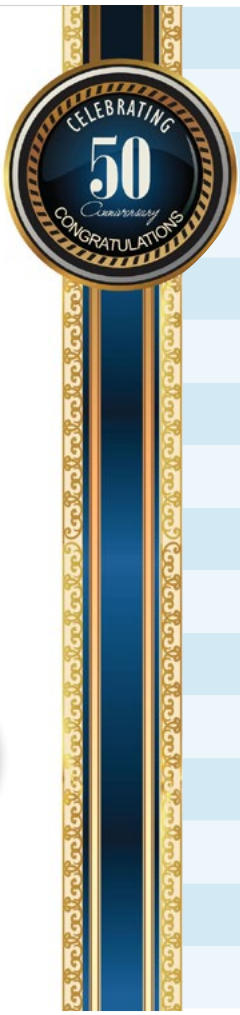
The Board is currently requesting public comment on the following rules on or before September 23, 2016:

- **20 CSR 2220-6.040** (Administration by Medical Prescription Order)
- **20 CSR 2220-6.050** (Administration of Vaccines Per Protocol)
- **20 CSR 2220-6.055** (Non-Dispensing Activities)
- **20 CSR 2220-2.650** (Standards of Operation for a Class J: Shared Services Pharmacy)

Comments may be submitted **online**, e-mailed to **MissouriBOP@pr.mo.gov** or mailed to the Board office.

GOLD CERTIFICATES

The following pharmacists will receive gold certificates in July in honor of maintaining a Missouri pharmacist license for 50 years. Congratulations to our newest "gold-certificate" pharmacists:



Anton H Amann
Ralph G Bixler
Robert E Brueggeman, Jr.
Vincent J Deblaze, Jr.
Albert D Durand
Joseph S Gialde
Fletcher M Gray
Dale D Heise
James B Mason, Jr.
Homer L Ruedin
Lew S Sanders
Robert F Schaefer
Alan J Schneider
George A Trebilcock
Larry D Tucker
Jeffrey S Wilson

DISCIPLINARY ACTIONS

PHARMACISTS:

Mark A. Greaves, #042059, Arnold, MO. Voluntary surrender of license, and cannot reapply for five (5) years. Admitted to diversion of controlled substances from employer. Pleaded guilty to violating 21 U.S.C.843 (a)(3). Section 338.055.2 (5), (6), (13), (15), and (17) RSMo.

Patricia A. Hoehn, #043616, Farmington, MO. Probation for five (5) years. Pleaded guilty to the Class D Felony of using "False Statements Relating to Health Care Matters" in the United States District Court, Eastern District of Missouri. Section 338.065.1, RSMo..

Grant M. Huning, #20130038703, Springfield, MO. Voluntary surrender of license, and cannot reapply for seven (7) years. Admitted to diversion of controlled substances from employer; adulterated drugs. Pleaded guilty to a Class C felony of tampering with consumer products. Section 338.055.2(1), (5), (6), (13), (15), and (17) RSMo.

Michael T. Jones, #045077, Lake Ozark, MO. Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to a felony regarding making false statements to federal officials. Section 338.065, RSMo.

Ryan T. Goff, New Baden, IL. Probation for two (2) years. Theft (non-drug). Section 338.055.2 (5) and (13), RSMo.

Mika L. Lindsey, #2004031557, Winona, MO. Probation for five (5) years. Found guilty, or entered a plea of guilty or nolo contendere to selling pseudoephedrine without proper certification. Section 338.055.2 (5), (6), (13), and (15) RSMo.

Teresa A. Lowe, #2001018155, Blue Springs, MO. Probation for two (2) years. Dispensing errors, Section 338.055.2 (5) and (13) RSMo.

Rhonda L. Maxwell, #2005007845, Monroe City, MO. Probation for three (3) years. As Pharmacist-in-Charge, failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Verified and dispensed prescriptions for pseudoephedrine not lawfully authorized by the doctor. Failure to report pseudoephedrine sales to the Missouri electronic pseudoephedrine tracking system, misbranding, record keeping violations, improperly labeled prescriptions. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.

Lee E. Ori, #2000148445, Des Peres, MO. Three (3) years probation. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and recordkeeping violations. Section 338.055.2 (4), (5), (6), (13), and (15), RSMo.

PHARMACIES:

County Market Pharmacy 375, permit #2011002754, Palmyra, MO. Probation for two (2) years. Failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Pharmacists verified and dispensed prescriptions for pseudoephedrine not lawfully authorized by the doctor. Employees created prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; recordkeeping violations; improperly labeled prescriptions. Section 338.055.2(5), (6), (13), and (15), RSMo.

Walgreens #09301, permit #2005014836, Sikeston, MO. Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain adequate security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.

Grove Pharmacy-Home Infusion Division, permit #005915, Springfield, MO. Probation for two (2) years. Dispensed compounded products to practitioners for office use and for administration on persons other than or in addition to the prescribed patient. Section 338.055.2 (6), (13), and (15), RSMo.