DECEMBER 2022

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Board to Discontinue Printing License and Registration Certificates

As of January 1, 2023, the Iowa Board of Pharmacy will no longer print certificates to mail to licensees and registrants. Upon issuance of a license or registration, including when renewed, the licensee or registrant will receive an electronic, printable certificate via email. Alternatively, licensees and registrants may log in to their Board online profile to print a certificate.

Reminder for Licensees to Ensure That Contact Information Is Current

Board staff would like to remind all licensees to make sure that their contact information (eg, email address and telephone number) is up to date. Individual licensees and registrants can review and update their contact information in their online profile. The Board's primary mechanism for communication to licensees for important functions, including license renewal, is email, so it is imperative that the Board has up-to-date information.

Compounding Records Rule Updated

The Board recently adopted an amendment to its rule for documentation of compounding of nonsterile and sterile products. The rule expands on the information required in the compounding record related to the components used in the preparation. The compounding record must now include the manufacturer or National Drug Code number, lot number, and expiration date of each component. Additionally, the compounding record needs to include the steps that were involved in the compounding

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of the preparation. Pharmacies should be reminded that the amended rule does not require a pharmacy to maintain a master formulation record above and beyond what is required in United States Pharmacopeia General Chapter <797>. Also, pharmacies that are preparing medications according to the manufacturer's package insert (eg, reconstituting and administering via intravenous bag according to the manufacturer's instructions) are not required to maintain documentation of these activities, as this type of preparation is not considered compounding.

Your Pharmacy's Social Media Presence

As social media presence continues to be an ever-growing market for many businesses, pharmacies should consider potential implications to operating in online spaces and establishing a policy for an online presence for both the pharmacy and its employees. A pharmacy's established policies for its social media accounts should include identification of which pharmacy staff members are authorized to post on behalf of the pharmacy, the content that is authorized, and the frequency of posting, among other considerations that the pharmacy might identify. A pharmacy's established policies should also address pharmacy employees who maintain personal social media accounts to ensure that employees are aware of the limitations of their personal posts, including via direct messaging functions with patients or the general public, as it relates to their work at the pharmacy. Whether a post is made by or on behalf of the pharmacy or a pharmacy employee in their personal capacity, all posts must remain compliant with patient privacy laws. Exercising professional judgment before posting anything online is crucial. Ensure that all posts adhere to the ethical and legal requirements of the Health Insurance Portability and Accountability Act and Food and Drug Administration.

Electronic Perpetual Inventory Logs

Pursuant to Board rule 10.18, a Controlled Substances Act registrant may utilize an electronic record to maintain its perpetual inventory for Schedule II substances. However, registrants must ensure that the system is compliant with the requirements set forth in the rule. Specifically, an electronic record system must be capable of hard copy printouts of all transactions for any specific period of time and must state the current inventory quantities of each drug at the time the record is printed. Perhaps the most likely aspect of an electronic record system that is not compliant with Board rule is the requirement that any changes are identified in an incident report. The incident report must include the information that was changed, including the information before and after the change, the individual making the change, and the date and the reason the record was changed. Some pharmacies have been observed utilizing a simple computerized spreadsheet (eg, Microsoft Excel) for perpetual inventory, but such spreadsheets are easily edited without the system capturing the change. Pharmacies must ensure that any electronic record utilized to maintain perpetual inventory is compliant with the Board's rule.

Board Updates Rule Relating to Care Facility Documentation of Immunizations

In response to a review of Chapter 23 required every five years and recommendations from a care facility's pharmacy stakeholders, the Board recently adopted a rule amendment that "provides a time frame for a care facility to submit documentation to the provider pharmacy relating to the administration of vaccines provided by the pharmacy for an immunization or screening program." The rule requires the care facility to provide the documentation back to the provider pharmacy no later than seven days following administration of the vaccine. The rulemaking was published as adopted, with an effective date of January 4, 2023.

