MISSOURI BOARD OF PHARMACY

NEWSLETTER

FEBRUARY 2022

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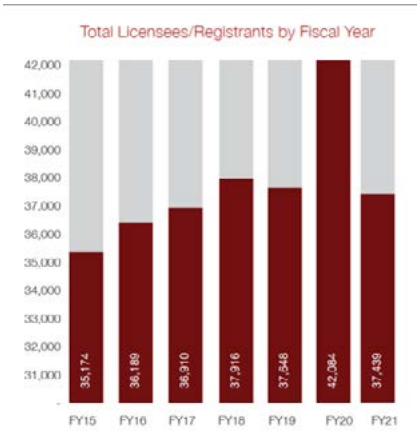
FY 21 BOARD ANNUAL REPORT

The Board's Fiscal Year 2021 Annual Report is now available on the Board's website. The Board is pleased to report another successful regulatory year! Highlights are reported below.

KEY HIGHLIGHTS:

- The Board held thirty (30) meetings during FY 21, including, twenty-two (22) virtual meetings, seven (7) email ballot meetings and one (1) Board sub-committee meeting [Rules Sub-Committee]. Additionally, the Missouri Hospital Advisory held six (6) virtual meetings facilitated by the Board. Total Board meetings increased by 30% from FY 19 and 42% from FY 18.
- Total appropriation and authorized transfers for FY 21 were $3,737,573. Board expenditures were $2,530,897.22, representing a 5.5% decrease. Board revenue remained consistent with a minor 1.7% increase.
- Total Board licensees/registrants at the end of FY 20 decreased by 11% to 37,439 licensees/registrants, as reflected below:
  - Drug Distributors (1,336)
  - Drug Distributor Manufacturer Registrants (101)

- Drug Outsourcers (45)
- Intern Pharmacists (1,699)
- Pharmacists- Active & Inactive (11,684)
- Pharmacists- Temporary (14)
- Pharmacies (2,663)
- Pharmacy Technicians (19,706)
- Third-party Logistics Providers (191)

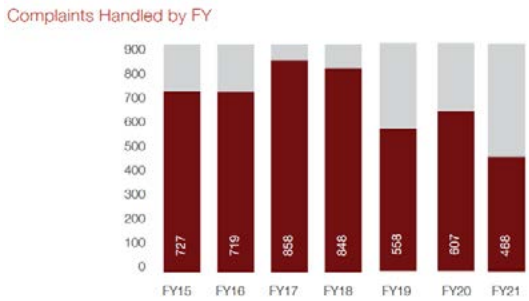


- Newly licensed pharmacists decreased by 25.4% representing the largest decrease in recent Board history

PHARMACIST LICENSE TOTALS

Active Licensees	11,375
Male	4,934
Female	6,528
Inactive Licensees	309
TOTAL LICENSED PHARMACISTS	11,684

- All Missouri counties now have a Missouri-licensed pharmacy for the first time since FY 13. Twenty (20) counties experienced an increase in the number of pharmacies. Eighteen (18) counties/areas declined in total pharmacies, compared to 37 counties in FY 20.
- The Board received/opened 468 new complaints in FY 21, representing a 22% decrease from FY 20. The decrease is likely attributable to the COVID-19 pandemic and fewer tax compliance cases from the Missouri Department of Revenue.

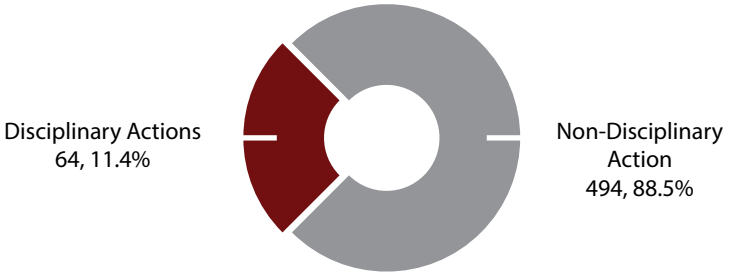


- The Board continued its modified inspection schedule due to COVID-19. 1,073 Board inspections were completed in FY 21, representing a 10% increase. Despite COVID-19 restrictions, total investigations remained consistent with a minor 2.3% decrease (206 investigations)
- Twelve (12) administrative rules were adopted or amended in FY 21, including two (2) COVID-19 related emergency rule amendments.
- Participants in the Rx Cares for Missouri statewide medication destruction program increased by 53% in FY 21 to 95 participants.
- Sixty-Five (65) licensees/registrants were disciplined in FY 21, including, 35 pharmacy technicians, 18 pharmacists, 2 intern pharmacists, 6, pharmacies & 1 drug outsourcer.

