



IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

DSCSA Resources for Dispensers Now Available in One Place

As the Drug Supply Chain Security's Act (DSCSA's) 2023 deadline for unit-level traceability approaches, the National Association of Boards of Pharmacy® and six other pharmaceutical organizations have launched *DSCSA.pharmacy*, which compiles a range of resources for dispensers. The website includes checklists, podcasts, and webinars to ensure that dispensers are prepared to comply with the law. Basic information, including an overview of the DSCSA, key milestones (such as when manufacturers, distributors, and dispensers must provide and receive transaction information and statements in a secure, electronic, and interoperable manner), and the definition of a dispenser per DSCSA, is also provided.

Take advantage of the resources available to ensure that you are meeting current requirements and to prepare for interoperability by 2023. New resources will be added to the website as they become available.

New Pharmacy Security and CS Accountability Rules in Effect

On July 6, 2022, **new rules** related to pharmacy security and controlled substance (CS) accountability became effective. The primary changes to the rules for community pharmacies (pharmacies subject to Chapter 6) include:

- use of a basic alarm system no later than July 6, 2023;
- use of a video surveillance system no later than July 6, 2023;

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- controlled access to computer records; and
- use of a designated, monitored area, away from drug storage and handling areas, where personal items of pharmacy staff may be stored while on site.

Changes that apply to all Controlled Substances Act registrants include:

- separation of duties related to purchasing, receiving, stocking, dispensing, and reconciling of CS inventory;
- development of a CS accountability program to document the review of CS inventory adjustments, review patterns of loss, and create an action plan following a theft/loss;
- reconciliation of Schedule II perpetual inventory after each transaction;
- documentation of exact counts of all CS in an inventory, except for liquids in non-incremented packaging, which can be estimated to the nearest one-fourth container;
- documentation of a complete CS inventory with each change of pharmacist-in-charge (PIC), including when the incoming PIC is temporary or interim, except that an inventory will not be required in the case of an interim PIC change when the pharmacy maintains perpetual inventory of all CS;
- development and implementation of an action plan within seven days of a theft or loss that addresses the conditions that contributed to the theft or loss; and
- utilization of at least one of the following measures to ensure accountability of Schedule III-V CS:
 - perpetual inventory log of all substances,
 - documented audit and reconciliation of all CS every six months,
 - routine documented cycle counts of substances, so long as all CS are counted every 90 days and identified discrepancies are investigated and documented, or
 - another measure preapproved by the board of pharmacy.

The Iowa Board of Pharmacy has developed a Pharmacy Security Self-Evaluation that can provide pharmacies with a tool to perform a gap analysis for the pharmacy's security measures. Pharmacies can email Amanda.woltz@iowa.gov to request a copy of the self-evaluation document. Pharmacies or registrants that have questions about the new rules can reach out to their assigned compliance officer for assistance.

New Rules to Allow Veterinarians to Dispense From Office Stock

Effective July 6, 2022, **veterinarians** who obtain compounded preparations for office stock use will be allowed to further dispense from the office stock in limited circumstances. The product can be

dispensed from office stock to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

New Rules to Allow Remote Technician Functions and Pharmacist Counseling

The Board recently adopted **rulemaking**, effective August 31, 2022, that allows a supervising pharmacist to delegate technical functions relating to prescription processing (eg, data entry) to a certified pharmacy technician who is performing the task at a location that is not a licensed pharmacy when certain safeguards are in place. The pharmacy must ensure that adequate security and supervision are maintained at all times to prevent unauthorized access to, and unauthorized storage/transfer of, confidential patient information or records; the supervising pharmacist has real-time access to the prescription processing system that the technician is using or patient record that the technician is processing; the supervising pharmacist is available to respond to technician questions via a real-time communication mechanism at all times when the delegated functions are being performed; and the pharmacy's prescription processing system is capable of documenting the functions performed by the technician. The rulemaking also allows a pharmacist to provide remote patient counseling from a location other than a licensed pharmacy if it is provided via a real-time interactive communication mechanism.

New Rules Relating to Pharmacy Ownership Changes, Provision of a Toll-Free Telephone Number by Nonresident Pharmacies, and Pharmacy Emergency Relocations

As of August 31, 2022, amended paragraph 8.35(6)c became effective, which alleviates the difficulties that pharmacies have encountered as a result of an ownership change that affects the majority ownership interest of the owner listed on the pharmacy's most recent pharmacy application. In such instances, the pharmacy will no longer be required to submit an application and fee for a new pharmacy license. This change will better align with how Drug Enforcement Administration (DEA) handles such ownership changes and will allow pharmacies to continue normal operations without the impacts that a new pharmacy license would otherwise require (eg, updating third-party or supplier contracts, 340B program, etc).

