

MISSOURI BOARD OF PHARMACY

NEWSLETTER



JANUARY 2020

TABLE OF CONTENTS

New At The Board	1
Upcoming Board Meetings	2
Revised Rules	3
Caution on Timely Rx Transfers	4
Pharmacy Technician Renewals	4
Scam Phone Calls	4
Free CDC Opioid MME Calculator App	5
It's a CE Year	5
CE Chart	6
Board Review of Pharmacist	
Working Conditions	7
Pharmacist Workforce Survey Results	8
Gold Certificates	9
Rx Cares for Missouri Updates	10
Disciplinary Cases	11
NABP News	13

NEW AT THE BOARD

A new year means a lot of new Board activity. Here are a few notes on what's happening at the Board:

- Have a compliance question for an Inspector? An ["Ask An Inspector"](#) link has been added to the Board's website. Questions submitted by noon on Monday through Thursday, will receive a response on the same day (excluding holidays/exigent circumstances).
- Have a question for the Board office? An ["Ask The Office"](#) link has also been added to the Board's website. Board staff will contact you with a reply if contact information is provided. Anonymous questions may be answered in a future newsletter or e-alert.
- To increase public feedback and input, the Board has added a public suggestion/comment time to its regularly scheduled Board meetings. Licensees or members of the public may provide suggestions or comments during this time for Board consideration. Due to Sunshine law requirements, the Board may be legally required to discuss the topic at a future meeting after providing public notice. The Board continues to value and encourage feedback from licensees. Get



involved, be active and join us at a future Board meeting!

- Practice Guide Revision: The revised 2020 Missouri Pharmacy Practice Guide will be available on the Board's website in February 2020. A revised 2020 Pharmacy Self-Assessment form will also be posted online in February. Both documents contain important updates and changes, including, recent rule and legislative changes and new Inspector tips. Don't wait until an inspection to find out if you're in compliance! Use the revised Practice Guide and Self-Assessment form to evaluate your compliance today.
- Inspector Tips for the New Year: Watch this [two-minute video](#) for Inspector tips and reminders as you enter the new year.



UPCOMING BOARD MEETING DATES



APR

14-16

Hilton Garden Inn
3300 Vandiver Drive
Columbia, Missouri



JUL

8-9

Courtyard by Marriot
3301 Lemone Industrial Blvd.
Columbia, Missouri

*Check the Board's website for upcoming meeting agendas and open session meeting times.



REVISED RULES

The Board recently revised the following rules. Below are highlights of some of the revisions, please review the entire rules [here](#):

20 CSR 2220-2.120 (Transfer of Prescription or Medication Order Information)

This [rule](#) has been revised to now include requirements for both new prescription and refill transfers. Previously, requirements for transferring new prescriptions were included in 20 CSR 2220-6.030, which has been rescinded and combined into [20 CSR 2220-2.120](#). In addition to general cleanup, the following revisions were made:

- The new rule incorporates medication orders as defined by [§ 338.165](#), RSMo.
- Records at both the transferring and receiving pharmacy must document the identity of the person involved in the transfer. [\[20 CSR 2220-2.120\(2\)\(A\)\]](#). If a technician is performing the transfer, the technician's name should be documented in the pharmacy's records. Reminder: All controlled substance prescriptions transfers must occur between two pharmacists. [\[20 CSR 2220-2.120\(2\)\(A\)\]](#)
- Class C Long Term Care pharmacies may now transfer up to a 72-hour supply to another pharmacy for the purpose of initial dispensing for a long-term care facility patient without having to void the remainder of the prescription or medication order at the Class C pharmacy. [\[20 CSR 2220-2.120\(4\)\]](#)

20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operations)

This [rule](#) was completely revised in November 2019 with the assistance of an industry working group. Nuclear permit holders/pharmacists should review the rule in its entirety to ensure compliance. In addition to updating rule language and eliminating unnecessary paperwork/requirements, the following changes were made (this list is not exhaustive):