TOP COMPLAINT CATEGORIES

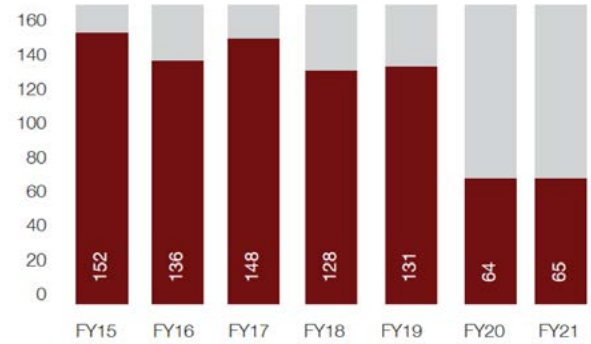
1. Disciplinary Action in Another State
2. Improper controls
3. Improper/Unauthorized Dispensing
4. Licensure Applicants
5. Unprofessional Conduct

NON-TAX RELATED COMPLAINT DISPOSITIONS



***Complaint dispositions includes complaints received in prior fiscal years but finally determined in FY 21. As a result, complaint dispositions in FY21 will not equal the number of new complaints received.*

PRACTICE RELATED DISCIPLINARY ACTION BY FY



2022 PHARMACIST CONTINUING EDUCATION & RENEWALS

2022 is a pharmacist renewal year. Renewal notices will be e-mailed on August 1st to the pharmacist address identified in the Board's records. Pharmacist renewals must be completed by October 31st. Pharmacists will not be able to practice after October 31st if their license is not renewed on time.

A few renewal tips:

- Update your e-mail address with the Board now to avoid renewal notification delays. E-mail updates can be sent to: MissouriBOP@pr.mo.gov. Please provide your name, license #, and your new e-mail address. You do not need to call the Board office.
- To renew your license, pharmacists must have completed **30-hours** of continuing education (CE) between November 1, 2020 and October 31, 2022. The required thirty (30) CE hours can be earned at any time during the renewal period (November 1, 2020, to October 31, 2002). Pharmacists do not have to complete fifteen (15) CE hours each year.
- Although the CE deadline is October 31st, pharmacists have to attest that their CE is complete to renew. This means your CE must be completed before a renewal is submitted. Submitting a false attestation is grounds for discipline. CE cannot be carried over from prior renewal years.
- Governor Parson issued a COVID-19 waiver that lowered the CE for the 2020 renewal period to 15-hours. The COVID-19 waiver has EXPIRED and does NOT apply to the 2022 renewals. **The full 30-hours of CE are required to renew in 2022.**
- For licensees tracking CE hours through a third-party vendor, make sure that the CE dates for Missouri are correct. Licensees have failed prior CE audits because they relied on a third-party vendor that used the wrong CE dates.

Eligible CE must be provided by either an ACPE accredited provider or approved by the Board in advance. The following non-ACPE classes/courses are eligible for approval:

1. CE courses/programs offered or provided by the Missouri Board of Pharmacy (e.g., Board webinar). Note: Pre-approval is not required for CE programs provided by the Board;
2. CE courses/programs offered by a state, federal or local governmental or regulatory agency that are pre-approved by the Missouri Board of Pharmacy;
3. Courses/programs that relate to the practice of pharmacy that are pre-approved by the Missouri Board of Pharmacy;
4. Training in suicide assessment, referral, treatment and/or management pre-approved by the Missouri Board of Pharmacy, or
5. Post-graduate college credits earned at an accredited pharmacy, medical, or dental educational institution of higher learning (see 20 CSR 2220-7.080(6)). CE credit will only be granted for post-graduate courses/classes. College courses/classes taken as part of your initial pharmacist degree curriculum are not eligible for CE credit.

Applications to approve a non-ACPE accredited course are available online 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.

Missouri law does not require continuing education in specific categories, except for pharmacists who are:

- Immunizing by protocol
- Providing medication therapy services, or
- Counseling bleeding disorder patients

Licensees should review 20 CSR 2220-7.080(6) for a complete listing of Missouri CE requirements. A CE Compliance Chart is also provided below. The Board randomly audits CE compliance. Proof of CE must be maintained in the licensee's records for two renewal cycles and provided on request.

