June 2021 News



lowa Board of Pharmacy

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Sunset of Code Allowing Practitioner-Signed Immunization Protocols

As a reminder, the law that authorizes pharmacists to administer vaccinations under a practitioner-signed protocol will sunset, or expire, on June 30, 2021. The law had been set to sunset on June 30, 2020, but was extended for one year during the 2020 legislative session. Beginning July 1, 2021, pharmacists are authorized to order and administer vaccinations under the Iowa Board of Pharmacy's statewide protocol or pursuant to a patient-specific prescription issued by a practitioner.

Reminder to Pharmacists Whose Licenses Expired in 2020

For pharmacists whose licenses expired June 30, 2020, the 2020 Iowa Legislature provided a one-year extension for renewal and completion of required continuing education (CE). Pharmacists whose licenses expired June 30, 2020, and have not yet renewed or completed the required CE are reminded that renewals must be completed by June 30, 2021, in addition to all CE. Also note that the one-year extension does not further extend the expiration of the license upon renewal. A pharmacist whose license expired June 30, 2020, and renews prior to June 30, 2021, will need to renew again no later than June 30, 2022. The one-year extension of the completion of CE also does not extend the subsequent requirement to complete 30 hours of CE prior to the pharmacist's 2022 renewal.

Certificates Going Digital

As of January 1, 2022, the Board will no longer mail out most physical copies of new or renewal certificates to licensees/registrants. Instead, licensees will be emailed a digital certificate from the Board. Or, they can download a certificate via their online profile through iLEMS. A profile must be set up for first-time users. Please note, the Board will continue to mail out original pharmacist wall licenses. You may request a duplicate pharmacist wall license by

emailing your request to melanie.givens@iowa.gov. The fees for a duplicate wall license will remain the same.

For questions, please contact Amanda via email at amanda.woltz@iowa.gov.

Update on the 2021 Session of the Iowa Legislature

The Iowa Legislature wrapped up its first session of the 89th General Assembly in early May, capping a productive session for the practice of pharmacy. The Board introduced two bills, which were both passed by the legislature and signed into law by Governor Kim Reynolds.

- ♦ The Board's controlled substance (CS) bill provides for the permanent placement in the Iowa Controlled Substances Act (CSA) of nine substances that had been temporarily scheduled via rulemaking over the previous year. The bill also provides conforming text to match federal CSA structure.
- ♦ The Board's pharmacy practice bill provides for the elimination of the one-year limitation of a technician trainee registration, allowing the Board to address renewal parameters via rulemaking; requires an outsourcing facility seeking licensure in Iowa to submit evidence of an inspection within the previous two years; and allows the Board to share complaints, investigative information, and data collected pertaining to compounded human drug products with Food and Drug Administration (FDA), including through an information sharing network, in order to comply with any memorandum of understanding with FDA.

The Iowa Pharmacy Association (IPA) also introduced a pharmacy practice bill, which was passed by both chambers and signed into law by Governor Reynolds. The bill provides for the inclusion of the coronavirus disease 2019 (COVID-19) vaccination into a Board statewide protocol;

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National Pharmacy Compliance News



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NABPF
National Association of Boards
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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19)*. The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations



This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in

confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a ninemonth-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription. However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan² and the American Society of Health-System Pharmacists (ASHP)³, to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

- 1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
- 2. www.mipedscompounds.org/
- 3. www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/ Compound-Oral-Liquid.ashx

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National

DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons*, reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting www. journalacs.org/article/S1072-7515(20)32336-X/fulltext.

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

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- ◆ authorizes the development of statewide protocols, in collaboration with the Iowa Department of Public Health, for pharmacists to provide point-of-care testing and treatment to patients ages six years and older for influenza, streptococcus A, and COVID-19, and to provide point-of-care testing to patients ages six years and older in response to a public health emergency; and
- codifies collaborative pharmacy practice as a practice of pharmacy and allows for health carrier payment for pharmacist services.

The Board will be promulgating administrative rules in the coming months to implement the legislation. Licensees are encouraged to sign up for notifications of Board communications to be alerted about published rulemaking and other important information by visiting *pharmacy.iowa.gov* and clicking on the envelope icon under "Social Media."

Medical Cannabidiol: CME Links Available

The Office of Medical Cannabidiol has partnered with TheAnswerPage and the Medical Cannabis Institute (TMCIGlobal) to roll out medical cannabidiol continuing medical education (CME) for providers. Both courses offer a comprehensive review of Iowa's regulations on medical cannabis as well as basic knowledge on therapeutic use, administration, potential risks, and special populations. Providers can also learn more and participate in the Iowa Medical Cannabis program. TheAnswerPage offers a four-hour CME/CE course (3.5 APA credits), "The Iowa Comprehensive Medical Cannabis Course Bundle," for \$189. TMCIGlobal offers a three-hour CME/CE version, "Iowa Provider Education: Medical Use of Cannabis v1.0," for \$159.

