SEPTEMBER 2024

NORTH DAKOTA BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

FDA Grants Small Dispensers Exemptions From Certain DSCSA-Related Requirements of FD&C Act

Food and Drug Administration (FDA) has granted small dispensers (pharmacies) and, where applicable, their trading partners an exemption from certain requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) until November 27, 2026. With this exemption, small dispensers will have more time to stabilize their operations and completely implement the Drug Supply Chain Security Act's (DSCSA's) drug distribution security requirements.

FDA classifies a dispenser as a small dispenser if "the company that owns [it] has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians." FDA notes, "Trading partners that do not qualify for the small dispenser exemptions and are unable to meet the enhanced drug distribution security requirements of [S]ection 582 of the FD&C Act by November 27, 2024, may request a waiver or exemption from those requirements." Additional details about requesting a waiver or exemption are available in the FDA press release; the agency states that the DSCSA one-year stabilization period will still end on November 27, 2024, and will not be extended beyond this date.

The North Dakota Board of Pharmacy continues to engage in conversations from a national perspective to learn more about various nuances and better understand the pharmacy industry's readiness for the impending deadlines. The Board suggests that you continue to discuss DSCSA compliance with your trading partners to ensure a

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FDA Grants Small Dispensers Exemptions From Certain DSCSA-Related Requirements of FD&C Act *(continued)*

smooth transition to compliance and begin work on the policies and procedures that DSCSA will require.

A trusted resource that the Board heavily relies on for information is the National Association of Boards of Pharmacy®, along with frequently updated resources on its website.

NCPDP SCRIPT Standard Version 2023011 Supports EPCS Transfers Between Pharmacies

Centers for Medicare & Medicaid Services (CMS) has issued a final rule requiring health information technology standards to adopt the new National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 2023011. Pharmacies are instructed by CMS to transition from the NCPDP SCRIPT Standard Version 2017071 to Standard Version 2023011 by January 1, 2028.

NCPDP SCRIPT Standard Version 2023011 has the capabilities to support transfers of electronic prescriptions for controlled substances (EPCS) between pharmacies and other enhancements, such as:

- improved extensibility;
- the addition of observation elements to Risk Evaluation and Mitigation Strategies transactions;
- added support for dental procedure codes, patient gender and pronouns, and patient conditions;
- redesigned Product/Drug groupings;
- modifications to Structured and Codified Sig Structure format;
- support for a three-way, multi-party transaction among prescriber, facility, and pharmacy to allow EPCS in long-term settings; and
- "specific, electronic" prior-authorization transactions that will be required.

NCPDP SCRIPT Standard Version 2023011 is backwards compatible with NCPDP SCRIPT Standard Version 2017071. Both NCPDP SCRIPT standard versions may be used simultaneously during the transition period to facilitate the implementation process and flexible adoption timeline for pharmacies, prescribers, health IT vendors, and others involved.

The new software has the data elements needed to document transfers between pharmacies, which allows them to follow Drug Enforcement Administration's (DEA's) final rule, *Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling.*

Under DEA's rule, pharmacies are permitted to submit EPCS in Schedules II-V between retail pharmacies for initial filling on a one-time basis only, after receiving a request from the patient, and must transfer any authorized refills on the prescription for Schedule III, IV, or V controlled substances with the original prescription. According to the rule, "the transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form; and the contents of the prescription required by 21 CFR part 1306 must be unaltered during the transmission."

2025 Legislative Session

The 2025 legislative session is right around the corner. It appears that this will be another busy session with many important topics to be debated and acted upon. As always, multiple legislative items involving pharmacy, either directly or indirectly, will likely be brought before the legislature.

In the lead-up to the legislative session, the Board encourages you to contact your legislators about issues and/or concerns that you have in your practice. Legislators may not be able to address each issue that we deal with; however, they must not only be made aware of the challenges that pharmacy is facing but also the successes that our profession has created. Our profession is increasingly sought after for solutions to health care delivery issues across the state. It is important that you, their constituents, educate them on your experiences and your professional perspectives on the issues.