E-ALERTS

Sign up on the Board's website to receive e-alerts on Board news, compliance updates and licensing changes.

PHARMACIST CE CHART

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, 2020 - Oct. 31, 2022; Nov. 1, 2022 - Oct. 31, 2024)	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, 2020 - Oct. 31, 2022; Nov. 1, 2022 - Oct. 31, 2024)	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, 2020 - Oct. 31, 2022; Nov. 1, 2022 - Oct. 31, 2024)	Yes	CE may also be 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, 2020 - Oct. 31, 2022; Nov. 1, 2022 - Oct. 31, 2024)	Yes	The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" 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	

Suicide Prevention: Section 324.046 provides training in suicide assessment, referral, treatment and management may qualify for pharmacist continuing education credit. However, non-ACPE accredited courses must be pre-approved by the Board. Credit will not be given for courses taken before the Board approves them. CE in suicide prevention is recommended by the Board but not required.

MOVING MISSOURI FORWARD

The Board is continuing its review of Missouri's pharmacy rules and statutes to modernize language, remove unnecessary/burdensome requirements, accommodate technology, and incorporate standards of practice in lieu of restrictive statutory/rule language.

Recent changes include:***

- 20 CSR 2220-6.040 & 6.050: Allows qualified pharmacy technicians to administer medication and immunize by protocol under a pharmacist's supervision
- 20 CSR 2220-6.055: Allows qualified pharmacy technicians to perform non-dispensing activities outside of a licensed pharmacy under a pharmacist's supervision
- 20 CSR 2220-2.725: Allows pharmacy technicians and intern pharmacists to perform remote data entry activities at a non-pharmacy site (e.g., from home. See below for pending emergency rule)
- 20 CSR 2220-6.200: Implements § 338.665, RSMo, and allows pharmacists to prescribe nicotine replacement therapy products as defined/authorized by statute
- 20 CSR 2220-3.040: Allows return-to-stock medication to be returned to the pharmacy automated dispensing system it was originally dispensed from (additional requirements apply)
- 20 CSR 2220-2.120: Allows Class C-Long Term care pharmacies to partially transfer initial non-controlled prescriptions without voiding the remaining prescription (72-hour supply limit).
- 20 CSR 2220-2.650: Broadens Class J Shared Service eligibility requirements to increase access to patient care [Effective 2/28/2022]

***Additional requirements apply for the above rules; Pharmacy technicians/intern pharmacists must be supervised by a pharmacist.

Pending Rule Changes (Filed but rulemaking process ongoing; Not currently effective)

- 20 CSR 2220-2.010 (Pharmacy Standards of Operation): Comprehensive rule update.
- 20 CSR 2220-2.090 (Pharmacist-In-Charge): Clarifies and updates PIC roles/responsibilities.

Rules Pending Approval (Submitted by Board for approval to initiate rulemaking process; Not currently effective)

- 20 CSR 2220-2.011 (Electronic Final Product Verification): Would allow a licensed pharmacist to use an electronic verification system to verify the accuracy of a final prescription and affixed label.
- 20 CSR 2220-2.012 (Technology Assisted Verification): Would allow licensed/registered pharmacy technicians and intern pharmacists to use a technology assisted verification system to verify final non-controlled prescriptions/medication orders that will be dispensed in the manufacturer's unopened unit of use package, or to verify medication repackaged in compliance with 20 CSR 2220-2.130 that has been previously verified by a pharmacist. ***Pharmacist supervision required.***

Draft Rules in Progress (In drafting process; Not effective)

- 20 CSR 2220-6.025: Would allow pharmacists to dispense HIV post-exposure prophylaxis under protocol with a Missouri licensed physician, as authorized by § 338.730. *Draft rule under review by the Missouri Bd. of Registration for the Hearing Arts.

EMERGENCY REMOTE DATA ENTRY RULE NOW EFFECTIVE

Emergency rule 20 CSR 2220-2.725 became effective on **February 4, 2022**, and allows pharmacy technicians and intern pharmacists to perform remote data entry activities from a remote site located in a U.S. state or territory. The extended allowance was previously authorized by a COVID-19 waiver that expired on December 31, 2021. A proposed amendment that mirrors the emergency rule will be effective in the spring of 2022. The emergency rule allows pharmacy staff to continue remote data entry activities in a U.S. state or territory until the official rule amendment is finalized. The full emergency rule is available now on the Board's website.