- New definitions and terms have been added, including "authorized nuclear pharmacist", "contingency prescription order", "nuclear pharmacy technician" and "preparing of radiopharmaceuticals"
- Only authorized nuclear pharmacists, intern pharmacists, and nuclear pharmacy technicians may prepare, compound, repackage, or dispense radiopharmaceuticals. [\[20 CSR 2220-2.500\(5\)\(D\)\]](#)
- All nuclear pharmacy technicians engaged in preparing, compounding, repackaging or dispensing radiopharmaceuticals must have completed a nuclear pharmacy technician training program provided by an accredited college or a nuclear pharmacy technician training program that meets the Guidelines for Nuclear Pharmacy Technician Training programs adopted by the American Pharmacist's Association (APhA). (Company sponsored programs that meet APhA's guidelines are acceptable.) [\[20 CSR 2220-2.500\(1\)\(I\) & \(5\)\(D\)\]](#)
- Nuclear pharmacies preparing, compounding or repackaging sterile preparations must now have a Class H Sterile Product Compounding permit, in addition to their current Class E permit. [\[20 CSR 2220-2.500\(3\)\]](#) Note: Currently licensed Class E permit holders can add a Class H classification by submitting a [Classification Change Application](#). No application fee will be charged to add Class H to an existing Class E permit if the application is received by March 1, 2020.
- Radionuclide generators must be stored and operated in an ISO 8 or better classified area [\[20 CSR 2220-2.500\(4\)\(A\)\]](#)



- A drug distributor license is no longer required for nuclear pharmacies using the exemption for non-patient specific prescriptions dispensed as allowed in the rule (see 20 CSR 2220-2.500(5)(D)).

Again, the Board encourages licensees to review the entire rule. Questions concerning the nuclear revisions may be submitted to Katie.DeBold@pr.mo.gov.

CAUTION ON TIMELY Rx TRANSFERS

The Board has received complaints from patients and licensees alleging that pharmacies are not transferring prescriptions within one (1) business day of receiving a request, as required by 20 CSR 2220-2.120(5). In some instances, the transferring pharmacy indicated they were attempting to contact the patient to confirm that the patient actually requested the transfer. Licensees have cited instances of suspected fraud/impersonation and expressed concerns with prescriptions being transferred without the patient's knowledge- especially for requests originated by a third party.

20 CSR 2220-2.120 does not prohibit the transferring pharmacy from contacting the patient for confirmation prior to providing the transfer. However, the rule provides the transfer must be completed within one (1) business day of receiving the request. Failure to make contact with the patient is not an exemption from this requirement. Delayed transfers could adversely affect patients by interrupting medication therapy. While the Board understands the concerns, the one (1) business day transfer requirement is mandatory.

The Board will be reviewing this issue in the future. In the interim, the Board cautions pharmacists *requesting* a transfer from another pharmacy to use their professional judgment and take any necessary steps if the source of a transfer request appears suspicious.

PHARMACY TECHNICIAN RENEWALS ARE HERE

Pharmacy technician renewals will be mailed on March 1st. The renewal fee this year will be \$35. Technician address changes should be submitted as soon as possible to avoid delays. As a reminder, pharmacy technicians must renew by May 31st. Pharmacy technicians not renewed by the May 31st deadline are not authorized to work.

SCAM PHONE CALLS

The Board has received multiple reports from licensees who have received scam calls from individuals claiming to be with the Board or a Board Inspector. According to the reports, licensees are told they are under investigation and may face discipline or criminal arrest if they do not pay a fine over the phone. In some instances, the scammer's name and phone number was identified as the "Board of Pharmacy" on caller ID.

THESE CALLS ARE SCAMS AND FAKE ATTEMPTS TO EXTORT MONEY FROM LICENSEES. A few notes:

- The Board of Pharmacy does not have fining authority and would NEVER request payment or bank account information over the phone.
- When in doubt check! A list of Board inspector names, phone numbers and e-mail addresses is available on the Board's [website](#).
- Hang up and call back! For calls reportedly from the Board office, hang up and call back on the Board's official line (573) 751-0091.



- Take action! If you receive a scam call from someone pretending to be with the DEA or the FBI, report the call to the [DEA's Extortion Scam Online Reporting Program](#) or the [FBI's Internet Crime Complaint Center](#). Scam calls can also be reported to the FCC using the Federal Communications Commission's consumer complaint form.

See the [DEA alert](#) on extortion scams targeting DEA registrants.

FREE CDC OPIOID MME CALCULATOR APP

In 2018, the Centers for Disease Control and Prevention (CDC) published the CDC Guideline for Prescribing Opioids for Chronic Pain. The CDC has also launched a free Opioid Guide App which includes a Morphine Milligram Equivalent (MME) calculator which may be helpful for pharmacists. For more information on the free app, visit the CDC's website at <https://www.cdc.gov/drugoverdose/prescribing/app.html>.

IT'S A CE YEAR!