Immunization and Medication Administration Guidance

As we approach the start of another immunization season, the Board wants to remind you that the scope for a pharmacist or intern to administer medications (including immunizations) was expanded in 2019. These changes removed the need for the Board to issue the two-year injection certificate based on an individual providing proof of the various requirements.

The new standards still require individuals to stay up to date with CPR or basic cardiac life support certification and obtain/maintain the continuing professional competencies necessary, according to the standard of care, for the administrations that they intend to provide.

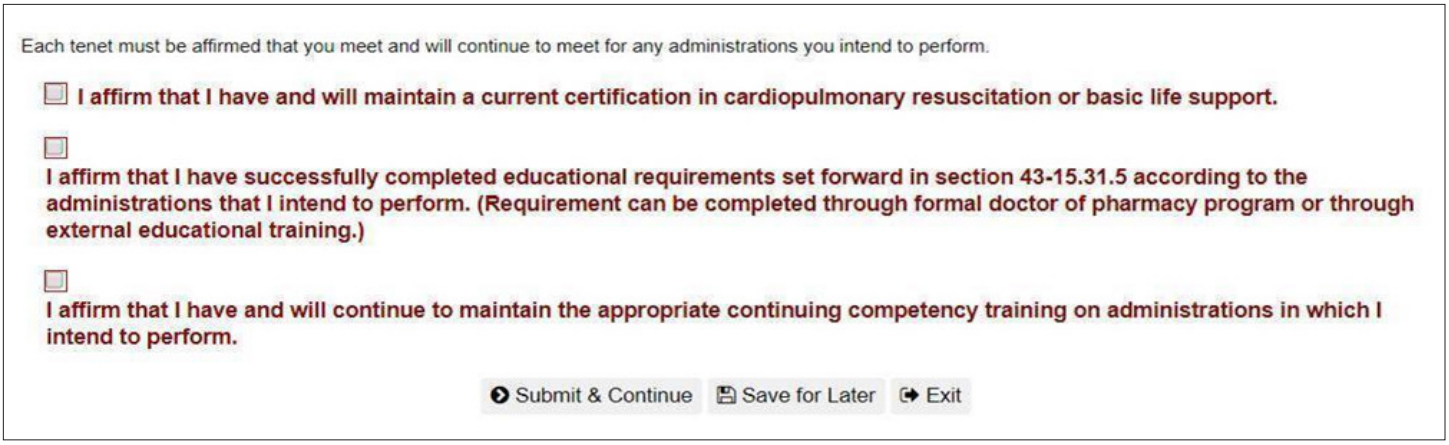
The Board has transitioned to a streamlined process for a pharmacist/intern to add the "administration authority" issued by the Board to their license. Once attestations are made and approved, this "administration authority" will be designated on an individual pharmacist/intern license, constituting legal authority for providing administrations according to a pharmacist's practice.

There are two ways to update and maintain the "administration authority" on your license:

1) During your next license renewal: Check the three boxes (shown below) affirming each standard. There is no need to submit certificates unless specifically requested by the Board.
2) Outside of your license renewal: You can add the "administration authority" by using the "Change Address/Data/ Administration Authority" function on the Board's website and attest to the standards below.

Immunization and Medication Administration Guidance

(continued)



If you have any questions, please feel free to contact the Board's office directly.

Address Changes

Please ensure that your address, email, and work information are promptly updated with the Board upon any change, as required by law. The Board has an easy process on its website to make any necessary changes to your records. Be sure to include a regularly maintained email address, as this is increasingly the way to communicate important changes and updates from the Board.

Reprinting and Verifying Licenses

You can verify any pharmacy license or registration on the Board's website. License verification printouts for various entities can be accomplished this way.

The Board's website also allows you to reprint your license or registration anytime. This technology is useful in ensuring that all licenses are properly posted at your facility.

The North Dakota Board of Pharmacy News is published by the North Dakota 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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