

MISSOURI BOARD OF PHARMACY

NEWSLETTER



JUNE 2021

TABLE OF CONTENTS

Board Statement on Working Conditions	1
Prescription Transfer Rule Change	2
Drug Utilization Review	2
E-Alerts	3
How are you?	4
Well-Being Resources	5
Mayo Clinic Signs & Symptoms	6
Reminder on Dispensing Errors	7
Controlled Substance Annual Inventories	7
Upcoming Board Meetings	7
Upcoming Board Discussion Items	8
Qualified Technicians Providing Administrations	8
DEA Manual Updates	8
Gold Certificates	10
Disciplinary Actions	11
Coping with COVID	12

BOARD STATEMENT ON PHARMACY WORKING CONDITIONS

The Board issued the below statement on April 29, 2021, to address recent concerns from licensees regarding pharmacy staffing and working conditions. The statement is [available on the Board's website](#) and reprinted below in its entirety. Licensees should review the guidance document and take appropriate steps to ensure patient safety.

The Board will continue meeting with permit holders and licensees to discuss this important topic. Additionally, the Board will be forming a Missouri task force to advise the Board on potential solutions (monitor the Board's website/e-alerts for additional information).



PRESCRIPTION TRANSFER RULE CHANGE

The Board recently amended 20 CSR 2220-2.120 to modify the timeframes for transferring a prescription/medication order. Similar to the previous rule, all transfer requests received directly from the patient or the patient's caregiver must be transferred within one (1) business day of the patient's request [[20 CSR 2220-2.120\(5\)](#)].

Effective May 30, 2021, transfer requests that are not received directly from the patient or the patient's caregiver must be completed in a timely manner, provided licensees/permit holders must ensure that no interruption in patient therapy will occur if the prescription is not transferred within one (1) business day [[20 CSR 2220-2.120\(5\)](#)].

The rule change was intended to allow licensees to use their professional judgment when additional time is needed to transfer a prescription, and should not be abused.

Communication is key here. The pharmacy requesting the transfer should communicate any urgent need when requesting a transfer. Similarly, the Board recommends the transferring pharmacy communicate if a transfer may have additional delays.

Licensees will be asked to explain/substantiate any transfer that is not completed in a timely manner. Transfer requests received directly from the patient or the patient's caregiver must still be transferred within one (1) business day, without exception.

DRUG UTILIZATION REVIEW

20 CSR 2220-2.195 provides a prospective drug utilization review (DUR) must be performed prior to dispensing or otherwise approving medication for patient use (new and refill). The required DUR must be performed by a Missouri-licensed pharmacist or by a Missouri-licensed intern pharmacist under a licensed pharmacist's supervision. If the DUR is delegated to an intern, the supervising pharmacist remains responsible for ensuring an appropriate DUR is performed in compliance with appropriate standards of care.

Licensees have asked for additional guidance on what needs to be documented when a DUR is performed:

- As part of the Board's standards-based regulatory approach, 20 CSR 2220-2.195 does not include specific documentation requirements. However, proof of compliance may be requested during an inspection or investigation. Licensees should use their professional discretion to determine what and how documentation is maintained. At a minimum, the Board recommends documenting the identity of the responsible pharmacist/supervised intern pharmacist and the date of the required DUR.



- The Board recognizes that pharmacy software systems may contain automatic DUR functions. Additionally, other third parties may generate or require DUR activities (e.g., PBMs, health plans). Regardless of the type or source, licensees will be asked for proof of compliance with the DUR required by 20 CSR 2220-2.195.
- Licensees have asked about documentation requirements when an electronic DUR alert generated by the pharmacy's software system is cleared/overridden. 20 CSR 2220-2.195 requires a prospective DUR and does not specifically address clearing/overriding DUR alerts. However, the Board recommends that licensees document the pharmacist or intern pharmacist responsible for overriding a DUR alert as a best practice, even if not required by rule (interns must be under a pharmacist's supervision).***
- Electronic DUR checks can be a helpful tool but pharmacists cannot abandon their clinical skills. Instead, a pharmacist must independently assess therapeutic appropriateness for the specific patient based on available records. While electronic DUR programs/tools can assist with this review, they should not replace the pharmacist's clinical skills or professional judgment.
- The Missouri Department of Health and Senior Services' (DHSS) has regulatory jurisdiction over pharmacy services provided within the "licensed premises" of a Missouri hospital. Pharmacy services under DHSS' authority would need to comply with DHSS requirements; The Board's DUR rule would not apply. However, Class-B hospital pharmacies are required to comply with 20 CSR 2220-2.195 for dispensing activity under the Board's jurisdiction.
- The Board recognizes that DUR procedures may be different/limited for nuclear pharmacies. Pharmacists dispensing radiopharmaceuticals should make a good faith effort to conduct the required DUR based on known/available information, which the Board recognizes may be limited in some instances.