The **rulemaking** also alleviates a burden for nonresident pharmacies that do not directly dispense prescription drugs or devices to Iowa residents. Pursuant to new subrule 19.2(6), only nonresident pharmacies that directly dispense to Iowa residents will be required to provide evidence of a prescription label that provides a toll-free telephone number for patients to have access to a pharmacist who has access to the patient's record during the pharmacy's regular business hours.

Finally, the rulemaking creates new subrule 8.35(10), which provides a framework for pharmacies that experience some exceptional circumstance or natural disaster that renders the pharmacy unsafe to temporarily relocate to continue pharmacy operations to serve their community.

COVID-19 Vaccinations Authorized for Patients Six Months and Older

Food and Drug Administration has amended its emergency use authorizations (EUAs) for some coronavirus disease 2019 (COVID-19) vaccinations to allow patients as young as six months to receive the immunization. Pharmacists have questioned if they are legally authorized to administer the COVID-19 vaccine to this patient population. Under the Board's statewide protocol for immunizations, pharmacists are authorized to administer immunizations to patients six months or older for influenza and "other immunizations in response to a public health emergency." So long as the federal public health emergency is in place, pharmacists are authorized to administer the COVID-19 vaccinations to this patient population in compliance with the EUAs.

Updating Your Current Contact Information

The Board would like to remind all licensees and registrants of the importance of keeping your online database profile current with the most updated contact information. All communication about license renewal and other important information is provided via the contact information that has been provided to the Board, and you may miss important information or renewal deadlines if you have not provided the Board with the best way to contact you. Be sure that the email address that you provide is one that you regularly check to avoid missing important information. Licensees and registrants can visit the Board's [website](#) and click on "User Profile and Update Demographics."

Nurses No Longer Required to Hold Board of Pharmacy Registration to Engage in Vaccinations or Protocols Under a Pharmacist's Order

As a result of the enactment of [House File \(HF\) 2169](#) during the 2022 legislative session, registered nurses who are actively licensed with the Iowa Board of Nursing are allowed to administer immunizations and perform nursing functions in the utilization of a Board of Pharmacy-approved statewide protocol without an additional technician registration with the Board of Pharmacy. Nurses who are engaged in these activities, under a pharmacist's order, are limited to those nursing practices and are not authorized to engage in any other technician duty without a pharmacy technician registration.

School Districts Now Authorized to Maintain Non-Patient-Specific Stocks of Bronchodilators and Opioid Antagonists

As a result of the enactment of two bills during the 2022 legislative session, school districts will be authorized to have additional stocks of non-patient-specific medications to assist students, staff, and guests who are having an emergency. The authorization mirrors that which currently exists for schools to have a non-patient-specific stock of epinephrine autoinjectors.

HF 2573 provides that a school district may obtain a prescription in the name of the school district for an opioid antagonist to be maintained on site. The bill also amends the definition of “person in a position to assist” to include a “school employee.”

HF 771 provides that a school district or accredited nonpublic school may obtain a prescription in the name of the entity for a bronchodilator or bronchodilator and spacer to be maintained on site.

The Board will be amending its rules in the coming months to implement the bills.

Hospital/Health System Network Fraud Alert

A recent report from the Nebraska Pharmacists Association noted that hospital pharmacies are the newest targets of ordering schemes where perpetrators have impersonated distributors, their state’s board of pharmacy, and the pharmacies themselves. They may request the pharmacy’s DEA number and/or account information for their main distributor. Distributors are then targeted by the perpetrators impersonating the hospital pharmacy to order products. The pharmaceutical and health care products most recently targeted have included antidepressants, blood thinners, anti-inflammatory and HIV drugs, AED defibrillator machines, stethoscopes, and blood pressure monitors. When these products are delivered to the hospital pharmacy, the perpetrators contact the pharmacy, impersonate the distributor, and claim the products were sent in error. They send a courier to pick up the order, then contact the pharmacy to confirm that the products were picked up. The courier is almost always an entity that the pharmacy has never used before. Be aware; they are likely to target the same pharmacy again if they are successful.

For more information please visit [here](#).

The Iowa Board of Pharmacy News is published by the Iowa Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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