Updated PMP Rules

As of May 12, 2021, the Board is requiring that all Schedule V controlled prescriptions be reported to the Iowa Prescription Monitoring Program (PMP). The newly adopted rulemaking also includes nonprescription sales of codeine-containing cough suppressants (eg, Robitussin-AC®) as reportable transactions. For nonprescription reporting to the Iowa PMP, the pharmacy should be identified as both the prescriber and the dispenser. The rule change does not require additional PMP reporting of nonprescription pseudoephedrine-containing products. Pharmacies should continue to report nonprescription pseudoephedrine sales via the electronic pseudoephedrine tracking system.

The rulemaking also requires a pharmacist to review a patient's or a client's prescription history report prior to dispensing a Schedule V medication without a prescription, pursuant to Iowa Administrative Code (IAC) 657—10.33(124, 155A).

All reportable prescriptions are required to be reported within one business day of filling.

For questions, please contact pmp@iowa.gov.

Other PMP News Iowa PMP Field Audit Project

Results covering the first six months (July 1-December 31, 2020) of the Iowa PMP field audit project were presented at the 117th National Association of Boards of Pharmacy® Annual Meeting by Emily Albers, PharmD candidate, Drake University College of Pharmacy, class of 2023. The audit utilized a "field audit" approach and included participation of compliance officers who collected copies of CS prescriptions as part of their routine inspections. Initial findings indicated that while data found in the Iowa PMP is generally accurate, notable gaps were found, including missing or invalid "days supply" (2.7%), incorrect date written or date dispensed (1.1%), and failure to report (1.9%). These results will be used to establish baseline measures of the Iowa PMP data and to track changes and trends over time. Rules regarding reporting to the Iowa PMP may be found in 657 IAC Chapter 37.

Naloxone Dispensing Program

The naloxone (Narcan®) dispensing program continues to be a great success, with over 1,000 kits dispensed to patients in the state of Iowa and over 200 Iowa pharmacies participating to date. All Iowa patients are eligible to receive Narcan at no cost (\$0 co-pay), and pharmacies are reimbursed the cost of Narcan plus a \$20 dispensing fee for patient education and counseling. A few Narcan promotion kits, which were mailed to all Iowa pharmacies earlier in the year, are available. Pharmacies that would like an additional promo kit or more information about participating in the program may contact the Iowa PMP via email at pmp@iowa.gov. The Iowa PMP thanks the Iowa Department of Public Health for its ongoing support of this project.

Reviewing Prescription Requirements

When processing and billing prescriptions for both CS and non-CS, pharmacies should be aware of prescription requirements. Iowa Code regarding controlled and non-controlled prescriptions requires the prescriptions to have, at a minimum, the following information:

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- ♦ date of issue:
- name and address of the patient for whom the drug is dispensed;
- name, strength, quantity, and dosage form of the drug prescribed;
- directions for use; and
- name, address, and written or electronic signature of the prescriber who issues the prescription.

Prescriptions for CS must also include a Drug Enforcement Administration (DEA) registration number to be considered valid, per 657 IAC 10.24(1). All practitioners operating in Iowa must register with the PMP using a registered DEA number. If a practitioner is prescribing under an institution's DEA registration, they will be required to enter a unique identifier such as a National Provider Identifier following the DEA number.

A registered DEA number is not necessary on prescriptions for non-CS to be considered valid for dispensing.

Get to Know Your Pharmacy Board Members – Brett Barker

Type of position held on the Board - Pharmacist

What brought you to the Board? I previously served for many years on the IPA Legislative Advisory Committee and was completing my term on the IPA Board of Trustees. I have always had a passion for improving patient care through more effective policy, and it was a natural fit to apply for a vacancy on the Board of Pharmacy.

What is your favorite part of serving on the Board? I enjoy making a difference in the health and safety of Iowans. The work that we do matters.

Favorite Board/pharmacy memory? Very early in my career as a new graduate, I attended a meeting, with

some legends of Iowa pharmacy, where it was decided to start working on developing a new practice model for community practice. I worked on the project in its pilot stages through my professional role with NuCara. I was an IPA trustee when the legislation for technician product verification was passed and was able to participate in the rulemaking process as a new member of the Board of Pharmacy. It was very rewarding to be able to work on that project at each step from idea to implementation.

What is one misconception you think people might have about the Board? The Board wants to attain compliance through education whenever possible. We understand that the vast majority of licensees want to do the right thing.

Any words of advice for current or future pharmacists? Always put the patient first. That should be the center of all that we do.

What is your favorite summer activity? I enjoy lazy days in the pool with our kids.

If you could go anywhere in the world (COVID-19 aside) where would it be? I would love to visit Israel and see in person the places that I have read about in the Bible.

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