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NORTH DAKOTA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

The Evolution of Biosimilar Products

By Mark Hardy, PharmD, RPh, Executive Director – North Dakota State Board of Pharmacy

It seems like it has been a long time since the initial discussion on biosimilar biological products and the concept of their "interchangeability" first came to North Dakota by way of a legislative bill in 2013. That legislation was passed and set standards for the process of interchangeability of biosimilar products for their biological counterpart.

This topic has once again risen to the top and been a source of many questions to the Board given the recent approval of **Semglee®**, which is an interchangeable biosimilar for **Lantus®** insulin. Third parties are seizing opportunities to use the biosimilar in their formulary, resulting in questions on the process to interchange based on a practitioner's prescription.

To reinforce the terminology, first, there are biological products that are considered brand-name products. Second, there are biosimilar drugs, which would be considered generic and highly similar structurally to the reference biological counterpart. The ability to deem a biosimilar as being interchangeable by Food and Drug Administration (FDA) standards means that there is no meaningful clinical difference between one product or the other in safety, potency, and purity. It is important to note that few biosimilars are deemed to be interchangeable at this point. The reference for you, the pharmacist, to know is the "Purple Book." The Board has the link to the "Purple Book" on its website, or a simple search will allow you to access it from FDA's site.

During the last legislative session, House Bill 1033 was passed and has been signed into law by Governor Doug Burgum, which modified the standards for pharmacies around interchangeability. Essentially, it broadened and reduced the burden on pharmacists for what is required for notification to the prescribing practitioner. The standards for interchangeability of biosimilars are set by FDA.

The pharmacy can substitute an interchangeable biosimilar for the referenced product as long as:

1) it is deemed to be interchangeable – reference the "Purple Book";
2) the prescription has not been designated by the prescriber as "brand medically necessary";

3) the patient does not refuse to receive the biosimilar product;

4) you keep a record of the interchangeable substitution that is made; and

5) the pharmacy notifies the prescribing practitioner within two business days of the substitution.

As you will note, there are multiple avenues to notify the practitioner in subsection 2 of Section 19-02.1-14.3 of the North Dakota Century Code. Included below is a copy of the language the law dictates:

2. A pharmacy may not substitute a prescription biosimilar product for a prescribed product unless each of the following requirements is met:
   a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product.
   b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting 'brand medically necessary' on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the 'brand medically necessary' language with an electronically transmitted prescription.
   c. The pharmacist or the pharmacist's designee informs the individual receiving the biological product that the biological product may be substituted with a biosimilar product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse.
   d. Within two business days following the dispensing of the biosimilar product, the pharmacist or the pharmacist's designee notifies the prescribing practitioner of the substitution. Notification under this subdivision must include the name of the substitution product and the name of the manufacturer, and may be made using facsimile, telephone, electronic transmission, an entry into an interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by the prescribing practitioner.
   e. The pharmacy and the prescribing practitioner retain a record of the interchangeable biosimilar substitution for a period of no less than five years.

The Board always recommends that you document the steps that you take for future reference should the need arise.

If you have any questions, please reach out to the Board for clarification as it is expected that more interchangeable biosimilars will be introduced and approved in the market.

Up-and-Coming Changes to the Role of Pharmacist

By Madison Nelson, PharmD Candidate – Creighton University

North Dakota recently passed legislation during the 2021 session that grants pharmacists prescribing authority for two public health issues. This means that pharmacists in North Dakota

can now independently prescribe and dispense orders for immunizations and for tobacco cessation drug therapy.

As the pharmacy profession has grown, so have the responsibilities of the pharmacist. Because of the coronavirus disease 2019 (COVID-19) pandemic and the implementation of the Public Readiness and Emergency Preparedness Act, pharmacists have been ordering and administering COVID-19 immunizations and other related therapies without needing a collaborative agreement with a prescriber. The precedent may have come about due to the emergent nature of the pandemic, but nonetheless, pharmacists can handle and perform more clinical roles even in the community setting.

The future is bright for pharmacy in North Dakota, and a growing prescribing authority for pharmacists is part of that future. Pharmacists have been adaptive to continually provide better care and more resources to their patients. Accessibility is always a concern, especially within rural North Dakota, and these laws will help to provide some relief to the health care system while also increasing accessibility to patients.

