



State of North Dakota
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
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STATE BOARD OF PHARMACY

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www.ndboard.pharmacy

Mark J. Hardy, PharmD
Executive Director

June 7, 2021

Ms. Vonette Richter
Assistant Code Revisor
North Dakota Legislative Council
State Capitol
600 East Boulevard, 2nd Floor
Bismarck, ND 58505-0360

Dear Ms. Richter:

The Notice of Intent to Adopt and Amend Administrative Rules and a copy of the proposed rules are enclosed as required by N.D.C.C. § 28-32-10(1).

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Hardy".

Mark J. Hardy, PharmD
Executive Director

MJH/eh

Enclosures

**FULL NOTICE OF INTENT TO ADOPT AND AMEND
ADMINISTRATIVE RULES RELATED TO THE PRACTICE OF PHARMACY**

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed new sections and amendments to existing sections of N.D Admin. Code relating to the ND State Board of Pharmacy Practice Act at 10:00 AM on Thursday, July 15th, 2021, at the Board of Pharmacy Office Conference Room – 1906 East Broadway Ave in Bismarck, ND. The proposed revisions include:

- 61-02-07.1-07 Pharmacy Technician Registration Requirements – modifies administrative code based upon Senate Bill 2175 for a provisional registration for military members
- 61-03-01-04 Licensure Transfer - modifies administrative code based upon Senate Bill 2175 for a provisional license for Military members
- 61-04-04-01 Unprofessional conduct – adds provision for concerning marketing practices in pharmacies
- 61-04-11 Administration of Medications and Immunizations – implements Senate Bill 2279 providing operational standards for a registered pharmacy technician to assist a pharmacist in administering medications and immunizations
- 61-04-14 Limited Prescription Authority for Immunizations – creates administrative code according to Senate Bill 2221 to allow limited prescriptive authority for pharmacists for immunizations based on a statewide protocol
- 61-04-15 Limited Prescription Authority for Tobacco Cessation Therapies - creates administrative code according to Senate Bill 2221 to allow limited prescriptive authority for pharmacists for tobacco cessation medications based on a statewide protocol

The proposed amendments and new sections are not expected to have an impact on the regulated community in excess of \$50,000. **A copy of the proposed rules are available at www.nodakpharmacy.com** or may be obtained by writing the North Dakota State Board of Pharmacy, calling (701) 328-9535 or by email ndboph2@ndboard.pharmacy. Also, written comments may be submitted to 1906 East Broadway, Bismarck, ND 58501 until July 28th 2021. If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the North Dakota State Board of Pharmacy at the above telephone number or address at least 14 days prior to the public hearing.

Dated this 7th day of June , 2021.

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- NDCC 28-32-08 - **Regulatory Analysis relative to amendments and adoption of rules in NDAC 61**
- 61-02-07.1-07 Pharmacy Technician Registration Requirements - modifies administrative code based upon Senate Bill 2175 for a provisional registration for military members
- 61-03-01-04 Licensure Transfer - modifies administrative code based upon Senate Bill 2175 for a provisional license for Military members
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Neither the Governor, nor a member of the Legislative Assembly has filed a written request for a Regulatory Analysis for these rules.

The proposed rules are not expected to have an impact on the regulatory community as a whole in excess of \$50,000. The regulated community consists of pharmacies, pharmacists, interns and pharmacy technicians engaged in the practice of Pharmacy in the State. These rules are intended to change the Administrative Code mostly in response to Legislative Bills passed in the 2021 67th Legislative Assembly.

Many of the proposed rules and amendments will affect pharmacists and pharmacy technicians in a positive way to allow them to expand in the professional practice outlined in the rules. The addition of Unprofessional Conduct is meant to address concerns from the public and healthcare professionals encountered in a small number of pharmacies.

The Board of Pharmacy will be impacted specifically in its implementation of the rules for the licensure and registration of military members. The Board will need to adjust licensure and registration Application processes to accommodate the rule changes. The Board will need to develop a Statewide protocol and update it on a regular basis for the purposes of the Limited Prescriptive Authority for Immunization and Tobacco Cessation Therapies. We anticipate the cost to be minimal and will not have any effect on State Revenue or licensure fees collected by the State Board of Pharmacy.