Pharmacist renewals will be mailed on August 1st and must be completed by October 31st. Pharmacists will need 30 hours of continuing education (CE) to renew. CE must have been earned between November 1, 2018 and October 31, 2020. CE cannot be carried over from prior renewal years. Although the CE deadline is October 31st, pharmacists must attest that their CE is complete as part of the renewal application. This means your CE must be completed before a renewal is submitted. Submitting a false attestation is grounds for discipline.





Eligible CE must be provided by either an ACPE accredited provider or approved by the Board in advance. [\[20 CSR 2220-7.080\]](#) To be approved, non-ACPE classes/courses must be:

- Offered by a governmental or regulatory agency and approved by the Board, or
- Related to the practice of pharmacy as approved by the Board.

Applications to approve a non-ACPE accredited course may be found at: <https://pr.mo.gov/boards/pharmacy/375-0419.pdf> and should be submitted at least thirty (30) days prior to the date of the program. Only non-ACPE courses have to be pre-approved. The Board will not approve non-ACPE classes that have already been taken.

For licensees using third-party vendors to track CE hours, make sure that the CE dates for Missouri are correct. A number of licensees failed the 2016-2018 CE audit because they relied on a third-party vendor that used the wrong CE dates. Once again, eligible CE must have been completed between November 1, 2018 and October 31, 2020. *Don't wait until the last minute!* Check your CE and complete and outstanding hours early.

EARN FREE CE - JOIN US FOR THE NEXT "LUNCH WITH THE CHIEF WEBINAR"

- | | |
|---|--|
|  2/20 - Pharmacy Rule Update |  8/6 - Legislative Update |
|  3/26 - BNDD Update |  9/17 - Inspector Q&A |

*Board approved for Missouri CE Credit



Who?	Number of hours required	CE DATE RANGE (Your CE must be earned in this date range)	Can I use it as part of my 30 hours?	Notes
All Missouri licensed pharmacists (In-state & out-of-state) [20 CSR 2220-7.080]	30	11/1 - 10/31 of EVEN numbered years (e.g., Nov. 1 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.)	Yes	
Pharmacists dispensing/providing patient counseling on blood clotting factor concentrates [20 CSR 2220 - 6.100(3)]	4 hours of approved CE related to blood clotting factor concentrates, infusion treatment or therapy or blood clotting disorders or diseases	11/1 - 10/31 of even numbered years (e.g., Nov. 1 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.)	Yes	The CE requirement only applies to certain pharmacists dispensing blood clotting factor concentrates and pharmacists who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients. See 20 CSR 2220-6.100(3) for definitions of "blood-clotting product" and a "bleeding disorder patient" and for more information on who needs to comply.
Pharmacist Immunizing by Protocol [20 CSR 2220-6.050(3)]	2 hours of approved CE related to administering vaccines or CDC Immunization Guidelines	11/1 - 10/31 of even numbered years (e.g., Nov. 1, 2018 - Oct. 31, 2020; Nov 1, 2020 - Oct. 31, 2022, etc.)	Yes	CE may be also used to satisfy your biennial pharmacist CE requirements; Notifications of Intent to Immunize by Protocol can now be renewed with your pharmacist license.
Pharmacists with a Certificate of Medication Therapeutic Services ("MTS Certificate") [20 CSR 2220-6.070]	6 hours of approved CE related to medication therapy management	11/1 - 10/31 of even numbered years (e.g., Nov. 1 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.)	Yes	The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "O1" Drug Therapy Related ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).
Intern Pharmacists/ Pharmacy Technicians	NO CE REQUIREMENTS	NO CE REQUIREMENTS	N/A	



BOARD REVIEW OF PHARMACIST WORKING CONDITIONS

The Board received multiple letters and e-mails from pharmacists in 2019 asking that the Board review Missouri's requirements for pharmacy working conditions and staffing. Licensees raised concerns that pharmacists are being required to work an excessive amount of hours with limited breaks or rest times resulting in an adverse impact on patient care. Pharmacists also raised the following concerns:

- Not being given time for restroom breaks or uninterrupted time away from the pharmacy
- Unrealistic performance metrics or standards resulting in pharmacists feeling rushed or unable to practice safely
- Insufficient or inadequately trained pharmacy technician staff
- Insufficient time to adequately verify patient prescriptions or counsel patients
- Insufficient time for clinical services (e.g., immunizations, DUR), and
- Insufficient time to consult with other pharmacists regarding patient care during shift changes due to reductions in allowed work hours.

