



NORTH DAKOTA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Administrative Rule Changes Implemented January 1, 2024

The North Dakota Board of Pharmacy finalized rule changes that became effective as of January 1, 2024. The finalized rules can be found on the Board's website at www.nodakpharmacy.com. The highlights of the rule changes are found below.

- 61-01-01: Updates the Board's contact information in the administrative code.
- 61-02-01-03: Updates the compounding standards to the newest revisions of the United States Pharmacopeia (USP) Chapters <795> and <797>. Also allows for a pharmacy to obtain compounded medications from a Food and Drug Administration (FDA)-registered outsourcing facility for further dispensing to a patient.
- 61-02-07.1: The changes add clarity to the definition of a "Pharmacy technician in training" and the tasks they can perform.
 - Changes will allow a technician in training to be the initial filler of a prescription as part of a tech-check-tech process in a pharmacy.
 - Like pharmacists, the technician (including technician in training) certificate and registration card no longer need to be displayed and visible to the public. The final version requires that the certificate and registration card, or a copy of each, must be readily available or on file. If a pharmacy desires to continue to post the registration certificates and cards, then that will continue to meet the standards.

National Pharmacy Compliance News

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- The other change would set a maximum reinstatement cost for a pharmacy technician reinstatement whose registration has lapsed.
- 61-03-01: Changes bring clarity to licensure processes for pharmacists. Pharmacy technicians must now post their license or have them on file at the pharmacy, which is similar for pharmacists. Language was adjusted to make the reinstatement procedures for a lapsed pharmacist license clearer and more streamlined. The last change was related to how an applicant with a Canadian pharmacy license can apply for licensure in the state of North Dakota. The applicant must meet all the following criteria:
 - have a pharmacist license in a Canadian province and be in good standing;
 - have passed the North American Pharmacist Licensure Examination® or both part I and part II of the Pharmacy Examining Board of Canada Pharmacists Qualifying Examination;
 - have completed educational requirements for a pharmacist license from a school of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE) or accredited by the Canadian Council for Accreditation of Pharmacy Programs;
 - have held a license for one year in Canada along with 1,500 hours logged as an approved intern or pharmacist; and
 - have passed the North Dakota law exam, along with having paid their fees for licensure.
- 61-04-10: This rule change allows a pharmacy technician, under the responsibility of the pharmacist, to assist in performing Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waived laboratory tests after having met all the education requirements. The responsible pharmacist must still be the one to interpret the results and provide any clinical education to the patient. The requirement of a pharmacy to notify the Board upon initiation of conducting a CLIA-waived test was eliminated. The hope is to eliminate any barriers to allow implementation of these important services for your communities and patients.
- 61-04-12: This rule change replaced the use of the word “naloxone” with “opioid antagonist.” This amendment comes from recent FDA drug approval of other opioid antagonists being available on the market. This allows pharmacists’ prescribing authority to extend to all opioid antagonists that are on the market or will come to market in the future.

Feel free to contact the Board office if you have any questions on the changes detailed above. The Board appreciates your diligence in reviewing and implementing changes, where appropriate.

2024 Inspection Cycle Changes

During the Board's January meeting, the Board decided that it will shift the inspection cycle to the spring portion of the year. The reason for this is due to the busyness of many pharmacies during the fall portion of the year and the emphasis on the Board having a meaningful visit at each pharmacy to address compliance and educational opportunities. The Board will move up the timeline on inspections to open the online inspection portal in March and begin inspecting pharmacies in April.

The compliance officers will have the following focuses for the pharmacy inspections:

- The Drug Supply Chain Security Act
- USP <797> and <795> standards
- Counseling on prescriptions, including an emphasis on warning notices for noncompliance
- Continuous quality improvement policies

Compliance officers will continue to monitor and ask about how pharmacies are using the practice advancements made legislatively and through rule changes to further patient care activities in their location. We look forward to the inspection cycle and visiting the pharmacy staff in each of your practices.