*****The Board has reviewed instances where pharmacy technicians have been allowed to independently override drug utilization (DUR) alerts without consulting with a pharmacist. DUR requires a pharmacist's professional judgment; DUR alerts should be reviewed by a pharmacist and only cleared/overridden with a pharmacist's approval.**



E-ALERTS

Sign up on the [Board's website](https://pr.mo.gov/pharmacists) to receive e-alerts on Board news, compliance updates and licensing changes. Board e-alerts are also available now under the "News/Publications/Resources" link on the Board's website at: <https://pr.mo.gov/pharmacists-e-alerts.asp>



SO...HOW ARE YOU?

The last several months have been demanding and unpredictable. Healthcare workers have been at the forefront of fighting COVID-19. For many licensees, pharmacy demand has increased while pharmacy resources have been stretched thinner.

A [September 2020](#) survey of healthcare workers by Mental Health America found the following:

- **Stressed out and stretched too thin:** 93% of health care workers were experiencing stress, 86% reported experiencing anxiety, 77% reported frustration, 76% reported exhaustion and burnout, and 75% said they were overwhelmed.
- **Emotionally and physically exhausted:** Emotional exhaustion was the most common answer for changes in how healthcare workers were feeling over the previous three months (82%), followed by trouble with sleep (70%), physical exhaustion (68%) and work-related dread (63%). Over half selected changes in appetite (57%), physical symptoms like headache or stomachache (56%), questioning career path (55%), compassion fatigue (52%) and heightened awareness or attention to being exposed (52%).
- **Not getting enough emotional support:** 39% of healthcare workers said that they did not feel like they had adequate emotional support.
- **Struggling with parenting:** Among people with children, half reported they are lacking quality time or are unable to support their children or be a present parent.


As we adapt to the “new normal” in pharmacy, don’t forget to take care of your mental health. Know the signs of mental illness. If you need help, there are ways to get help.

Use the resources below to learn more about protecting your mental health or to find help for you, a friend or a family member.




WELL-BEING RESOURCES

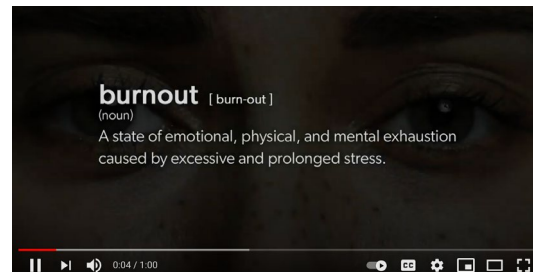
(The following list is provided for informational purposes only. This list is not comprehensive and does not constitute an endorsement by the Board)

DON'T MISS OUT! If there's a blue  next to a resource, the information is clickable. Click on the area to go directly to the resource mentioned.

Missouri Dept. of Mental Health Resources 

Suicide Prevention Lifeline Chat 

Who Saves Me? Healthcare Burnout 



U.S. National Helpline: SAMHSA's National Helpline is a free, confidential, 24/7, 365-day-a-year treatment referral and information service (in English and Spanish) for individuals and families facing mental and/or substance use disorders. Call 1-800 662-HELP (4357)




National Suicide Prevention Lifeline: The Lifeline provides 24/7, free and confidential support for people in distress, prevention and crisis resources for you or your loved ones, and best practices for professionals.


Crisis Text Line Missouri: Crisis Text Line is free, 24/7 support for those in crisis to text with a trained Crisis Counselor. **Text MOSAFE to 741741**

CRISIS TEXT LINE |



Veterans Chat: Veteran's Suicide Prevention Lifeline Chat "is a service of the National Suicide Prevention Lifeline, connecting individuals with counselors for emotional support and other services via web chat.  Lifeline Chat is available 24/7 across the U.S."




Deafline Missouri: A crisis hotline for Deaf and Hard of hearing individuals: 1-800-380-DEAF (3323) (Voice/TTY). 



GRAD RESOURCES

National Graduate Student Crisis Line - Call 1-877-GRAD-HLP (1-877-472-3457).

The National Grad Crisis Line helps graduate students reach free, confidential telephone counseling, crisis intervention, suicide prevention, and information and referral services provided by specially-trained call-takers (available 24/7). 



MAYO CLINIC SIGNS & SYMPTOMS

[PROVIDED BY MAYO CLINIC](#)

Signs and symptoms of mental illness can vary, depending on the disorder, circumstances and other factors. Mental illness symptoms can affect emotions, thoughts and behaviors.

