



State of North Dakota  
Doug Burgum, Governor

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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.

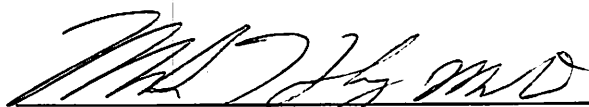
Many of our hospitals have already begun compliance with these rules and will be required by their accreditation agency to be in compliance with United States Pharmacopeia [USP] 795-797-800 standards.

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, PharmD', written over a horizontal line.

Mark J. Hardy, PharmD  
Executive Director