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NORTH DAKOTA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Single-Sheet DEA Form 222

Drug Enforcement Administration (DEA) has issued a direct final rule to amend DEA regulations that either the purchaser or the supplier may enter a supplier's DEA registration number on the single-sheet DEA Form 222, effective October 18, 2021.

In September 2019, DEA issued a final rule to implement a new single-sheet DEA Form 222 (single-sheet form) to replace the three-part carbon copy form (triplicate form). On the single-sheet form, the field for the supplier's DEA registration number is located directly above a section titled "to be filled in by purchaser," which has led to some confusion regarding who must record the supplier's DEA registration number on the single-sheet form. Therefore, DEA is amending its regulations to clarify that either the purchaser or the supplier may fill in this information on the single-sheet form.

DEA also notes that the single-sheet form has been modified – and approved by the Office of Management and Budget – by the addition of a line that separates the field for the supplier's DEA registration number from the field titled "Part 2: To be filled in by the purchaser," in which the supplier's business name and address are recorded. The revised version of the form is being provided to any registrant requesting paper DEA Forms 222 pursuant to Title 21 Code of Federal Regulations §1305.11.

Furthermore, DEA notes that this rule does not impose any new requirements as the supplier's DEA registration number is already required to be entered on the single-sheet form. This direct final rule is effective on October 18, 2021, without further action unless there are significant adverse comments. If DEA receives significant adverse comments, it will publish a withdrawal of the rule in the *Federal Register* by September 20, 2021.

Drug Supply Chain Security Act Updates

By Hannah Scheetz, PharmD Candidate 2022

Changes are coming for traceability of prescription drugs. Food and Drug Administration's (FDA's) Drug Quality and Security Act was enacted by Congress in 2013, and Title II contains the Drug Supply Chain Security Act (DSCSA). The goal of this act is to have an electronic, interoperable system to identify and trace prescription drugs distributed at a package level and establish national licensure standards for wholesale distributors and third-party logistics providers (3PLs) by November 27, 2023.

An electronic, interoperable system to trace prescription drugs will allow companies to know who has touched the products and if there are any vulnerabilities or threats. This system will also use product identifiers to verify products and quickly respond to any suspect or illegitimate products, improve efficiency of recalls, and allow FDA to track counterfeit, stolen, contaminated, or harmful drugs. Products that are covered under this act include prescription drugs that are in finished dosage form for patient administration without further manufacturing. This includes capsules, tablets, and lyophilized products before reconstitution.

Under the DSCSA, key requirements include having authorized trading partners, verification, product tracing, and product identification. Trading partners include manufactures, repackagers, wholesale distributors, dispensers, and 3PLs. For trading partners to be considered authorized, manufactures and repackagers need a valid registration with FDA; dispensers need a valid state license; and wholesale distributors and 3PLs need a valid state or federal license with reporting requirements to FDA annually. Verification includes quarantining and investigating suspect drugs. An investigation requires validating applicable transaction information and transaction history along with verifying lot number and product identifiers; notifying FDA and trading partners within 24 hours if a product is illegitimate; responding to manufacturers about illegitimate drugs to avoid patient use; and, finally, storing records for six years.

Current product tracing requirements include lot-level tracing in paper or electronic formats; however, by November 2023, tracing will be to the package level and in electronic formats. Product tracing requirements include receiving drugs only if there is valid transaction information, transaction history, and transaction statements; providing tracing information with all prescription drug transactions; responding to recalls or investigating a suspect or illegitimate product; storing tracing information for at least six years; and returning product to the trading partner the pharmacy originally bought the drug from when necessary. Pharmacies are required by law to confirm whom they are doing business with. This includes checking the licensing of wholesale distributors, 3PLs, and pharmacies, and the registration of manufactures and repackagers on the North Dakota State Board of Pharmacy's website. The last requirement – product identification – includes a National Drug Code, serial number, lot number, and an expiration date readable to humans and a barcode for machines.

FDA is currently developing regulations to enhance drug distribution systems for interoperable, electronic tracing of a product at the package level and released of a draft guidance in June 2021. Final guidance on the necessary system attributes for secure tracing is estimated to be released in November 2022. This will allow pharmacies to become compliant with the needed technology by the November 27, 2023 date.

Passage of Senate Bill 2221 – Practice Changes

Previously published in the Board's June 2021 Newsletter with edits

The North Dakota Legislature passed, and Governor Doug Burgum has signed into law, Senate Bill 2221. This legislation carried an emergency clause, which makes it effective immediately upon signature of the governor.