Board Updates Rules Relating to Licensure of Outsourcing Facilities

In response to a review of Chapter 41 required every five years, the Board recently adopted amendments to rules governing licensed outsourcing facilities operating within or into Iowa. The amendments provide more detailed information for applicants relating to the inspection requirements provided in Iowa Administrative Code (IAC) 155A.13C(1)"e": "[c]larification on when a change of ownership is determined to have occurred, necessitating a license change; late penalty fees to be assessed when an outsourcing facility is not timely in submitting an application for license changes; and a fee to be assessed to a licensee for written verification of a license when the Board's online verification system is available at no charge." The rulemaking was published as adopted, with an effective date of January 4, 2023.

Board Narcan and Disposal Programs

The Board continues to be encouraged by pharmacy participation in its two programs aimed at reducing opioid or other controlled substance (CS) misuse or overdose. But more work can be done! Pharmacies can dispense a medication disposal kit, eg, DisposeRx or Deterra (no prescription required) or naloxone, eg, Narcan®, generic, or Kloxxado® (prescription can be generated under the Board's statewide protocol or the Department of Health and Human Services' (HHS's) statewide standing order) to Iowa patients and submit an electronic claim for reimbursement with no cost to the patient. For providing patient education and the respective product, pharmacies are reimbursed $7.50 for a disposal kit or HHS actual acquisition cost reimbursement plus a $20 dispensing fee for naloxone.

More information about these important programs can be found at *pharmacy.iowa.gov/disposal-kit-dispensing-program.*

Since January 1, 2022, Iowa pharmacies have dispensed 2,191 naloxone kits and 13,432 disposal kits.

Funding for both opportunities is made available through the State Opioid Response 2 grant, which is funded by the Substance Abuse and Mental Health Services Administration.

Receipt of a Hard Copy Prescription During Prescriber Technical Difficulties

The Iowa law that requires all prescriptions, including CS, to be electronically transmitted to a pharmacy has been in effect for nearly three years. Inevitably, practitioners will experience technical difficulties in their electronic prescribing platforms and need to issue hard copy prescriptions temporarily for their patients. In this event, prescriptions should be issued with notation by the practitioner that the practitioner is experiencing temporary technical difficulties. The law does not prohibit pharmacies from filling prescriptions that are issued in an alternative manner and does not require pharmacists to verify if the prescriber or prescription is covered by one of the several exemptions provided by IAC 155A.27 or 124.308. Pharmacists should always utilize their professional judgment and exercise due diligence in assessing any prescription for fraud, but they are not strictly prohibited from filling legitimate prescriptions that are issued in an alternative manner.

Schedule II Prescription Annotations

The Board periodically receives questions from licensees about the elements of a prescription issued for a Schedule II CS that can be changed after it has been issued by the prescriber. Elements that may never be changed include the patient's name, the CS prescribed (except for generic substitution), or the name or signature of the prescriber. Other elements of the prescription that may be changed or added, after consultation with the prescriber or the prescriber's agent, include the drug strength, dosage form, or quantity; the directions for use; the prescriber's address; or Drug Enforcement Administration registration number. Confusion often arises from the date elements of a Schedule II prescription. The date that the prescription is issued by the prescriber is an element that can be added or changed after consultation with the prescriber or agent. If the prescription is issued with a future date for the prescription to be filled (ie, the prescription may not be filled prior to the future fill date), this date may not be altered, even if the prescriber wishes to amend the date. Pursuant to 657 IAC 10.29(4), the authorized fill date is unalterable, regardless of the provisions of 657 IAC 10.30. In the event that a prescription is issued with a future (authorized) fill date and the prescriber has determined that they would like the patient to be able to have the medication prior to the established date, the prescriber is required to issue a new prescription.

Board Meeting Schedule Published for 2023

The Board meets six times a year, and the dates for its 2023 meetings are now available. The current schedule is January 10, February 28-March 1, May 2-3, June 27-28, August 29-30, and

November 7-8. The Board may condense a meeting into one day if the agenda of materials for the Board's consideration can be accomplished in that length of time. An agenda is published approximately one week prior to the scheduled meeting. Pharmacists and technicians may obtain one hour of law continuing education for their attendance. A sign-in sheet is available for those attending in person or virtually.

Meeting information, including posted agendas and approved minutes, can be found at *pharmacy.iowa.gov/meetings*.

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