SAFE-AT-HOME OPIOID SAFETY INITIATIVE

MO HealthNet and the Missouri Board of Pharmacy continue to respond to the opioid crisis afflicting Missourians. The Missouri Board of Pharmacy recently announced the "Safe at Home" medication disposal initiative, in partnership with MO HealthNet and the Missouri Department of Health & Senior Services (DHSS). Effective January 15, 2022, MO HealthNet will now reimburse pharmacy providers who dispense at-home medication disposal packets to eligible MO HealthNet participants who are at risk of experiencing an opiate-related overdose.

MO HealthNet has selected DisposeRx® packets as the preferred medication disposal packet. DisposeRx® is an at-home oral medication disposal packet composed of FDA-approved materials and provides a simple, convenient and effective solution for the disposal of unused or expired medication. These convenient at-home medication disposal packets will allow MO HealthNet participants to safely and easily dispose of unused opioids, preventing accidental overdoses.

DHSS has issued a statewide standing order authorizing Missouri licensed pharmacists practicing in the state of Missouri to order and dispense DisposeRx® packets to eligible MO HealthNet participants at risk of experiencing an opiate-related overdose. Pharmacists may bill MO HealthNet for DisposeRx® packets:

- Pursuant to DHSS' statewide standing order for DisposeRx packets, or
- Pursuant to a prescription from an enrolled MO HealthNet provider with prescriptive authority.

Pharmacy providers can bill MO HealthNet for the cost of the DisposeRx® packet, up to $1.20 per packet, plus the current professional dispensing fee at the time the product is dispensed, currently $12.70. Pharmacies must submit a Usual and Customary cost that equals or exceeds the allowed amount to receive the full reimbursement allowed. A pharmacist **must** counsel participants on overdose risk factors and safe medication disposal whenever a DisposeRx® packet is dispensed.

All MO HealthNet pharmacy providers are eligible to submit MO HealthNet claims for DisposeRx® packets under the "Safe At Home" initiative. Visit MO HealthNet's website for additional information on enrolling as a MO HealthNet provider.

"Improving patient health and safety are the Board of Pharmacy's top priorities," said Board President James L. Gray, II, Pharm D., MBA. The Board looks forward to partnering with MO HealthNet on this important patient safety initiative.

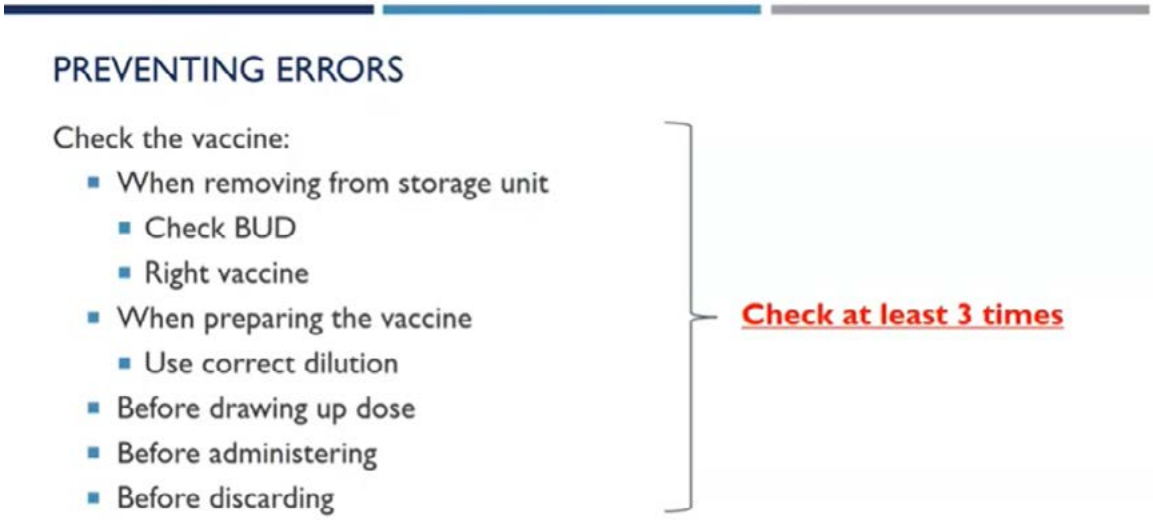
The MO Health Net bulletin and the DHSS Standing Order for Drug Deactivation and Disposal Products are available on the Board's website.