Included in the bill are three distinct provisions that expand pharmacists' authority to further impact patients.

1. This legislation authorizes pharmacists to provide immunizations, injections, and other administrations to patients as young as three years of age or older.
2. This legislation expands the pharmacist's ability to provide "emergency pharmacy practice" dispensing. This extends the one-time emergency fill from 72 hours to a 30-day supply and allows the pharmacy to bill using the pharmacist's National Provider Identifier number. This is a similar authorization to an executive order from Governor Burgum, which has been in place since April. Please note that any decision to dispense via emergency pharmacy practice must be based on provisions a-e, which are listed in the law.
3. This legislation gives the Board the authority to establish statewide protocols for public health issues. The Board intends to establish statewide protocols for pharmacists' ability to provide immunizations and tobacco cessation products by drafting and implementing rules. At this point, there is no actionable authorization that you can establish within your practice. However, please be aware that this will be forthcoming and prepare. The Board is working through the rulemaking process and hopes to have rules finalized with the statewide protocols for both the immunization and tobacco cessation prescriptive authority in January 2022.

As always, if you have any questions, please feel free to contact the Board office.

North Dakota Drug Repository: Benefits for Everyone

By Jake Bloms, PharmD Candidate 2022

The North Dakota Prescription Drug Repository is a program dating back to 2006, when the American Cancer Society reached out to the Board to develop a program that obtains voluntarily donated medications, devices, and supplies from the public. It allows participating pharmacies to redistribute these items back to those in need. From this conversation in 2006, former North Dakota governor and current United States senator, John Hoeven, signed House Bill 1256 in April

2007. A short time later, in July 2007, the bill took effect. Since then, the program has allowed individuals to get rid of unwanted medications, avoid pharmaceutical waste that can harm the environment, and provide others with medications at an affordable price.

Where can someone donate or obtain these medications?

Registered pharmacies and practitioners may accept the medications, devices, and/or supplies that fit the following criteria: items must be in the original, unopened, sealed, and tamper-evident unit-dose packaging. However, except a drug packaged in single-unit doses may be accepted and dispensed if the outside packaging has been opened and the single-unit-dose package is unopened. Examples of single-unit doses would be medications in blister packs/punch cards or nebulizer capsules.

To find out which registered pharmacies or practitioners participate in the program for North Dakota, visit the Board's website. After scrolling down slightly, an image for the drug repository program will appear on the right-hand side of the screen. Clicking on this image will take you to the main page for the program. From here, click on "Search for a Donated Drug or Supply" or "Search for a Participating Pharmacy or Prescriber," both of which are found under the Searches header. The latter of these two options pulls up an alphabetical list of all participating pharmacies and practitioners in the state of North Dakota. Clicking on the name of the location displays all the medications currently on hand through the repository program. To look up a specific medication, go to the "Search for a Donated Drug or Supply" tab. Search by the medication's name, and/or by a certain location to see if there is a current supply. The website also shows users the name of the medication, device, supply, strength of the drug, and expiration date. Clicking on the name of the pharmacy participant again will bring up the store's contact information.

What does someone need to participate in the repository program?

Both donors and recipients must provide their name, address, and a signature. Donors must also provide a telephone number and the name of the patient for whom the medication was originally prescribed. Recipients must also have a valid prescription from their provider for the medication they wish to obtain. The forms for both donors and recipients can be found on the main page of the drug repository program located on the Board's website. If someone is interested in receiving long-term prescription assistance, the "Prescription Connection" link at the bottom of this same page will connect patients with the North Dakota Insurance Department. This program helps people of all ages obtain free or discounted medications.

How does this program reduce costs for patients?

When a medication, device, or supplies are donated to the program, the pharmacy cannot resell the medication. Instead, the pharmacy may redistribute the medication at no charge but with a small dispensing/handling fee. This fee has a maximum cost of 2.5 times $4.60, which equates

to $11.50. For certain medications such as insulin, diabetic testing supplies, or inhalers, the cost savings can be enormous.

Increasing drug prices continue to be an area of debate and have left lawmakers struggling to come up with a solution. The drug repository program is one way that pharmacists and practitioners may provide patients with affordable medications so they may receive necessary treatments. It is equally as important that patients donating medications know about this program as it is for recipients looking to obtain the medication. Without donations from patients, nursing homes, hospitals, and local hospices, the program is unable to function. The drug repository program can significantly reduce costs for patients, but it is only as effective as the people who know about it. Pharmacies and pharmacists are encouraged to fully participate in the program and do their best to assist patients with donations and navigating access to needed medications.

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