DECEMBER 2023

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

The Board Has Moved!

In November, the Iowa Board of Pharmacy joined other professional licensing agencies within the Licensing Division of the Department of Inspections, Appeals, and Licensing (DIAL) and moved from its long-time office at the RiverPoint Business Park to a new office located at 6200 Park Avenue, Des Moines, IA 50321. Pursuant to 2023 Iowa Acts, Senate File 514, enacted by the Iowa Legislature and signed by Governor Kim Reynolds during the 2023 legislative session, the Professional Licensing and Regulation Bureau previously within the Iowa Department of Health and Human Services (DHHS) officially became the Licensing Division within DIAL on July 1, 2023.

To further the department's efficiency and effectiveness, all divisions of the department are moving to the new location after previously being split between nine different state office buildings. The Licensing Division comprises four bureaus: Investigations/Inspections, Licensing, Monitoring, and Board Support. Additional changes are still to come, as they relate to the realignment and restructuring, to meet your needs more efficiently and effectively through better coordination as one team. Please check the Board's website for additional information and updates in the coming months.

Compounding Reminders

Pharmacies engaged in nonsterile and sterile compounding are reminded that the latest revisions to United States Pharmacopeia (USP) General Chapter <795> for nonsterile compounding and USP Chapter <797> for sterile compounding became official on November 1, 2023. As such, the standards provided in those

National Pharmacy Compliance News

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chapters are enforceable under the Board's rules found at 657 Iowa Administrative Code (IAC) 20.3 and 20.4.

Additionally, pharmacies that ship compounded preparations to other states are reminded to submit data related to their 2023 interstate dispensing to the National Association of Boards of Pharmacy® no later than April 1, 2024. The reporting requirement was in response to and in compliance with Food and Drug Administration's (FDA's) memorandum of understanding (MOU) in fulfilling FDA's legislative mandate. Although the MOU is currently on pause while legal challenges are addressed, the Board's rule at 657 IAC 20.24 remains in effect.

Vaccine Administration Under the Board's Statewide Protocol – 'Shared Clinical Decision-Making'

One of the most recent additions to the Centers for Disease Control and Prevention's (CDC's) approved vaccination schedule for adults was for the FDA-approved and Advisory Committee on Immunization Practices-recommended respiratory syncytial virus vaccine. The vaccine recommendation was based on the practice of "shared clinical decision-making." There are five such vaccinations on the approved schedule that have the "shared clinical decision-making" recommendation. Per CDC's website,

> For routine, catch-up, and risk-based recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default – the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered.

CDC includes pharmacists in its consideration of who is defined as a health care practitioner regarding shared clinical decision-making recommendations.

Change of Equivalency Rating for Tacrolimus Capsules by Accord

In September, FDA changed the therapeutic equivalency rating for Accord Healthcare Inc's tacrolimus capsules from AB to BX following review of additional data that found the Accord product may provide peak blood concentrations of tacrolimus, which are increased compared to the brand-name drug, Prograf®. The BX determination provides that the Accord product may not be automatically substituted for the brand-name drug, Prograf, but may still be prescribed and dispensed.

OTC Narcan Nasal Spray Added to the Board's Naloxone Dispensing Program

The Board is thrilled to report that the Naloxone Dispensing Program, developed in collaboration with the United States Department of Health and Human Services (HHS) and administered by MedOne Pharmacy Benefit Solutions, has expanded once more. The program allows Iowa community pharmacies to submit electronic claims for reimbursement for Narcan®, Kloxxado®, and generic naloxone nasal sprays and, most recently, the program added the National Drug Code for the over-the-counter (OTC) Narcan nasal sprays. Under the program, pharmacies can submit claims for reimbursement for these products to provide the medication to the recipient at no charge. Claims through the program may be submitted in response to a pharmacist's order via the Board's Opioid Antagonist Statewide Protocol, the HHS statewide standing order by Dr Robert Kruse, or a patient-specific prescription issued by a practitioner. To date, Iowa pharmacists have dispensed over 8,000 potentially life-saving naloxone kits to Iowans.

Funding for the Naloxone Dispensing Program comes from the Substance Abuse and Mental Health Services Administration (SAMHSA) State Opioid Response grant and is limited, so pharmacies are encouraged, but not required, to process coordination of benefits claims. Pharmacies are reimbursed according to the HHS actual acquisition cost list plus a $20 dispensing fee. Pharmacies are strongly encouraged to use the least costly naloxone alternative available.

Iowa DHHS Medical Director Updates Naloxone Statewide Standing Order

Dr Kruse has issued an updated standing order for dispensing naloxone. The updated standing order **does** include OTC naloxone products but **does not** include the recently FDA-approved OPVEE® (nalmefene). The standing order also includes authorization for secondary distribution to implement a recent change to Iowa law. Information and the application to obtain naloxone for secondary distribution can be found on the Iowa DHHS website. Dr Kruse's standing order and the Board's statewide protocol are both available on the Board's website.