COVID-19 VACCINE SAFETY

The Missouri Department of Health and Senior Services recently reported that COVID-19 vaccine error rates are increasing according to the weekly reports to the national Vaccine Adverse Event Reporting System (VAERS). According to DHSS, common errors include:

- Vaccines are being administered after expiration
- Vaccines administered after "Beyond Use Date"
- Vaccines administered when a temperature excursion has occurred
- Ages are not checked prior to vaccine administration
- Pfizer product diluted incorrectly
- Wrong dose of vaccine
- Wrong vaccine administered

DHSS recommends the following steps to prevent errors:



PHARMACY ROBOTICS & ERRORS

Many pharmacies have introduced dispensing robots into their workflow to improve efficiency, accuracy, and security. Robotics can be a powerful tool in achieving these goals, but only if proper protocols are established and consistently followed.

Pharmacy robotics frequently employ a system of cassettes (canisters/units/cartridges), each containing a specific drug/strength. Generally, these cassettes are filled from stock bottles, and information about the contents entered into the system using barcode technology or a combination of barcode technology and manual entry. Errors related to these systems are often due to human error during the cassette filling process.

The Board recommends the following patient safety steps when working with pharmacy robotics:

- Staff should be properly trained on system operations and the pharmacy's policies/procedures. Don't just teach...observe! Watch pharmacy staff in action to make sure they're not missing critical steps.
- Pharmacy staff should NOT fill multiple cassettes at the same time or have multiple stock bottles for different medication open simultaneously. This could lead to pouring contents from a stock bottle into the wrong cassette.
- Built in safeguards, such as barcode technology, should be used appropriately.

    1. For example, many cassettes are large enough to hold contents from multiple stock bottles. Board inspectors have observed errors due to staff scanning one representative stock bottle (either once or multiple times), instead of scanning each stock bottle being used to fill the cassette. This process is dangerous and could lead to the wrong drug or strength being used- especially when look-alike packaging and/or dosage units are involved.
    2. The Board recommends individually scanning each stock bottle prior to filling a cassette. For systems that can't scan stock bottles individually, the Board recommends only allowing pharmacy staff to use one stock bottle at a time when filling cassettes.

- Board Inspectors have observed instances where pharmacy staff scanned an empty stock bottle for convenience purposes, instead of scanning the actual stock bottle being used. This could lead to inaccurate label information being recorded (e.g., wrong manufacturer, lot number, expiration date). More critically, pharmacy staff may not catch when they're using the wrong medication or strength. Make sure staff are properly trained and safeguards are in place to prevent errors.
- Missouri pharmacy rule 20 CSR 2220-3.040 was recently amended to allow return-to-stock (RTS) medication (those never received by or delivered to the patient) to be returned to a pharmacy's automated dispensing system it was originally dispensed from (additional requirements apply). RTS medication may not be comingled with other manufacturers within the same cassette, and the new expiration date for all medication in the cassette must become the shortest of any of the medication contained within the cassette/automated dispensing unit. Additionally, a pharmacist must verify that RTS is properly stocked and loaded in the automated system.
- Pharmacy management and staff should collaboratively discuss errors and near misses and take appropriate steps to prevent future issues. Be proactive and make sure the pharmacy's policies/procedures address potential challenges, such as, what checks should be in place when making cassette assignment changes, training new staff on the robotics system, and when/how to contact the manufacturer if additional challenges or concerns arise.

GOLD CERTIFICATES:

Congratulations to our newest "gold certificate" pharmacists who will have maintained a Missouri pharmacist license for 50 years:

Dennis	R	Bond	
Nancy	N	Wilhelm	
Charles	W	Bond	
Edward	J	Pusczek	Jr
David	L	Lutz	
Edwin	L	Powers	
Gail		Orr	
Roy	H	Eberhart	II
Bernard	D	Heit	
Bernard	J	Bristow	
Michael	J	Stephens	

Donald	W	Grove	Jr
Eugene	W	Perkins	Jr
Russell	U	Nesbitt	Jr
Ronald	P	Hartman	
Mark	J	Beckwith	
Judith	K	Peipert	
Benjamin	M	Tally	Jr
Herbert	J	Simon	
James	A	Cordes	
Robert	D	Lewis	
John	R	Flow	

DISCIPLINARY ACTIONS

DRUG DISTRIBUTORS:

Focus Laboratories Inc., #2019005961 – North Little Rock, AR. Public Censure. Operated without a valid license. Section 338.055.2(6), (8), and (15), RSMo.

The Atlanta Dental Supply Company, #2021046452 –Duluth, GA. Two (2) years probation. Failed to renew the pharmacy permit; continued shipping prescription medications into Missouri without a valid pharmacy permit. Section 338.055.1 and 338.055.2 (6) RSMo.

