



State of North Dakota  
Doug Burgum, Governor

FEB 19 2019

OFFICE OF THE EXECUTIVE DIRECTOR  
1906 E Broadway Ave  
Bismarck ND 58501-4700  
Telephone (701) 328-9535  
Fax (701) 328-9536  
**STATE BOARD OF PHARMACY**  
Email= [Mhardy@ndboard.pharmacy](mailto:Mhardy@ndboard.pharmacy)  
[www.ndboard.pharmacy](http://www.ndboard.pharmacy)

Mark J. Hardy, PharmD  
Executive Director

February 15, 2019

Mr. John Bjornson  
Code Revisor  
ND Legislative Council  
600 E Blvd – Capitol Bldg  
Bismarck ND 58505-0360

Dear Mr Bjornson:

As required by N.D.C.C. §§ 28-32-03(5), 28-32-10, this letter is to submit the attached:

- Copy of the full Hearing Notice and the Abbreviated Notice as well
- Copy of the Regulatory Analysis
- Copy of the Small Entity Economic Impact and Regulatory Statement
- Copy of Fiscal Note statement
- Copy of all the individual proposed Rule Changes
- A list of people / agencies that were sent a full Hearing Notice

Sincerely,

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

Mark J. Hardy, PharmD  
Executive Director

MJH/eh

Enclosure(s)

## FULL NOTICE OF INTENT TO ADOPT, AMEND AND REPEAL ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address a proposed new section, amendments to existing sections and repeal a section of N.D Admin. Code relating to the ND State Board of Pharmacy Practice Act and Controlled Substances Act at 2:30PM on Saturday, April 6<sup>th</sup>, 2019, at the annual NDPhA Convention held in the New York New York Room of the Radisson Inn – 506 East Broadway Ave in Bismarck, ND. The proposed revisions include:

- 61-01-01-01            Organization of Board of Pharmacy - removes out-dated email address
- 61-02-01-03            Pharmaceutical Compounding Standards – update to Compounding of  
Drugs to USP 795-797-800 standards
- 61-02-02-01            Building Standards for Pharmacies – updates Drug Storage areas
- 61-02-04-02            Handling of Hazardous Drugs (USP800) new section
- 61-02-06-02            Computer Pharmacy Regulations –adds electronic tracking of prescriptions
- 61-02-07.1-03            Pharmacy Technician Education preparation – clarifies Certification  
Requirements
- 61-02-07.1-04            Pharmacy Technician – adjusts the ratio of Pharmacists to Technicians
- 61-02-07.1-10            Pharmacy Technician Continuing Education –removes paper tracking  
requirements
- 61-03-02-04            Consultant Pharmacist Regulations for LTC Facility- addresses controlled  
substance drug destruction process
- 61-03-03.1-01            Internship – clarifies educational requirements for eligibility
- 61-03-04-02            Pharmacist Continuing Education - removes paper tracking requirement
- 61-03-04-04            CE Advisory Board - repeal
- 61-04-03-01            Destruction of Controlled Substances – update to DEA standards
- 61-08-01-08            Out-of-State Pharmacy – modifies Administrative Inspection requirements
- 61-08-01-09            Out-of-State Pharmacy – Prescription Records availability
- 61-12-01-03            Prescription Drug Monitoring Program [PDMP] – Operation of Program
- 61-12-01-04            Prescription Drug Monitoring Program [PDMP] – use for certain dispensing  
situations
- 61-13-01-03            Controlled Substances Schedules – Remove codified substances scheduled  
in NDCC 19-03 by legislature in the 63<sup>rd</sup> assembly.

The proposed amendments and new sections are 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](http://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](mailto:ndboph2@ndboard.pharmacy). Also, written comments may be submitted to 1906 East Broadway, Bismarck, ND 58501 until April 22<sup>nd</sup> 2019. 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 13<sup>th</sup> day of February, 2019.

Mark J. Hardy, PharmD  
Executive Director

**ABBREVIATED NOTICE OF INTENT TO ADOPT, AMEND AND  
REPEAL ADMINISTRATIVE RULES**

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed changes to N.D Admin. Code relating to the ND State Board of Pharmacy Practice Act and Controlled Substances Act at 2:30PM on Saturday, April 6<sup>th</sup>, 2019, in the New York New York Room of the Radisson Inn – 506 East Broadway Ave in Bismarck, ND.

The proposed amendments and new sections are 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](http://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](mailto:ndboph2@ndboard.pharmacy). Also, written comments may be submitted to 1906 East Broadway, Bismarck, ND 58501 until April 22<sup>nd</sup> 2019. 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 13<sup>th</sup> day of February, 2019.

Mark J. Hardy, PharmD  
Executive Director



State of North Dakota  
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR  
1906 E Broadway Ave  
Bismarck ND 58501-4700  
Telephone (701) 328-9535  
Fax (701) 328-9536  
**STATE BOARD OF PHARMACY**  
Email= [Mhardy@ndboard.pharmacy](mailto:Mhardy@ndboard.pharmacy)  
[www.ndboard.pharmacy](http://www.ndboard.pharmacy)

