BOARD OF PHARMACY
State of North Dakota

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NDCC 28-32-08.1 – Regulatory Analysis relative to amendment of rules in NDAC 61 Specifically Chapter 61-02-01-03 – Pharmaceutical Compounding Standards.

Neither the Governor, nor any member of the Legislative Assembly has filed a written request for a Regulatory Analysis.

This proposed rule is 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 anticipate preparing sterile and non-sterile compounded prescription products.

Many of our larger hospitals have already begun compliance with this rule and will be required by their accreditation agency to be in compliance with United States Pharmacopeia [USP] 795 and 797 standards. The modification and installation of primary engineering controls can amount to substantial amounts of money. This amount can vary significantly from facility to facility, based on their current level of readiness and their plans for the future. Some of our medium size to smaller facilities will have to begin preparations for compliance with this rule. They do have a period of three years to come into compliance or to alter their procedures to reduce the modifications necessary in their operations to come into compliance.

The cost directly to the North Dakota Board of Pharmacy will be 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 asses the level of compliance and help with anticipated needs to bring each facility into compliance with the rule.

There should be no effect on state revenues with this rule.

The North Dakota State Board of Pharmacy has already deferred for approximately three years, in working to develop this rule. We have consulted at two state conventions and with numerous preliminary meetings involving stakeholders, primarily hospital pharmacists. We have attempted to write these rules to be the least onerous for our facilities. We feel that federal agencies, accreditation bodies and payers will require some kind of compliance with United States Pharmacopeia [USP] 795 and 797 standards. The accreditation agencies will usually defer to the state's requirements, if they are adopted in rule or statute. For protection of the public health it is necessary that the Board of Pharmacy move forward with these rules to establish standards for compounding pharmaceuticals and sterile pharmaceutical products.

More information on the affect on small entities is available in the Small Entities Analysis which is included with this packet, or is available from the Board of Pharmacy Office.

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