Z & D Medical Services., #2021031142 –Mayflower, AR. License issued on two (2) years probation. Operated on an expired license; shipped medical Oxygen without a current drug distributor license. Section 324.038.1 RSMo.

DRUG DISTRIBUTOR REGISTRANTS:

Parnell Manufacturing Pty Ltd., #2021038836 – Alexandria, Australia. License issued on two (2) years probation. Operated on an expired license; shipped legend veterinary drug product into Missouri without a current drug distributor registrant license. Section 338.055.2 (6) RSMo.

PHARMACISTS:

Dykes, Cori N., #2006025294, Crane, MO. Public Censure. As pharmacist-in-charge, loss of controlled substances; failed to maintain adequate security to deter theft of drugs by personnel; and unable to maintain accurate controlled substance records. Section 338.055.2(5), (6), (13), and (15), RSMo.

Fruend, Ryan A., #2014021629, St. Louis, MO. Three (3) years probation. As pharmacist-in-charge, loss of controlled substances; failed to maintain adequate security to deter theft of drugs by personnel; and unable to maintain accurate controlled substance records. Section 338.055.2(5), (6), (13), and (15), RSMo.

Litten, Kevin, #040729, Cadott, WI. Voluntarily surrendered. Pharmacist's license disciplined in Wisconsin for dispensing C-II without a valid prescription or authorization. Section 338.055.2 (8) RSMo.

Mehrle, Andrew L., #2014030498, Jefferson City, MO. Revoked and cannot reapply for three (3) years. Violation of discipline regarding failure to enroll/participate in the Missouri Association of Osteopathic Physicians and Surgeons Physician Health and Health Professional Wellness Program (MAOPS), failure to enroll/participate in FSSolutions's Professional Health Monitoring Program, and failure to submit documentation of support group attendance. Section 338.055.3 RSMo.

Paradis, Mallory, #2013037638, Kansas City, MO. Two (2) years probation. Dispensed legend and controlled substance prescriptions to himself without valid prescriptions, and early refills. Section 338.055.2(5), and (13), RSMo.

Patrick R. Wehmeier, #2007027808, Santa Barbara, CA. Five (5) years probation. Violated previous disciplinary order. Section 338.055.3.

Woosley, Andrea B., #2010031684, Vandalia, IL. Public Censure. As pharmacist-in-charge reuse of medications from returned multi-dose medication packages. Section 338.055.2(5), (6), (8), (13), and (15), RSMo.

PHARMACIES:

BET Pharm LLC, #2007036535, Lexington, KY. Probation until September 1, 2025. Entered into an order with Kentucky Board of Pharmacy for inspection violations; sold misbranded and adulterated drugs; failed to compound sterile preparations pursuant to USP Chapter 797; failed to compound non-sterile preparations pursuant to USP Chapter 795; failed to maintain complete and accurate compounding records. Section 338.055.2 (8), and (15) RSMo.

CVS Pharmacy #6745, Florissant, MO. Three (3) years probation. Multiple inspection violations: unsanitary conditions in the pharmacy, outdated drug products in active inventory, failed to include active or therapeutic ingredients on the label of compounded preparations. 338.055.2 (5), (6), (13), and (15) RSMo.

Lakeland Pharmacy #3, #2006027988, Crane, 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.

Omnicare of Kansas City, Kansas City, MO. Probation for 5 years. Multiple inspection violations: outdated drug products in active inventory, no electronic recordkeeping system policy and procedure, improper drug storage, unsanitary conditions, improper labeling of repackaged drug products. Section 338.055.2 (5), (6), (13), and (15) RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - FEBRUARY 2022

(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.)

ISMP PROVIDES SAFE PRACTICE RECOMMENDATIONS TO PREVENT COVID-19 AND FLU VACCINE MIX-UPS

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate.

Multiple mix-ups between the pediatric formulation (ages five through 11 years; orange cap and label border) and the formulation for individuals 12 years old or older of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) Vaccine have been reported to the Institute for Safe Medication Practices (ISMP) since Food and Drug Administration (FDA) authorized emergency use of the vaccine for children ages five through 11 on October 29, 2021. While details about the contributing factors were not provided in many cases, below is a highlight of what we have learned from the reports.