Mark J. Hardy, PharmD  
Executive Director

February 13, 2019

**NDCC 28-32-08 – Regulatory Analysis relative to amendments and creation of rules in NDAC 61**

61-01-01-01	Organization of Board of Pharmacy
61-02-01-03	Pharmaceutical Compounding Standards
61-02-02-01	Building Standards for Pharmacies
61-02-04-02	Handling of Hazardous Drugs
61-02-06-02	Computer Pharmacy Regulations
61-02-07.1-03	Pharmacy Technician Education preparation
61-02-07.1-04	Pharmacy Technician
61-02-07.1-10	Pharmacy Technician Continuing Education
61-03-02-04	Consultant Pharmacist Regulations for LTC Facility
61-03-03.1-01	Internship
61-03-04-02	Pharmacist Continuing Education
61-03-04-04	CE Advisory Board
61-04-03-01	Destruction of Controlled Substances
61-08-01-08	Out-of-State Pharmacy
61-08-01-09	Out-of-State Pharmacy
61-12-01-03	Prescription Drug Monitoring Program [PDMP]
61-12-01-04	Prescription Drug Monitoring Program [PDMP]
61-13-01-03	Controlled Substances Schedules

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 61-02-01-03-Pharmaceutical Compounding Standards and 61-02-04-02 - Handling of Hazardous Drugs USP 800 are expected to have an impact on the regulatory community as a whole in excess of \$50,000. The regulated community consists of hospital pharmacies, retail pharmacies and any others, who handle, prepare and dispense hazardous drugs, either through compounding preparations or traditional dispensing mechanisms.

Many of our hospitals have already begun compliance with these rules and will be required by their accreditation agency to be in compliance with United States Pharmacopeia [USP] 795-797-800 standards.

Any modifications and installations of segregated compounding areas for hazardous drugs can amount to substantial amounts of money. It can certainly vary from facility to facility, depending upon their level of readiness and their plans for the future. Most of the hospitals have already begun modifications as it will be required to be in compliance with USP 795-797-800 standards for accreditation. Retail pharmacies will also have to make modifications to account for USP 800 Hazardous Drugs Handling and compliance dependent on the level and type of business they are conducting.

The Board of Pharmacy has determined to assist with the development of template forms, which can be modified to individual practices, to anticipate needs to comply with the standards in USP 800.

The cost directly to the North Dakota Board of Pharmacy will be fairly minimal. We will spend some time and energy in consulting with facilities and our inspectors will spend some additional time when visiting facilities during the annual inspection visit to assess the level of compliance and help develop the templates to bring each facility into compliance with the rule.

There should be no effect on state revenues with the rules. The other rules changes are not expected to have an impact on the regulatory community as a whole in excess of \$50,000.

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

Mark J. Hardy, PharmD  
Executive Director



State of North Dakota  
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR  
1906 E Broadway Ave  
Bismarck ND 58501-4700  
Telephone (701) 328-9535  
Fax (701) 328-9536

## **STATE BOARD OF PHARMACY**

Email= [Mhardy@ndboard.pharmacy](mailto:Mhardy@ndboard.pharmacy)  
[www.ndboard.pharmacy](http://www.ndboard.pharmacy)  
Mark J. Hardy, PharmD  
Executive Director

**NDCC 28-32-08.1 – Small Entity Economic Impact and Regulatory Statement Pertaining to adoption of NDAC 61-02-01-03 – Pharmaceutical Compounding Standards and 61-02-02-01 Building Standards for Pharmacies and 61-02-04-02 - Handling of Hazardous Drugs and**

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 is very aware of the impact on small entities to comply with these rules and have taken efforts to mitigate the impact.

All those who prepare compounded pharmaceutical products and those who handle hazardous pharmaceutical products will potentially be affected by this rule. These may include pharmacies, hospitals and some practitioner offices. Those benefiting from these rules are the patients who will receive these compounded preparations or will have them administered, or injected as in the case of sterile products. Also minimizing exposure to hazardous drugs to those working in medical facilities is important for long-term health.

Depending on the current progress of modification or remodeling of the pharmacy or compounding area, the impact may vary considerably. The Joint Commission and the Center for Medicare and Medicaid Services has moved towards requiring compliance with United States Pharmacopeia [USP] 795 -797 and 800 as a condition of their accreditation, mostly in hospital locations. For some pharmacies there will be almost no costs, for others who are just beginning the transition to USP compliant operations and need major remodeling, the costs could be quite high. Most of our hospitals in North Dakota have already begun compliance, if they desire, and many have completed the transition, comply with these standards. The impact for retail pharmacies will be low in regards to modifications or remodeling unless complex compounding is conducted. All pharmacies will need to develop a plan to comply which involves developing Policies and Procedures and best practices specific to their location. The Board of Pharmacy is providing resources for small pharmacies to create and adjust their procedures and trainings for compliance.

Specific to 61-02-02-01 Building Standards for Pharmacies, pharmacies will likely need to implement a continuous temperature monitoring system into their, both freezer and refrigeration and drug storage areas. These monitoring systems vary in price. However, a standard unit is around \$300 to implement. It is important to note from our experience with pharmacies that the traditional pharmacy may have more than \$50,000 in inventory stored in the refrigerator and freezer.



State of North Dakota  
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR  
1906 E Broadway Ave  
Bismarck ND 58501-4700  
Telephone (701) 328-9535  
Fax (701) 328-9536

**STATE BOARD OF PHARMACY**  
Email= [Mhardy@ndboard.pharmacy](mailto:Mhardy@ndboard.pharmacy)  
[www.ndboard.pharmacy](http://www.ndboard.pharmacy)

Mark J. Hardy, PharmD  
Executive Director

**NDCC 28-32-08.2 - Fiscal Note Pertaining to adoption of NDAC**  
**61-02-01-03 - Pharmaceutical Compounding Standards and**  
**61-02-02-01 Building Standards for Pharmacies and**  
**61-02-04-02 - Handling of Hazardous Drugs and**

The Board of Pharmacy does not expect any fiscal impact on the operations of the Board in the adoption of these rules.

The compliance will be determined based on the regular annual Inspection that is provided the pharmacies.