Overall, licensees expressed fears that patient safety was being jeopardized in favor of company profits.

So, what is the Board doing about it? First, the Board appreciates all of the licensee comments, letters and feedback. Your voice plays a vital role in helping the Board fulfill its mission to protect Missouri patients. Second, the Board has taken the following steps:

- The Board's General Counsel has been asked to review the Board's jurisdiction over the concerns raised. As a statutory agency, the Board can only exercise the powers delegated by statute. Several of the concerns implicate the federal Fair Labor and Standards Act as well as Missouri's labor laws. General Counsel has been asked to identify the scope of the Board's legal authority and what matters the Board is statutorily authorized to address.
- The Board discussed the workload/staffing concerns during its April, July and October 2019 open session meetings. Licensees and the public were invited to attend and provide comments. The Board also conducted an informal survey of Missouri pharmacists to gather additional feedback. Almost 1,000 survey responses were received (see summary of survey responses below).
- After reviewing the survey responses and comments, the Board voted to meet with selected Missouri pharmacy permit holders to gather input from a pharmacy owner perspective. The Board is particularly interested in how pharmacy owners determine staffing levels and what/how performance metrics are developed and enforced. The Board will be exploring several issues during these conferences, including, workflow design and the role reimbursement may play in staffing decisions. The Board anticipates concluding the permit holder meetings in April 2020.
- Board staff was asked to consult with other state boards of pharmacy to discuss regulatory approaches that have been implemented in other states. Staff subsequently consulted with several states, including, states with mandatory pharmacy-technician ratios and/or mandated rest breaks. So far, state responses have been mixed. While some states expressed support for measures such as mandatory rest breaks, other states reportedly received complaints from pharmacists that mandatory rest breaks impede workflow and patient care during high volume periods. Staff received similar feedback regarding pharmacy ratios. Several states indicated ratios allowed pharmacists to more effectively manage staff and allowed time for enhanced pharmacist clinical services, while other states are considering a repeal of their ratio requirements because of patient access and pharmacy operational concerns.



So, what's next? As you can see, this issue is complex and multi-faceted. What may work for a large retail chain may not be a viable solution for an independent pharmacy or for a specialty closed-door pharmacy. The Board's goal is to protect patients by finding a solution that will not adversely impact patient care.

The Board anticipates reviewing pharmacy working conditions/staffing at the July 2020 Board meeting after the pharmacy permit holder meetings are completed. The July discussion will be held in open session; Licensees and the public are welcome to attend.

In the interim, the Board cautions permit holders to review their business practices to ensure pharmacy staffing and working conditions are sufficient to safely provide patient care. Pharmacist burnout and fatigue are serious and can result in dangerous mistakes. The Board is particularly concerned with metrics or performance goals that adversely impact a pharmacist's ability to practice safely (e.g., # of immunizations provided/prescriptions dispensed). While the Board recognizes profit is a necessary goal for any business, patients should not be placed at risk by metrics that may not account for time needed to properly perform patient care activities.

Failure to maintain a safe working environment could result in official Board review. However, don't wait for the Board! Review your pharmacy's activities and performance standards now to make sure patients are protected.

For pharmacists: Please know that your concerns have been heard and the Board is working with staff, licensees and general counsel to identify the most effective approach for both licensees and Missouri patients. Licensees should remember their primary goal is to protect patients. Never do anything that places patients or your license at risk! Thank you for your continued patience as the Board continues to address this important issue. Licensees with complaints about specific patient care issues may file a complaint on the Board's [website](#).

PHARMACIST WORKFORCE SURVEY RESULTS

- 52% of respondents disagreed or strongly disagreed that they have adequate time to complete their jobs in a safe and effective manner; 11% were neutral while 38% agreed or strongly agreed.
- 57% of respondents disagreed or strongly disagreed that they have sufficient technician staffing to safely provide patient care; 11% were neutral while 32% agreed or strongly agreed.
- 46% of respondents disagreed or strongly disagreed that they have sufficient pharmacist staffing to safely provide patient care; 15% were neutral while 39% agreed or strongly agreed.
- 60% of respondents agreed or strongly agreed that they feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care at their practice site; 13% were neutral while 28% disagreed or strongly disagreed.
- 64% of respondents disagreed or strongly disagreed that they are given sufficient time away from the pharmacy for lunch or rest breaks during their shifts to allow them to safely provide patient care; 9% were neutral while 27% agreed or strongly agreed.

*Percentages have been rounded and may exceed 100%.



