MISSOURI BOARD OF PHARMACY

NEWSLETTER

JUNE 2019

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Yes, It's Counseling and No, Technicians Can't Do It!

OBRA-90 and Board rule 20 CSR 2220-2.190 require that patients be offered an opportunity to consult with a pharmacist each time a prescription is dispensed (new and refill). Once requested, patient counseling may only be conducted by a pharmacist or an intern pharmacist operating under the pharmacist's direct supervision.

The Board has recently reviewed instances where pharmacists told a technician what to say in response to a counseling request instead of the pharmacist personally talking with the patient. In other instances, technicians advised patients on how over-the-counter (OTC) medication may interact with the patient's prescription medication or which OTC medication would complement their medication therapy. All of these activities constitute patient counseling that may only be performed by a pharmacist or supervised intern.

Patient counseling is one of the most important clinical services a pharmacist can provide and can help identify dispensing errors. Make sure your technicians are compliant with the law and are not counseling patients, either directly or indirectly.

Documenting DUR Overrides

Documenting why a Drug Utilization Review (DUR) alert is overridden is a good best practice that can be useful for more than just billing. While not required by the Board's rules, recording why a DUR was overridden and the pharmacist responsible for the override can be a valuable tool for tracking or supporting clinical activities. This information may also be helpful to other pharmacy staff or in the event of a staffing change.

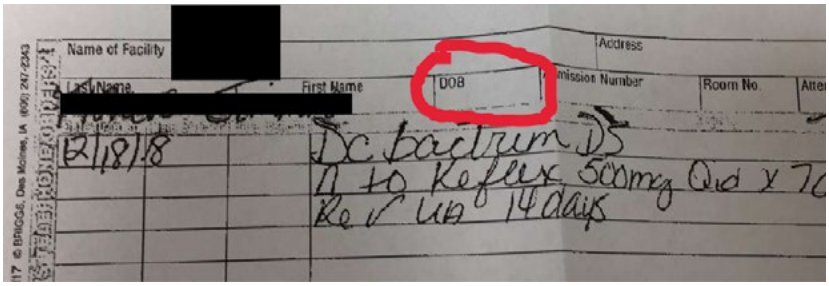
Proper documentation of DUR activities may also be beneficial in the event of a patient complaint. The Board has reviewed a number of complaints/investigations where a DUR was overridden, however, the pharmacy was unable to produce any information to support why the override was appropriate. In some instances, the pharmacist reported having lengthy discussions with the prescriber but failed to note or record any of their activities. If you do it, document it!

2019 Renewals

2019 is a renewal year for pharmacies, drug distributors, drug outsourcers and third-party logistics providers (3PLs). Renewal postcards will be mailed after August 1st. A few renewal tips to prevent delays:

- Your license/permit must be renewed by October 31, 2019. Do not wait until the deadline! Due to volume, it may take 3-5 days for the Board office to process your renewal. You may not continue operating in Missouri if your renewal is not completed in the Board's system by October 31st.
- All licenses/permits with an October 31, 2019 expiration date must be renewed in 2019, including, recently issued 3PL and drug outsourcer licenses/permits.
- Pharmacist-in-Charge (PIC) and Manager-In-Charge (MIC) changes must be submitted before you renew online. PIC and MIC change applications are available on the Board's website.
- Entities with multiple licenses must renew each license individually. For example, drug distributors who also hold a 3PL or a drug outsourcer license must renew each license separately.

Long Term Care Dispensing Patient Safety Concern



Pharmacies servicing long term care facilities (LTCF) regularly receive handwritten verbal order sheets from the LTCF. Sometimes these sheets have nothing more than the patient's name to identify the patient, with no other identifier such as date of birth or room number. The Board is aware of one instance where a pharmacy mistakenly entered orders for the wrong patient, resulting in a patient being hospitalized. Patient names can look and sound alike. Pharmacies servicing LTC facilities should make sure the pharmacy has adequate policies and procedures in place to ensure the pharmacy is receiving sufficient information from the facility when processing orders. When in doubt, ask!