Five reports described cases in which 12-year-old children received doses (underdoses) that were appropriate for five- to 11-year-old children (10 mcg/0.2 mL rather than 30 mcg/0.3 mL). In three of these cases, those administering the vaccine were unaware of the proper dose for 12-year-old children. In addition, several reports indicated that children five to 11 years old received doses intended for individuals 12 years and older. In one case, those administering the vaccine had not yet been made aware that a pediatric formulation existed, and that the dose was different for individuals 12 years and older. So, the children were given 30 mcg/3 mL of the Pfizer-BioNTech COVID-19 Vaccine in error. High patient volume was mentioned as a factor in other reports.

Finally, the 30 mcg/0.3 mL Pfizer-BioNTech COVID-19 Vaccine (intended for individuals 12 years and older) was used to vaccinate some children ages five to 11 years as it was thought to be acceptable if only 10 mcg was given, either as 0.1 mL of the 30 mcg/0.3 mL vaccine (10 mcg) or by diluting the 10 mcg dose in a syringe to 0.2 mL. In one event reported via the news media, 112 children aged five to 11 years received their vaccine in this manner. Neither method would be correct though, since the pediatric vaccine is specifically formulated to be more diluted to ensure accurate measurement. Withdrawing 0.1 mL in a 1 mL syringe will result in an inaccurate volume, as it is recommended that no less than 20% of the nominal syringe capacity is measured to limit instrumental error. Also, if a needle different from the one used for drawing up the vaccine is used for administration, some of a 0.1 mL dose would likely be lost to any dead space. Or if a 0.1 mL dose is drawn up and the same needle and syringe are used to draw up a 0.9% sodium chloride diluent, then the vaccine in any dead space of the needle and syringe hub will be initially drawn into the syringe as it is pulled back to withdraw the diluent. Depending on how evenly the vaccine is distributed in the syringe, this could result in too much or too little vaccine reaching the patient upon injection.

Segregate and store these vaccines in refrigerators and freezers that are organized and properly labeled. Store the adult (12 years and older) and pediatric COVID-19 vaccines apart from one another, such as in separate labeled plastic bins. During the production and/or verification phase of the dispensing process, use barcode scanning whenever possible to verify that the correct product has been retrieved. Clearly label all individual syringes containing vaccines. To facilitate proper labeling, print labels for each patient or provide vaccine preparers with strips of preprinted labels that differentiate adult and pediatric doses. Ideally, prior to administration, barcode scanning should again confirm the correct vaccine. Also, only bring the intended and labeled vaccine syringe(s) for one patient into the vaccination area at a time. Involve the parent or patient in verifying the vaccine by reading the label to confirm the correct vaccine.

BEWARE OF THREE UNIQUE PHISHING SCAMS IMPACTING PHARMACY

The information published in this column was provided by the Healthcare Distribution Alliance Pharmaceutical Cargo Security Coalition

There are three types of phishing scams making the rounds within the pharmacy and pharmaceutical industries, according to Healthcare Distribution Alliance (HDA) Pharmaceutical Cargo Security Coalition (PCSC). Below are brief summaries of the three types of phishing schemes to be aware of:

- **Product recall fraud (pharmacy/manufacturer):** Scammers call a pharmacy distributor first, posing as an employee of a legitimate manufacturer. During the call, the scammers indicate that there has been a product recall and that the pharmacy needs to send the alleged "affected" product back. To make the scheme seem more realistic or legitimate, the scammers then follow up with what looks to

be a legitimate product recall request in the form of a letter. The contents of the letter again identify the product that is supposedly being recalled, with instructions to re-package the product and have it ready for pickup. The scammers then arrange for an unwitting mule or other courier (such as FedEx or UPS) to pick up the product. The letter indicates that the recalled product will be replaced with proper product, which never actually happens.

- **Pharmacy/wholesaler fraud:** In this scheme, scammers first pose as a legitimate pharmacy to place an order from the wholesaler. When the wholesaler sends the product to the pharmacy, the scammer contacts the pharmacy, posing as the wholesaler, to say they have shipped the product to the pharmacy in error and ask for the wholesaler to box the shipment back up and a courier (again, an unwitting mule or other courier like FedEx or UPS) will come and pick it up.
- **Bank account/payment fraud:** The scammers pose as a legitimate wholesaler and, through a business email compromise, contact the pharmacy to indicate that the terms of payment for product orders have changed and that there is a new account routing number to be used when a payment is made for an order. The "new account" is actually the scammers' account and not where the payment should be made.