GOLD CERTIFICATES

Congratulations to our newest "gold certificate" pharmacists who have maintained a Missouri pharmacist license for 50 years as of January 1, 2020:

Anderson, Ray F	Naber, James J
Beauchamp, Gene L	Prather, William R
Bradfield, James E	Rawley, Elizabeth L
Bridges, Joseph F	Roberts, Margaret A
Bussen, Carolyn L	Sachan, Richard C
Clasen, William E	Seibel, John E
Crain, Jimmie L	Siler, Jon M
Daniel, Ronald	Tiburzi, Richard W
Desneux, Larry E	Toll, Mary Anne S
Dungan, Lamoyne	Way, William Z
Feuer, Daniel J	Wicke, Wallace R, III
Haynes, Harvey H	Willard, David T
Hendrickson, Dennis L	Yant, Neil A
Juenger, George I	Dunn, Heather B
King, Larry L	Goble, John L
Klostermann, Edward A	Koerble, George W
Kohler, Melvin E	Snyder, John C
Lima, Esther R	Windmoeller, Lawrence G
Littrell, Jack E	Morris, Wilford V
Manchester, Robert F, Jr	Weber, Mary S
Martin, John C	Schuch, Edward C, Jr
McHugh, William C, Jr	Cohen, Sanford

*Due to supplier changes, the Board is experiencing delays in issuing new gold certificates. Gold certificates should be available shortly. Thank you for your patience.



Rx CARES FOR MISSOURI UPDATES

Section 338.142, RSMo, which was enacted in 2017 gave the Board authority to establish a drug take-back program for controlled substances. The Board subsequently initiated the Rx Cares for Missouri Medication Destruction and Disposal Program (the "Program") in conjunction with Sharps® Compliance. The Program provides funding for collection receptacles and medication destruction costs for approved Program participants operating a public take-back program.

The Board began accepting initial applications in the fall of 2019. Approximately 65 Rx Cares Program participants have been approved so far with many of the collection receptacles already installed or scheduled for delivery. All of the Program participants are Missouri licensed pharmacies, including, a significant number of rurally located pharmacies. "As pharmacists, we want to make a difference in the lives of the patients and the communities we serve. It is with great pleasure that the Missouri Board of Pharmacy is providing assistance to Missouri pharmacists to make that difference. All of us have experienced the effects of prescription drug abuse on our patients, families, loved ones and our communities across this state. While we will not be able to solve this issue today, the Board is providing a foundational tool to increase the ability to dispose of unwanted medications from patients households with the support of public policy makers, our licensees and registrants. The Board applauds those pharmacists that have sought to be involved in this program in order to make our communities safer from this public health issue and to assist the Board in its mission of protecting the public," said President Douglas Lang.

Applications for this fiscal year are currently closed; The Board will begin accepting new applications for FY 21 on June 1, 2020. (See the Board's [website](#) for application and participation requirements).

Lisa Umfleet and Angela Ibaviosa
Parkland Healthmart in Desloge, Missouri



Miranda Phillips
Family Medicine Pharmacy



Troy Heckman
Savannah Family Pharmacy



David Gardner
Greenhills Pharmacy



Brandy Wirz, R.Ph. and
Marty Michel, R.Ph., M.B.A., C.D.E.
Key Drugs





Disciplinary Cases

● DRUG OUTSOURCERS:

Qualgen LLC, #2015029209, Edmond, OK.
Probation for the same period of time drug distributor permit is under discipline in Oklahoma. Licensee was disciplined in Oklahoma for deficiencies in practices for producing and compounding sterile drug products, failure to perform adequate investigations into sterility failures and engaging in the manufacturing of drugs and selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs. Section 338.055.2 (8), and (15).

Keown, James M., #040289, Columbia, MO.
Voluntarily surrendered. As staff pharmacist, diverted clonazepam and trazodone for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (5), (6), (13), (15) and (17), RSMo.

Mehrle, Andrew, #2014030498, Springfield, MO.
Temporary Suspension. Admitted to being under the influence of alcohol while practicing. Section 338.055.2 (1), (5), and, (13), RSMo.

● INTERNS:

Elmore, Jody L. #2014032970, Bethany, MO.
Revoked/Probation pending reapplication. Pled guilty to four felony counts of fraudulently attempting to obtain controlled substances. Section 338.055.2 (1), (5), (6), (13), (15), and (17), RSMo.