Examples of signs and symptoms include:

- Feeling sad or down
- Confused thinking or reduced ability to concentrate
- Excessive fears or worries, or extreme feelings of guilt
- Extreme mood changes of highs and lows
- Withdrawal from friends and activities
- Significant tiredness, low energy or problems sleeping
- Detachment from reality (delusions), paranoia or hallucinations
- Inability to cope with daily problems or stress
- Trouble understanding and relating to situations and to people
- Problems with alcohol or drug use
- Major changes in eating habits
- Sex drive changes
- Excessive anger, hostility or violence
- Suicidal thinking

Sometimes symptoms of a mental health disorder appear as physical problems, such as stomach pain, back pain, headaches, or other unexplained aches and pains.



REMINDER ON DISPENSING ERRORS

Board inspectors routinely review prescriptions for dispensing accuracy as part of the inspection process. When a discrepancy is discovered, the inspector issues a Quality Assurance Report that asks the pharmacist-in-charge to investigate the discrepancy. The most common discrepancy that inspectors observe involves "PRN" in the label directions. Either "as needed" is omitted from the label directions when prescribed as "PRN," or "as needed" is included in the label directions when not prescribed as "PRN".

While this may seem minor, the inclusion or exclusion of "PRN" can be clinically significant. "PRN" directs the patient to either take the medication on a scheduled basis regardless of symptoms or on a more limited basis based when needed. The omission/inclusion of "PRN" may be especially important with opiates in light of the ongoing opioid crisis. Omitting "PRN" may direct the patient to take more medication than actually needed which could lead to dependency. Pharmacists should pay careful attention when verifying prescriptions to make sure the prescribed directions are correct.

CONTROLLED SUBSTANCE ANNUAL INVENTORIES:

(Provided by the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD))

"DHSS waived the requirement to perform an annual inventory of controlled substances during the earlier stages of the COVID-19 emergency [19 CSR 30-1.042(3)]. This waiver was terminated on April 30, 2021. All registrants should make sure they have performed an annual inventory within the past 12 months and perform an inventory if one has not been completed."

Upcoming 2021 Board Meetings:

July 14-15th

August 18th

September 15th

October 19-20th

November 17th

December 15th

Due to COVID-19, all Board meetings will be held virtually via WebEx. Meeting information will be available on the [Board's website](#) approximately 1-week before the meeting, including instructions/links for participating in the meeting.



Upcoming Board Discussion Items

- Pharmacy Workforce Conditions
- Class J Shared Services Definition/Requirements
- Class K Internet Pharmacy Definition
- 2021 Legislative Implementation
- Proposed 2022 Legislation
- Pharmacy Technician Training & Authorized Activities
- Electronic Patient Counseling

Visit the [Board's website](#) for additional meeting/agenda information.

QUALIFIED TECHNICIANS PROVIDING ADMINISTRATIONS

With the recent changes to 20 CSR 2220-6.040 Administration by Medical Prescription Order and 20 CSR 2220-6.050 Administration of Vaccines Per Protocol allowing pharmacists to delegate the administration of a drug/vaccine to a qualified technician (see [2/2021 newsletter](#) for more information), the Board has received inquiries on what functions a qualified technician may perform in this new role. A qualified technician may prepare the dose and administer the drug/vaccine to the patient but may not make the determination if the patient qualifies for a vaccine per protocol, only the pharmacist or supervised intern pharmacist may make this determination after reviewing the patient information. Patient counseling must be provided by a pharmacist or a supervised intern pharmacist, a technician may not perform this function. A technician may provide written information to a patient but may not answer their drug/vaccine related questions, such as what side effects to expect or how to treat them. Also, a pharmacist must be physically present on-site when a qualified technician is administering a drug/vaccine under the Board's rules.

DEA MANUAL UPDATES

The U.S. Drug Enforcement Administration (DEA) has released its [2020 revised Pharmacist's Manual](#). The [revised manual](#) includes multiple updates, including, the following section on corresponding responsibility:

A pharmacist has a corresponding responsibility for the proper dispensing of controlled substances. An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 U.S.C. 841(a)(1), 21 U.S.C. 842(a)(1), and 21 CFR 1306.04(a).



A pharmacist is required to exercise sound professional judgment, and to adhere to professional standards, when making a determination about the legitimacy of a controlled substance prescription. 21 CFR 1306.04(a), 21 CFR 1306.06. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious medical legitimacy. To the contrary, the pharmacist who deliberately ignores the high probability that a prescription was not issued for a legitimate medical purpose and fills the prescription, may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. *United States v. Veal*, 23 F.3d 985 (6th Cir.1994). Such action is a felony offense, which upon conviction, may result in a term of imprisonment and a fine. 21 U.S.C. 841(b). Unlawful dispensing of controlled substances by a pharmacist may also be subject to criminal actions against the pharmacy or pharmacist, and to civil enforcement actions against the pharmacy or pharmacist for money penalties or injunctions. 21 U.S.C. 842, 843. Moreover, DEA may revoke a pharmacy's registration based on a finding that its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of proceedings against their state licenses. *Jones Total Healthcare, L.L.C., v. DEA*, 881 F.3d 823 (11th Cir. 2018).