To avoid becoming victim to one of these phishing schemes, pharmacies should ask themselves the following questions:

- Does anything appear to be out of the norm from how business has traditionally been done between partners;
- Does a request seem rushed, unusually elevated, or does not make sense; or
- Does something just not feel right?
- If answering yes to any of the above questions, confirm what is being requested with a trusted business contact. A simple phone call to a trusted connection could mitigate potential issues from any of these incidents.

EXAMPLE OF RECENT FRAUD CASE

A recent pharmacy fraud attempt was discovered that is consistent with the phishing scams summarized above. In this particular case, a pharmacy distributor had been contacted by a woman who used the name "Marianne." She stated she was calling from a pharmacy in Arkansas, which is actually a legitimate customer of the distributor. The caller ID on the distributor's phone displayed the correct telephone number for that legitimate customer. "Marianne," when asked, had the pharmacy customer's account number – exactly as it should have been – as well as the correct address location. This was followed by a fairly innocent conversation; and an order was eventually placed.

After the order had been placed, the pharmacy in question then received a call from what would appear to be the legitimate distributor. Again, the caller ID shown on the pharmacy phone matched the distributor's number exactly. The pharmacy was told that the shipment needed to be returned and provided information about a courier that would come to pick it up. The courier (in this case an unwitting FedEx contractor) ends up taking the parcel to a postal shipping store. Just prior to the arrival of the parcel(s), the postal shipping store gets a call that the "ship to" address needs to be changed. Again, the caller ID on the phone at the shipping store displays the number/name of the legitimate pharmacy distributor. In this particular case, the parcel was going to be re-routed to an address in Pennsylvania. That process, however, was able to be stopped.

Please note, there are some signs that encompass the usual operation of these fraudulent actors, including the example case summarized above. In many of these instances:

- the subjects who call are female. The most common names used are "Marianne" and "Heather"
- the caller can cause the correct pharmacy telephone number to appear on the caller ID, when calling a distributor
- the caller can cause the correct distributor telephone to appear on caller ID, when calling a pharmacy
- the caller will be familiar with the addresses of both locations – and freely offer that information up as confirmation they are legitimate
- the suspect will know the correct pharmacy account number when speaking with the distributor – and vice versa
- the caller will not have a specific item number, but will offer some type of a National Drug Code number
- when questioned about prior order history, the caller will politely indicate that they cannot recall or are a new representative
- when the caller is asked to place the eventual order online, that caller will request the person to whom they are speaking to manually enter the order instead – to avoid the traditional process the suspect caller is not familiar with
- the time from the order being placed to when the order would be picked up by courier is usually quite rapid, rarely more than 24 hours
- the caller indicates that she is the one who will arrange for the courier, and that there is no need for the person who has been called to do that
- the courier(s) is an unwitting participant

There are federal authorities from both the FDA and the Federal Bureau of Investigation that are working these types of cases.

Anyone who has experienced one of these scams may contact PCSC staff at 401/623-1344 to be put in contact with the investigating agents.

HHS RELEASES TREATMENT-FOCUSED OVERDOSE PREVENTION STRATEGY

The United States Department of Health and Human Services (HHS) announced the release of their new treatment-focused Overdose Prevention Strategy in response to the rising trends in drug overdoses. The Overdose Prevention Strategy is designed to increase access to care and services for individuals who use substances that put them at risk for overdoses, and for their families. HHS's strategy focuses on four target areas that include:

1. primary prevention,
2. harm reduction,
3. evidence-based treatment, and
4. recovery support – to increase access to integrated care and treatment services.

More details are available in a press release in the News section of the HHS website.

FDA APPROVES UPDATE TO IPLEDGE REMS PROGRAM, URGES MANUFACTURER GROUP TO SOLVE WEBSITE ISSUES

FDA has approved an update to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program. The centralized system helps inform pharmacies, prescribers, and patients about any serious risks associated with isotretinoin to prevent fetal exposure. Since the system changes were implemented in mid-December 2021, some users have experienced problems with the updated website, including patients having difficulty gaining access to the website and call center. FDA has acknowledged these issues and is urging the Isotretinoin Products Manufacturers Group to propose a workable solution.

FDA indicates that the agency is ready to exercise "regulatory flexibility on a temporary basis as needed" for some iPLEDGE REMS requirements so long as "IPMG proposes a workable solution that also ensures necessary safe use conditions are maintained." FDA will continue to post any timely updates related to iPLEDGE REMS in its effort to provide isotretinoin information to prescribers, pharmacies, patients, and distributors.

More information is available via a press release and statement published on the FDA website.