APR 16 2010

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

April 15, 2010

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

Dear Mr. Walstad:

Enclosed please find copies of the Rules in ND Admin. Code Article 61; Chapter 61-02 amended sections 61-02-01-03 Pharmaceutical Compounding Standards; new section 61-02-07.1-13 Pharmacy Technician Reinstatement and new section 61-13-01 Identification Required for Controlled Substances plus tramadol and carisoprodo prescriptions.

Also enclosed, although not required, are copies of a Small Entity Economic Impact Statement and Small Entity Regulatory Analysis pertaining to 61-02-01-03 Pharmaceutical Compounding Standards. The other two sections would have no impact.

Sincerely,

Howard C. Anderson, Jr, R.Ph.
Executive Director

HCA/eh

Enclosure(s)

Full Notice

NOTICE OF INTENT TO [ADOPT, AMEND, OR REPEAL] ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed N.D. Admin. Code Article 61; Chapter 61-02 amended sections 61-02-01-03 Pharmaceutical Compounding Standards; new section 61-02-07.1-13 Pharmacy technician reinstatement and new section 61-13-01 Identification Required for Controlled Substances plus tramadol and carisoprodol at 11:00 AM on Thursday, May 20, 2010, at Candlewood Suites – 1831 NDSU Research Park Drive in Fargo ND 58102.

The purpose of these proposed rules in 61-02-01-03 are to set standards for both non-sterile and sterile compounding. These rules, once adopted, will give specificity to those individuals and entities in North Dakota wishing to compound pharmaceuticals, both non-sterile and sterile. United States Pharmacopeia guidelines have been in place since June 2008. These rules will give North Dakota entities a basis for coming into compliance with professional standards and a timeline for doing so. 61-02-07.1 allows for a Registered Pharmacy Technician to reinstate their registration after letting it go for non-payment of their renewal fee by paying the unpaid fees and proving Continuing Education. 61-04-03.1 requires a person picking up a controlled substance prescription to be asked to show Identification.

The proposed compounding rules may have an impact on the regulated community in excess of $50,000. The regulatory analysis can be obtained at the location bellow.

The proposed rules may be reviewed at the office of the ND State Board of Pharmacy – 1906 E Broadway – Bismarck ND 58501 or Board website www.nodakpharmacy.com. A Copy of the proposed rules and/or a regulatory analysis may be requested by writing P O Box 1354 Bismarck ND 58502-1354; emailing ndboph2@btinet.net or calling 701-328-9535. Written or oral comments on the proposed rules sent to the above address or telephone number and received by June 18th, 2010 will be fully considered.

If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the ND State Board of Pharmacy at the above telephone number or address at least two weeks (14 days) prior to the public hearing.

Dated this 15 day of April 2009.

Howard C. Anderson, Jr, RPh.
Executive Director

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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. 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. 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.

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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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.

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

Although the Board of Pharmacy is exempt form this analysis as an occupational professional licensing authority, I do want to point out the following:

There is a range of compliance standards available in the rule. Facilities adopting Level 1 compounding procedures and immediate use procedures will reduce their compliance costs significantly.

There is a schedule for coming into compliance which will allow small entities flexibility to plan their remodeling and changes in their policies & procedures.

Small entities who have lower levels of compounding will have a smaller work load in keeping logs and will need to conduct testing less frequently as their number of compounds will be lower.

We do not wish to exempt any entities, as every patient is as important as the next. We want every patient to receive quality pharmaceuticals from those compounding medications for them.