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State of North Dakota

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NDCC 28-32-08.1 – Small Entity Economic Impact Statement Pertaining to adoption of NDAC 61-02-01-03 – Pharmaceutical Compounding Standards.

Although the Board of Pharmacy, as the Board of Pharmacy is a professional or regulatory Licensing Board authority is exempt from the sections on Small Entity Regulatory Analysis, I believe it is prudent to describe some potential impacts, so the regulated parties will understand the rules implications.

All those who prepare compounded pharmaceutical products will potentially be affected by this rule. These may include pharmacies, hospitals, an occasional nursing home 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.

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 Medicaid and Medicare Services are gradually moving towards requiring compliance with United States Pharmacopeia [USP] 795 and 797. These rules will help entities establish a state accepted standard, along with a transitional period for adoption of the new standards in their practice and give them guidance for planning, which might not otherwise be in place. 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 the larger hospitals in North Dakota have already begun, and many have completed the transition, which will comply with these standards. There may be a few hospitals that either need remodeling or are building new facilities, which will need to spend $20,000 to $30,000 if they intend to comply with the higher level sterile compounding standards.

The North Dakota State Board of Pharmacy routinely conducts annual inspections and we do not expect the additional costs to monitor compliance with this rule to be substantial. Obviously, if a for profit facility spends money complying with the rule, that money will reduce their profits and the subsequent taxes on revenue may be diminished.

Alternative methods are available within the rule to reduce the costs of compliance to entities. An entity may chose to change their operations so they adopt the lowest level of use and immediate administration of compounded products. Many facilities have already done this. We will place in the rule a transitional period of perhaps three years, which will allow planning and transition for facilities to come into full compliance. Specific facilities may ask for variances if they are planning remodeling or new construction in the near future and have specific plans to come into compliance.