Rehan Rana, #2005011055, Ellisville, MO. Revoked, and cannot reapply for three (3) years. Pled guilty in the United States District Court, Eastern District of Missouri, to felony submitting a false tax return in violation of 26 U.S.C. 7206 (1), and felony Conspiracy to Commit an Offense against the United States in violation of 18 U.S.C. 371. Section 338.065, RSMo.

● PHARMACISTS:

Botts, Jerry E., #044270, Carl Junction, MO.
Revoked, and cannot reapply for seven (7) years. Pled guilty to Health Care Fraud in violation of 18 U.S.C 1347 in the United States District Court, Western District of Missouri.

Schafer, Steven J., Belton, MO. Probation for three (3) years. As Pharmacist-In-Charge, failed to obtain and comply with Class J permit requirements, violating state and federal drug laws and rules. Section 338.055.2 (6) and (12), RSMo.

Hoffmann, Kevin P., #2011000409, Troy, IL
Suspension six (6) months followed by probation two (2) years. As Pharmacist-in-Charge, practiced while suspended for failure to file/pay Missouri taxes. Section 338.055.2, (5), (6), (12), and (13), RSMo.

Spurgin, Andrew, Estherville, IA. Probation for five (5) years. Drug test revealed possession/use of Marijuana. Section 338.055.2 (13), (15) and (17), RSMo.

Turner, Courtney, #2013026235, Chaffee, MO.
Censure of license. As pharmacist-in-charge, administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo.



● PHARMACIES:

Downing Labs, #2017026657, Dallas, TX. Pharmacy permit surrendered, cannot reapply for five (5) years. Violated previous disciplinary order. Failed to produce records as requested. Multiple inspection violations: refused to allow inspectors access to the clean room, compounding commercially available products, assigning beyond use dates greater than ingredients expiration date, risk level 3 violations. Failure to submit compliance reports, failure to reimburse for inspection costs. 338.055.2(5), (6), (13) and (15) RSMo.

Howard Stark Professional Pharmacy, #002551, Kansas City, MO. Surrendered, cannot reapply for five (5) years. Pharmacy failed to have Class J license and failed to follow Class J requirements. Compounded in anticipation of need, failed to maintain accurate records. Section 338.055.2 (5), (6), (12), (13), and (15).

Stark Pharmacy, #2011033273, Overland Park, KS. Probation for three (3) years. Pharmacy failed to have Class J license and failed to follow Class J requirements. Compounded in anticipation of need, failed to maintain accurate records. Section 338.055.2 (5), (6), (12), and (15).

Walgreens #04406, permit #006627, Kansas City, MO. Publically Censured. Loss of controlled substances due to failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.

Walgreens #05278, Kansas City, MO. Probation for thirty (30) months. Violated previous disciplinary order. Loss of controlled substances. Multiple inspection violations: unlicensed technicians, unsanitary conditions in the pharmacy, outdated drug products in active inventory, failure to have a current signed and dated immunization protocol. Pharmacy failed to maintain complete compounding records. 338.055.2(6), (12) and (15) RSMo.

Wells Pharmacy Network, #2012040933, Ocala, FL. Probation for three (3) years. Shipped controlled substances to Missouri patients without a valid patient-practitioner relationship. Pharmacy has been disciplined in other states. Section 338.055.2 (5) (6), (8), (13), and (15), RSMo.



NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - JANUARY 2020



(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

DEA PROPOSES NEW REGULATIONS TO ADDRESS OPIOID EPIDEMIC

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, Federal Register announcement at <https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals>.

FDA ISSUES REPORT ON ROOT CAUSES AND SOLUTIONS TO DRUG SHORTAGES

Food and Drug Administration (FDA) has released a new report, Drug Shortages: Root Causes and Potential Solutions, which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;

- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management, which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at <https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages>.

HHS ANNOUNCES GUIDE FOR APPROPRIATE TAPERING OR DISCONTINUATION OF LONG-TERM OPIOID USE

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, covers important issues to consider when changing



a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA RELEASES DRAFT BEST PRACTICE DOCUMENT FOR POSTMARKET DRUG SURVEILLANCE

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at <https://www.fda.gov/media/130216/download>.

FDA ISSUES REVISED DRAFT GUIDANCE ON REGULATION OF HOMEOPATHIC PRODUCTS, WITHDRAWS 1988 COMPLIANCE POLICY GUIDE

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA

website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the Federal Register announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA WARNS OF INCREASE IN SCAM CALLS TARGETING PHARMACISTS AND OTHER DEA-REGISTERED PROVIDERS

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.