The protocols for these two laws have been approved by the Board. These protocols, and their supplementary guidance documents, will be available on the Board's website. The guidance documents are quick references that are simplified versions of the full protocol. Please refer to the full protocol for greater detail, or for any questions that are not addressed in the guidance document. The Board may also be contacted for any questions regarding the protocols. Referenced below are the guidance documents for prescribing immunizations and tobacco cessation drug therapy.

Pharmacist Prescribing Authority for Immunizations

Now, with the enactment of legislation and the Board's rules, the Board's current protocol states that authorized pharmacists may independently order and administer immunizations while exercising their professional judgment for patients three years old or older. An authorized pharmacist may also delegate administration to a qualified pharmacy technician (according to North Dakota Administrative Code (NDAC) 61-04-11) or another health care professional (if authorized by their respective health care act). Please refer to the full protocol for more information.

Addressing conflict of guidelines: Protocol is based upon current criteria established by the US Centers for Disease Control and Prevention (CDC) and/or the Advisory Committee on Immunization Practices (ACIP). If a conflict does arise between this protocol and future guidelines, the most current CDC and/or ACIP guidelines will supersede.

Types of immunizations: This protocol applies to ACIP/CDC-approved vaccinations from their regular and catch-up schedules, immunizations recommended for travel, and emergency immunizations approved during a public health emergency.

Provided to the patient: Patient handouts and/or vaccine information statements should be given to the patient prior to administration. Authorized pharmacists shall screen each patient for appropriateness of receiving a vaccine and provide recommendations to the patient prior to vaccine ordering and administration. The patient shall be observed for immediate adverse reactions by the authorized pharmacist. The patient should be requested to remain in an observation area for a minimum of 15 minutes.

Records and reporting: Must obtain informed consent prior to administration. This consent may be provided verbally or written. Must record all immunizations ordered and administered. These records need to be kept at least five years from the date of administration. Any immunization ordered and administered must be reported to the North Dakota Immunization Information System within 14 days of its administration. This step can be completed by either the authorized pharmacist or their designee. Report any adverse events following an immunization administration, even if the cause of said event is unclear. Also notify a patient's primary care provider of any events if they occur.

Safety: Authorized pharmacists shall have CPR or basic life-support certification and access to epinephrine and other related emergency supplies. They will also follow Occupational Safety and Health Administration regulations and state law for injection needle safety and disposal.

Prescribing Tobacco Cessation Products Guidance Document

With the development of e-cigarettes and vaping, nicotine dependence has begun to steadily increase, and so has the demand for tobacco cessation resources. To increase accessibility for those who want to pursue quitting, NDAC 61-04-15 grants qualified pharmacists independent prescribing authority for tobacco cessation, as outlined in the protocol. For greater detail, please refer to the full protocol.

Tobacco products: Includes traditional tobacco-containing products, such as cigarettes, smokeless tobacco, etc, and/or e-cigarettes, and other devices used for nicotine inhalation/dependence.

Qualifications: Must have an active North Dakota pharmacist license. Have completed training approved by the Board for prescribing tobacco cessation drug therapy, or training in line with NDAC 61-04-15-02. Be acting in good faith and providing care that aligns with current clinical guidelines.

Products that can be prescribed: Any FDA-approved medication with an indication for tobacco/smoking cessation. May not prescribe medications for off-label use according to the current protocol.

Procedure: Process can start by patient request or by pharmacist offering to initiate based on professional judgment. May offer tobacco cessation services even if patient is not deemed ready

to quit. Patient readiness should be assessed using the 5 A's approach for quitting or by a similar strategy. Assessment should be performed using current evidence. A health screening must be performed and documented. This should be used to identify candidates for treatment by the pharmacist or to identify high-risk patients who should be referred to an appropriate provider.

Counseling and follow-up: Are highly recommended to be done with the patient. Encourage the patient to ask questions. Counseling includes medication and tobacco cessation behavioral counseling, as providing both is best practice. Tobacco cessation behavioral counseling can be done by the pharmacist or referred to an appropriate source.

Therapy options: Shall be decided in consultation with the patient. May select and dispense either single or combination tobacco cessation therapy. Combination therapy options can be selected based on clinical guidelines and/or on published peer-reviewed literature. Product selection should be based on patient factors and preferences.

Reporting and documentation: Informed consent can be obtained verbally but should always be documented. The pharmacist shall provide product information and educational material to the patient. Notify the patient's primary care provider of the therapy provided within a reasonable time frame if the patient has one. Maintain all records of interaction for at least five years.

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