Online Submission of Technician in Training Applications

The Board and its database vendor are working on an online application for new and renewal applications for technicians in training. The goal is to streamline the submission of applications along with offering an electronic payment process. All existing application requirements will be in place, including the need for a precepting pharmacist to authorize an individual's application. The Board will communicate the new process and the steps needed to complete an application as it is ready and available. The Board hopes this will reduce the burden on pharmacies for encouraging individuals to enter the profession and become employed.

North Dakota Pharm-Assist Committee

The North Dakota Pharm-Assist Program is voluntary for impaired pharmacists, interns, technicians, and pharmacy students who need support and assistance for either alcohol or chemical abuse or other stressors.

Through this program, members of the pharmacy family can receive help from caring colleagues in a confidential, noncoercive, and nonpunitive manner.

Impaired individuals can be helped with the following:

- Substance abuse education
- Awareness of factors leading to impairment

- Understanding the warning signs of impairment
- Help from the ND Pharm-Assist Program

The goals of the ND Pharm-Assist Program include providing continual support and assistance to the pharmacist, intern, technician, or pharmacy student, thereby preventing the loss of a professional career, preserving the pharmacist's, intern's, or technician's professional reputation, and restoring the individual's ability to practice competent and professional pharmacy.

How It Works

1. Once a committee member from the Pharm-Assist Program receives a request for assistance, one of the co-chairs will initiate steps to verify expressed concerns.
2. If there is sufficient reason for concern, the co-chair will arrange for a personal visit with the person and other involved individuals.
3. The pharmacist, intern, technician, or pharmacy student will be encouraged to seek help voluntarily. An initial evaluation to assess the need for treatment will be provided at no charge to the person.
4. A program member will assist the pharmacist, intern, technician, or pharmacy student with entering treatment. They will maintain contact and provide encouragement and support during and after treatment.
5. The program will provide support after treatment and during reentry into practice.

Pharmacy Professionals Helping Pharmacy Professionals

Committee members have a genuine concern about the welfare of colleagues seeking assistance.

If a person has direct knowledge about an impaired pharmacist, intern, technician, or pharmacy student and they are concerned, they should contact the ND Pharm-Assist Program. That person could be a colleague, spouse, family member, employer, employee, concerned citizen, or even the impaired pharmacist, intern, or technician themselves.

The Board is **not** contacted when a pharmacist, intern, or technician becomes involved with the program. **All** information is kept strictly confidential.

A pharmacist, intern, technician, or pharmacy student in need of assistance who refuses to seek help is a danger to the health and welfare of the community. In such cases, the program **must** notify the Board of Pharmacy Investigative Committee, but not the Board itself.

Contact information for the members is found on the Board's website under Pharm-Assist Committee.

Free CPE Opportunity on Ensuring Quality PMP Data

The National Association of State Controlled Substances Authorities, in conjunction with 12 state prescription monitoring program (PMP) administrators, has published a free continuing pharmacy education (CPE) activity for pharmacists and pharmacy technicians that will provide insight into how

pharmacy staff's data entry process affects PMP data, clinical decision making, and downstream data analysis.

The online CPE activity, titled "Data Quality in Prescription Monitoring Programs," offers one hour of CPE credit and analyzes the importance and value of complete, accurate data reported by dispensers to PMPs and assesses the impact of intentional or unintentional data entry errors and data omissions on patient safety. It also discusses the downstream impact of pharmacy-reported PMP data on clinical decision-making processes and helps pharmacy staff identify and implement changes that can be made in their practice setting to improve PMP data integrity.

This application-based activity is hosted on the Talem Health [website](#), which is a continuing education provider accredited by the Accreditation Council for Continuing Medical Education, ACPE, and the American Nurses Credentialing Center. For general questions, please call 800/913-9370 or email cme@cmeruralhealth.com. Full details about the activity, including learning objectives and activity requirements, are available at <https://ce.talemhealth.com/a/HLQIJS>.

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