Free CE for Pharmacists and Technicians

The National Association of State Controlled Substances Authorities (NASCSA) has partnered with Talem Health to create a one-hour, on-demand continuing education (CE) activity for pharmacists and pharmacy technicians to improve prescription monitoring program (PMP) data. Please visit *https://ce.talemhealth.com/a/HLQIJS* for one hour of free Accreditation Council for Pharmacy Education-accredited CE credit for pharmacists and pharmacy technicians. This program will provide insight into how pharmacy staff data entry processes affect PMP data, clinical decision making, and downstream data analysis. This program, developed in partnership with NASCSA and 12 PMP administrators, analyzes the importance and value of complete, accurate data reported by dispensers to PMPs and assesses the impact of intentional

or unintentional data entry errors and data omissions on patient safety. It also discusses the downstream impacts of pharmacy reported PMP data on clinical decision-making processes and helps pharmacy staff identify and implement changes that can be made in their practice setting to improve PMP data integrity. To access the program, visit *https://ce.talemhealth.com/a/HLQIJS.*

DEA Transfer of CS Prescriptions for Initial Filling

Pharmacies are reminded that, while Drug Enforcement Administration (DEA) regulations permitting the electronic transfer of controlled substance (CS) prescriptions for initial filling have been finalized and are effective, current National Council for Prescription Drug Programs (NCPDP) SCRIPT standards may not be sufficient to complete such transfers in compliance with DEA regulations. It has been reported that the current version of NCPDP SCRIPT standards are not compliant with DEA regulations. The new standards are ready but will not be released until Centers for Medicare & Medicaid Services publishes its new regulations.

Fraudulent Prescriptions and How the PMP Can Help You

Although pharmacies are likely aware of the many red flags that indicate a prescription may be fraudulent, the red flags listed below can be found within the PMP data and may help identify a fraudulent prescription:

- Prescription is issued for promethazine with codeine along with albuterol and/or Z-Pak
- Quantity authorized for promethazine with codeine exceeds 120mL
- Prescription is issued for hydrocodone products in quantities of 90 tablets or greater
- Prescription is issued from a nonresident prescriber
- Patient has a nonresident address or ID
- Prescription is paid for with cash
- Patient has fewer than three prescription records on the PMP

Board Assigned 2024 Red Tape Review

In January 2023, Governor Reynolds issued Executive Order 10, in which she directed all state agencies to conduct a comprehensive review of all administrative rules during an assigned year. During each agency's assigned year, the agency is required to complete a Red Tape Review Rule Report for each existing chapter of administrative rules, determine if the rules should be re-promulgated, and submit the reports with the agency's recommendations and drafts for re-promulgated rules by September 1 to the governor's administrative rules coordinator.

The Board was assigned its Red Tape Review for 2024. The executive order expressed a preference that agencies undertake a "zero based" approach to their rules review. Since the

issuance of the executive order, the Board's Rules Committee has directed its primary focus to this comprehensive review and working on draft rules from a "zero based" perspective. The stated goals of the Red Tape Review include, but are not limited to, reducing the page and word count in administrative rules, removing duplicate or redundant language (such as language found in Iowa Code or federal law and regulations), adopting the least costly means to protect the public health, reducing restrictive language, and adhering to the rulemaking authority granted by the Iowa Legislature.

Interested stakeholders are encouraged to sign up for the Board's contact list to ensure receipt of press releases to be alerted to publications of the Red Tape Rule Reports in the *Iowa Administrative Bulletin* as well as the dates and times of the public hearings that will be held in accordance with the executive order.

Iowa Monitoring Program for Pharmacy Professionals

The Iowa Monitoring Program for Pharmacy Professionals (IMP3) believes the skills and reputation of pharmacy professionals and student pharmacists can be maintained if monitoring and supportive services are put in place at an early stage. IMP3 may confidentially assist pharmacy professionals and student pharmacists in obtaining the necessary support for healthy recovery from substance use, mental health, and/or physical conditions. If you or a colleague are struggling with substance abuse or any mental or physical health conditions, you are encouraged to confidentially self-report to IMP3 early. It is in a pharmacy professional's best interest to self-report to IMP3 as soon as possible if any of the following applies:

- missing work for more than two weeks due to a mental health or physical condition of a chronic or debilitating nature;
- diagnosis of a chronic illness with a known mental health component;
- issues related to drug and/or alcohol use, such as operating while intoxicated and/or other alcohol- or drug-related offenses; disciplinary action by a federal or state agency for this reason; pilfering CS for personal use; or practicing pharmacy under the influence of alcohol and/or other mood altering substances;
- experiencing anger management concerns; or
- being urged by friends, family, or colleagues to get help for mental health issues such as depression, a physical condition, and/or substance use.

Once an individual contacts IMP3 about a possible situation that could affect their ability to practice pharmacy, IMP3 will gather information about their situation. This may result in referral for further evaluation and/or treatment (a SAMHSA treatment locator is available on the Board's website), if indicated. IMP3 then determines whether the pharmacy professional would benefit from ongoing support and monitoring. If so, an individualized contract is developed that

includes safeguards that are designed to allow the individual to continue/return to practice with reasonable skill and safety. It is IMP3's hope that most of the participants in IMP3 are actively practicing pharmacy. Please review the Board's website for more information or contact the IMP3 program coordinator via email at rebecca.carlson@dia.iowa.gov.

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