Upcoming 2019 Board Meeting Dates

'19
JUL 10-11
Columbia, Missouri

'19
AUG 21-22
Columbia, Missouri
Strategic Planning Meeting

'19
OCT 15-16
Columbia, Missouri

Current Issues Under Board Review

The Board is currently researching/reviewing the following topics:

- Standards-based regulation
- Pharmacist working conditions/performance standards
- Pharmacy technician training, education & authorized duties
- Pharmacy technician alternative roles (e.g., community health workers, health liaisons)
- Automated dispensing machines in ambulatory settings

Monitor the Board's website for future Board agenda information.

Gold Certificates

Congratulations to our newest "gold certificate" pharmacists who will have maintained a Missouri pharmacist license for 50 years as of May 31, 2019:

Richard L. Poore	William Weeks III

Disciplinary Cases

PHARMACISTS

Bagby, Sara, #028306, Fayette, MO. Three (3) years' probation. As pharmacist-in-charge, dispensed prescription medication without a valid prescription. Section 338.055.2(5), (6), (13), and (15) RSMo.

Baraban, Steven D., #044793, Stilwell, KS. Voluntarily surrendered. As Pharmacist-in-charge, billed Medicaid for medications that were not shipped to patients.

Nance, Susann, Blue Springs, MO. Surrendered license. As staff pharmacist terminated from employment, accepted a returned prescription from a patient and filled a stock bottle with returned medication. Section 338.055.2 (5), (6), (13), and (15), RSMo.

Newton, Brian R. #042917, High Ridge, MO. Voluntarily surrendered, cannot reapply for 5 years. As pharmacist-in-charge, diversion of controlled substances for personal use without a valid, patient specific prescription. Section 338.055.2(5), (6), (13), (15), and (17), RSMo

Obermeier, Tina L, #041286, Webster Groves, MO. Surrendered, and cannot reapply for five (5) years. As staff pharmacist terminated from employment, admitted to personally taking and consuming controlled substances without a valid prescription. Section 338.055.2(5), (13), (15) and (17), RSMo.

Voyles, Collin, #2015010698, St. Louis, MO. Public Censure. As pharmacist-in-charge, administered immunizations without a current signed protocol or notification of intent. Section 338.055.2 (5), (6), (13), and (15) RSMo

Wang, Xiaojun, #2015031325, Stilwell, KS. Two (2) years' probation. As pharmacist-in-charge, dispensed C-II prescription medication without a prescription and proper labeling. Section 338.055.2(5), (6), (13), and (15) RSMo.

Wanyonyi, Robert W., #2017026909, Olathe, KS. Public Censure. As staff pharmacist, administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo

PHARMACIES

Central Drugs, #2009024959, La Habra, CA
Probation until September 3, 2023. Entered into an order with California Board of Pharmacy. Licensee was placed on probation for five years for aiding and abetting an employee practicing as an unlicensed pharmacist technician, failing to document end product testing for sterile injectable drug products. Section 338.055.2 (8) and (15)

Distinguished Pharmacy, #2016008670, Houston, TX. Revoked. Failed to renew the pharmacy permit; continued shipping legend drugs into Missouri. Section 338.055.2 (5), (6), (10), (12), (13), and (15) RSMo.

Earl Veterinary Supply Inc., #2014004560, Fayette, MO. Three (3) years' probation. Dispensed legend drugs without a valid prescription or proper authorization from prescriber, failure to follow pharmacy's policies and procedures. Section 338.055.2 (5) (6), (13), and (15), RSMo.

Wellfount Pharmacy/Beauvois Manor, #2018014360, St. Louis, MO. Three (3) years' probation. Operated Automated Dispensing System without an active permit. Section 338.055.2 (6) RSMo.

Wellfount Pharmacy/Hillside Manor, #2018013829, St. Louis, MO. Three (3) years' probation. Operated Automated Dispensing System without an active permit. Dispensed controlled substances prior to obtaining a registration from the Bureau of Narcotics and Dangerous Drugs. Section 338.055.2 (6) and (15), RSMo.

