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NORTH DAKOTA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Proposed Rule Amendments for Consideration

By Jaxson Schmaltz, PharmD Candidate 2024 – North Dakota State University School of Pharmacy

The North Dakota Board of Pharmacy held a public hearing on Thursday, July 20, 2023, in the Board's conference room at 10 AM. This required hearing was about the proposed rule changes that are to be considered for implementation. The proposed rules can be found on the Board's website at *www.NoDakPharmacy.com*.

Multiple rule changes are being considered, but some of the more important ones are summarized below:

- 61-04-12: This rule looks to replace the use of the word "naloxone" with "opioid antagonist." This amendment comes from recent Food and Drug Administration drug approval of other opioid antagonists being available on the market. This rule change should allow pharmacists prescribing authority to not just naloxone, but other medications within the same class. There are no other proposed changes for this rule.
- 61-03-01: The most important part of this rule change is how an applicant with a Canadian pharmacy license is able to apply for licensure in the state of North Dakota. The applicant must meet all the following criteria:
  - have a pharmacist license 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 (PEBC) Pharmacists Qualifying Examination;

- have completed educational requirements for a pharmacist license from a school of pharmacy accredited by ACPE or accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP) ;
- 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.

- 61-02-07.1: This rule change adds clarity to the definition of a "Pharmacy technician in training" and the tasks they are able to perform. Proposed changes would allow a technician in training to be the initial filler of a prescription as part of a tech-check-tech process in a pharmacy. Additionally, there are a couple of other changes in this section, one of them being that technician certificates and registration cards no longer need to be displayed and visible to the public; the certificate and registration card must just be readily available or on file. The other change would set a maximum cost for pharmacy technician reinstatement.

- 61-04-10: This rule change would allow pharmacy technicians, 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, if necessary. The removal of the requirement for a pharmacy to notify the Board upon initiation on conducting a CLIA-waived test has also been proposed.

- 61-02-01-03: Lastly, this is an update to adopt the revisions that were made to United States Pharmacopeia (USP) Chapter <795> and USP Chapter <797>, which will be effective on November 1, 2023.

All changes can be found on the Board's website, and you are encouraged to view them prior to the finalization of these changes. The tentative date to conclude the revision process of the rules and implement them is January 1, 2024.

2023 Inspection Cycle

The Board's compliance officers will soon begin their inspection cycle for 2023. A letter to all pharmacies will be sent when the online self-inspection portal is open for completion prior to the inspectors being on site.

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

- The Drug Supply Chain Security Act

- USP <797> and <795> updated standards
- Counseling on prescriptions, including an emphasis on warning notices for noncompliance
- Continuous quality improvement (CQI) 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.

The Importance of CQI Programs in Pharmacy Practice

By Mark J. Hardy, PharmD, Executive Director

The Board will soon begin the pharmacy inspection cycle for the 2023 year. During previous visits, compliance officers noted that some of the pharmacies had made stark improvements in various areas of practice, and we continue to see a dynamic profession across the state of North Dakota, providing excellent care to our patients and citizens. We thank you for all your efforts!

I would like to highlight an important requirement that the Board continues to focus on and will strictly monitor through the compliance officers. This is North Dakota Administrative Code 61-02-09, which is the requirement for pharmacies to maintain an active CQI program.

While CQI programs are not new in health care, it is true that North Dakota is once again leading the country in ensuring that these programs are initiated, implemented, and working in all our pharmacies across the state. The reason that the Board is requiring this in our pharmacies is simple. If your pharmacy makes an error, at the very least, the public should expect your pharmacy to learn from that error. This means taking the steps to document the incident, reviewing how the incident happened, and discussing what can be done to prevent a repeat error in the future.

The compliance officers continue to witness variability in pharmacies complying with this rule of practice. They found pharmacies with vigorous CQI programs and heard great feedback on the improvements that these programs have made in their practices. They also found pharmacies that may not have vigorous CQI programs where the staff does not understand the function of CQI. This indicates that leadership in the pharmacy is not driving regular reporting of events or meetings to determine improvement of their practice. This finding is deeply concerning.

I want to highlight a few important points that are set forth in the rule:

- There are three types of occurrences that a CQI program tracks:
  1) **Incident** – means a patient safety event that reached the patient, whether or not the patient is harmed.
  2) **Near miss** – means a patient safety event that did not or could not have reached the patient.

3) **Unsafe condition** – means any circumstance that increases the probability of a patient safety event.

- Pharmacies get to set the policies and procedures around the incidents, near misses, and unsafe conditions that they may track in a CQI program. Some pharmacies may utilize a contract with a patient safety organization, like Pharmacy Quality Commitment+. Other pharmacies may use an internal program to document and evaluate events. Either solution can certainly work. However, the second option involves a bit more commitment to ensure that tracking and evaluations are completed. The Board expects you to set and comply with policies and procedures around your CQI program.
- The CQI program requires the pharmacy to complete a review, at least quarterly, of the documented events and determine if any changes in the pharmacy's practice should occur to account for these events to prevent similar errors. Those changes are communicated to relevant staff to ensure that they are implemented.
- There are built-in protections for a pharmacy's CQI events from discovery, which are being tracked. These records are completely confidential and privileged information to the pharmacy, so third parties (including pharmacy benefit managers), legal proceedings, and others cannot access them without the pharmacy's authorization. So, simply stated, this is used strictly to improve your practice, not as a punitive rule.
- The Board expects each pharmacist-in-charge to designate someone as responsible for ensuring that reporting occurs, meetings happen, and discussions ensue in accordance with this rule of professional practice. This is often a task delegated to a registered pharmacy technician.

I cannot stress this enough – CQI programs are not meant to be punitive. Instead, they are meant to be used to track and prevent errors. This allows your pharmacy to learn from events and take the necessary steps to prevent a future occurrence.

No professional likes to make a mistake, but the reality is that we are human, and no one is perfect. However, taking steps to ensure that mistakes are minimized and not repeated is the professional way to practice and should be a public expectation of the profession.

While a working CQI program may seem like just another duty and task in the long list that you need to complete, the reality of a working CQI program can ensure that error rates are low, providing quality service to your patients and the citizens of North Dakota. It represents a true commitment to the profession and your patients.

From the large retail pharmacies and medical centers to a critical access hospital and a small telepharmacy, CQI programs are truly impactful!

2021-2023 CE Audits

Continuing education (CE) audits were conducted by two PharmD students on rotation with the Board for the two-year period from March 1, 2021, to March 1, 2023. Separate audits for registered pharmacists and registered pharmacy technicians were conducted. A total of 67 pharmacists were audited, and 63 were found to be compliant, while four were initially found to be noncompliant. Upon follow-up with the four noncompliant pharmacists, three were found to be short credit hours and one was able to provide proof of CE hours completion. This audit is considered complete, and no further follow-up is warranted.

A total of 46 pharmacy technicians were audited, and 41 of those were found to be compliant, while five were initially found to be noncompliant. Upon follow-up, two technicians have responded with proof of CE hour completion and one responded without enough hours. The Board is still awaiting responses from the final two technicians.

The Board has instructed staff to assess a uniform fine for any licensee found noncompliant during an audit and to ask for remediation credits to be performed as part of an administrative resolution to any noncompliance found in CE hours.

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