GOLD CERTIFICATES:

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

Gary D Fox
Thomas J Ginther
Leroy Graham
David F Hagedorn
Robert W Jaeger
George I Juenger
Larry L King
Robert F Manchester Jr
John C Martin
William C McHugh Jr
Beverly K Notestine
Dennis D Pezzani
Margaret A Roberts
Mary A Robinson
Richard C Sachan
Edward C Schuch Jr
David H Silverman
Mary Anne S Toll
William Z Way
Larry D Webber
David T Willard
Neil A Yant



DISCIPLINARY ACTIONS

PHARMACIES:

CVS Pharmacy #5655, Liberty, MO. Three (3) years probation. Violated previous disciplinary order. Multiple inspection violations: unsanitary conditions in the pharmacy, outdated drug products in active inventory, dispensing errors, incomplete vaccine administration records. 338.055.2 (5), (6), (12), (13), and (15) RSMo.

Hy-Vee Pharmacy Fulfillment Center (4016), #2013037675, Des Moines, IA. Two (2) years probation. Failed to renew the pharmacy permit; Continued shipping prescription medications into Missouri without a valid pharmacy permit. Section 338.055.2 (6), (12), and (15) RSMo.

PHARMACISTS:

Heather-Chappius, Tamara., #043843, Washington, MO. Two (2) years probation. As pharmacist-in-charge, dispensed prescription medication without a valid prescription. Section 338.055.2(5), (6), (13), and (15) RSMo.

Mitchell, Brian, #2021015902, Kennett, MO. Probation for five (5) years. Previous disciplinary action in Missouri, Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program. Section 338.055.1 and RSMo.. Section 338.055.2(2), (5), (6), (13), (15), and (17), RSMo.

Nyachira (Kolacny), Tamara, #2019010826, Pittsburg, KS. Six (6) months suspension followed by five (5) years probation. Misappropriated prescription medications including controlled and non-controlled substances from employers; Created, forged and dispensed prescriptions that were not authorized. Pleaded guilty to felony offense of obtaining a controlled substance by fraud or forgery under 21 U.S.C. § 843(a)(3) in the United States District Court, Eastern District of Missouri. Pharmacist license is currently disciplined in Kansas. 338.065.1 RSMo; Section 338.055.2 (2), (4), (6), (8), (13), (15), and (17), RSMo.

Witt, Eric D., #043943, Chillicothe, MO. Suspension for one year beginning 10/5/2020 followed by five (5) years probation. Pharmacist admitted to diverting controlled substances, including oxycodone, hydrocodone/acetaminophen, oxycodone/acetaminophen, lorazepam, and clonazepam and consumed the drugs at work. Section 338.055.2 (5), (6), (13), (15), and (17), RSMo.

COPING WITH COVID-19

Front Line and Healthcare Workers

MANAGE WHAT YOU CAN

In times of uncertainty, many things are outside of our control. One of the best ways to manage emotions during times of uncertainty is to focus on what is within our control: Try some of these micro steps.



Take a short nap.



Stretch or go for a short walk.



Set aside recovery time after a challenging moment.



Help others if you have a safe way of doing so.



Keep a water bottle at your station or in the break room.



Set a news and social media cut-off time.



When you feel overwhelmed, focus on your breathing instead of reaching for your phone.



If you're unable to practice self-care, pause and choose a new mindset.



Avoid tobacco and alcohol.



Above all, remember that you are going through extremely uncertain and unsettling times; everyone else is as well. It is normal to feel on edge and anxious right now. In fact, it is even GOOD that you are feeling this way, because that anxiety and stress can push us to do things to cope in healthy ways. It pushes us to listen to the medical community and follow guidelines to keep ourselves and our families safe. It also pushes us to connect with others, which helps to manage stress and anxiety in healthy ways.

RESOURCES

Disaster Distress Helpline
800-985-5990

Crisis Text Line
Text **MOSAFE** to **741741**

National Suicide Prevention Lifeline:
1-800-273-8255

Access Crisis Intervention (ACI)
mohelpnow.org

SAMHSA's National Helpline
1-800-662-HELP | 1-800-662-4357

Missouri First Responder Provider Network
www.missouricit.org/first-responders

USEFUL WEBSITES

nowmattersnow.org Website for crisis situations, including strategies to safely cope with suicidal thoughts.

go.edc.org/covid19-resources (lots of resources including ones specifically for adults and for children)