Wellfount Pharmacy/Rancho Manor, #2018013784, Florissant, MO. Three (3) years' probation. Operated Automated Dispensing System without an active permit. Dispensed controlled substances prior to obtaining a registration from the Bureau of Narcotics and Dangerous Drugs. Section 338.055.2 (6) and (15), RSMo.

Wellfount Pharmacy/Rosewood Care Center, #2018013424, Independence, MO. Three (3) years' probation. Operated Automated Dispensing System without an active permit. Section 338.055.2 (6) and (15), RSMo.

Wellfount Pharmacy/Seasons Care Center, #2018013423, Kansas City, MO. Three (3) years' probation. Operated Automated Dispensing System without an active permit. Dispensed controlled substances prior to obtaining a registration from the Bureau of Narcotics and Dangerous Drugs. Section 338.055.2 (6) and (15), RSMo.

Key Pharmacy, #2008019160, Federal Way, WA
One (1) year probation. Multiple FDA inspection violations. Voluntarily recalled certain sterile compounded drugs. Shipped products that were subject to the recall into Missouri. Section 338.055.2 (5), (6), (13), and (15). (Revision from February 2019 Newsletter)

DRUG DISTRIBUTORS

Cantrell Drug Company Inc., #2010023401, Little Rock, AR Three (3) years' probation. Multiple FDA inspection violations. Voluntarily recalled sterile compounded drugs. Disciplined by multiple states based on FDA inspections. Section 338.055.2 (5), (6), (8), (13), and (15) RSMo

Rochester Drug Cooperative Inc., #2014005393, Rochester, NY. Voluntary Surrender. Entered into a consent order with the United States District Court, Southern District of New York. Licensee admitted to record-keeping violations of the Controlled Substances Act. Section 338.055.2 (5), (13), and (15) RSMo

Stericycle, #2010004477, Springfield, MO. Five (5) years' probation. Continued to operate as a drug distributor after license expired. Section 338.055.2 (5), (6), (10), (12), (13), and (15) RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 2ND QUARTER 2019

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FDA LAUNCHES PILOT PROGRAM TO IMPROVE SECURITY OF DRUG SUPPLY CHAIN WITH AN INNOVATIVE APPROACH

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innova- tive and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and- trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the Federal Register.

FDA ANNOUNCES NEW EFFORTS TO INCREASE OVERSIGHT AND STRENGTHEN REGULATION OF DIETARY SUPPLEMENTS

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commis- sioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate prod- uct safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strate- gies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treat- ing, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at https://www.fda.gov/newsevents/ newsroom/ pressannouncements/ucm631065.htm.

TRUMP ADMINISTRATION RELEASES NATIONAL DRUG CONTROL STRATEGY TO REDUCE DRUG TRAFFICKING AND ABUSE

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its National Drug Control Strategy. The Strategy breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.

- **Treatment and recovery recommendations** in the Strategy include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.
- **Reducing availability** strategies are focused on dis- rupting illegal supply chains, defeating drug traffick- ers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal govern- ment to work closely with state and local governments, as well as other stakeholders. Additional information, includ- ing the full strategy document, is available on the White House website at https://www.whitehouse.gov/opioids.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWAR E® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dis- pose of medication and help prevent misuse and abuse of prescription medications. For more information about

PMP InterConnect and the AWARXE program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

NEW STUDY PREDICTS OPIOID EPIDEMIC WILL WORSEN OVER THE NEXT DECADE

More than 700,000 people will die from opioid over- doses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to JAMA Network Open. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the im- pact of the ongoing opioid overdose epidemic. The full article is available at https://jamanetwork.com/journals/ jamanetworkopen/fullarticle/2723405.

FDA WARNS OF POTENTIAL BLOOD PRESSURE MEDICATION SHORTAGES DUE TO RECALLS

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medi- cations containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a state- ment posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medica- tions with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufac- turing processes where we now know these risks could arise," the statement notes. The FDA press release is available at https://www.fda.gov/newsevents/newsroom/ pressannouncements/ucm629796.htm.

FDA RELEASES TWO DRAFT GUIDANCES RELATED TO REMS PROGRAMS

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS as- sessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at https://www.fda.gov/drugs/drugsafety/rems.