A handwritten signature in black ink, appearing to read 'Mark J. Hardy', written over a horizontal line.

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NDCC 28-32-08.1 – Small Entity Economic Impact and Regulatory Statement to adopt and amend rules in NDAC 61

- 61-02-07.1-07 Pharmacy Technician Registration Requirements – modifies administrative code based upon Senate Bill 2175 for a provisional registration for military members
- 61-03-01-04 Licensure Transfer - modifies administrative code based upon Senate Bill 2175 for a provisional license for Military members
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Although the Board of Pharmacy, as a professional or regulatory Licensing Board authority is exempt from the sections on Small Entity Economic Impact and Regulatory Analysis, I believe it is prudent to describe some potential impacts, so the regulated parties will understand the implications of the rules identified above.

The Board of Pharmacy does not believe there will be any significant negative financial impact on small entities with these rule changes. Most of the proposed rules will actually ease regulatory conditions for pharmacies to operate within.

Rules relative to military members are meant to streamline the licensure and registration process for pharmacists and pharmacy technicians. While there will be a distinct process similar to the one created for a provisional licensure of military spouses under both professions, the impact will be minimal, with each individual situation dealt with independently. The Board will need to modify licensure applications to identify military members. We anticipate the number of military members to be just 1 or 2 annually.

Generally, we do not believe the addition under Unprofessional Conduct should impact many pharmacies in North Dakota. However, there have been a few pharmacies that have been identified that may have engaged in activities relating to marketing that may need to adjust business practices, with most of these instances being out-of-state pharmacy locations.

The allowance for pharmacists to utilize pharmacy technicians in the administration of medications, as authorized by Senate Bill 2279, will assist pharmacists in addressing the increasing demands for immunizations and other medication administration needs in their pharmacy models of care. A similar authorization was enacted Federally through a HHS Prep Act Memo, specifically related to the COVID pandemic. Many states have or will enact similar allowances for pharmacy technicians. Pharmacy Technicians in North Dakota are well educated and certified in order to carry their registration and are well positioned to take on this additional responsibility under the pharmacist's purview in each individual pharmacy location. The goal of this will be to free up pharmacists' time to further interact with patients and enhance their models of care.

Lastly, the ability for pharmacists to have limited prescriptive authority for immunizations and tobacco cessation therapies is enacting the authority in Senate Bill 2221. This authority is not new, and many states are leveraging the expertise of pharmacists to build innovative approaches to public health. A recent example in North Dakota is Pharmacist's ability to prescribe Naloxone. There is currently a requirement for pharmacists to get standing orders or individual prescriptions from practitioners for immunizations. This current approach is proving to be difficult to providers. It was determined by the Legislature that pharmacists should have prescriptive authority to streamline care for patients who desire their pharmacist to provide an immunization. The pharmacist's ability to prescribe tobacco cessation products could prove to be a very important public health initiative. We expect the pharmacist's ability to engage any individual at the counter and assist them with obtaining cessation therapies could uniquely help them quit tobacco products. Each one of these rules will have a comprehensive statewide protocol behind it, which the Board of Pharmacy will maintain and update for pharmacists to follow.



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June 7, 2021

NDCC 28-32-08.2 – Fiscal Note Pertaining to adoption and amendment of rules in NDAC 61

- 61-02-07.1-07 Pharmacy Technician Registration Requirements – modifies administrative code based upon Senate Bill 2175 for a provisional registration for military members
- 61-03-01-04 Licensure Transfer - modifies administrative code based upon Senate Bill 2175 for a provisional license for Military members
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The Board of Pharmacy does not expect any fiscal impact on the operations of the Board in the adoption of these rules.

Changes will be made to the North Dakota State Board of Pharmacy database Applications and Forms and will have an impact of less than \$2,000.

Compliance with proposed rules will be determined based on the regular annual Inspection that is provided to pharmacies.

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