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**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.

Some of our rule changes will ease the regulatory burden such as, 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; 61-08-01-08 and 61-08-01-09 Out-of-State Pharmacy; as well as 61-12-01-03 and 61-12-01-04 Prescription Drug Monitoring Program [PDMP]. Each relaxes some of the standards and can be viewed as deregulation with the input of our professional community. Others are just codifying language that was not clear in the regulations that the Board enforces.