



BOARD OF PHARMACY
State of North Dakota

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NDCC 28-32-08.1 – Regulatory Analysis relative to amendment of rules in

N.D. Admin. Code Chapters: 61-02-01 Pharmacy Permits to add a Class L; Article 61-11 to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session; Chapter; 61-04-02 Physician Exemption to expand the exemption; Chapter 61-04-08 Limited Prescriptive Practices to clarify the signature requirements and form; Chapter 61-12-01 Prescription Drug Monitoring Program to designate the submission standard.

None of the above rules are expected to have an impact on the regulated community of \$50,000 or more.

NDAC Chapter: 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement. This rule will require pharmacies to create or purchase a Continuous Quality Improvement, if they do not already have one in place. Many pharmacies already have a program in place and there are some good ones such as the Pharmacy Quality Commitment program, developed by Pharmacists Mutual Insurance Company available at a reasonable cost. The requirement for a written or electronic Policy and Procedure manual consolidates this requirement already in force for most specialty practices and extends it to retail pharmacies. Both requirements will benefit patient care, error reporting analysis and clear up issues relative to how operations of the pharmacy are conducted. Estimate of cost for the approximately 100 pharmacies that do not have a program is \$200 each for a \$20,000 cost.

NDAC Chapter 61-08-01 Requirements for Out-Of-State Pharmacies; This requirement for an inspection by a National Inspection Service is in response to the disasters created by compounding pharmacies, licensed with us but for which we relied on the inspections from their home states, which, in retrospect, were not always adequate. For example we had a clear inspection report on file for the New England Compounding Center. To inspect these pharmacies ourselves would be more expensive. The best benefit to us and the pharmacies is that one inspection will be recognized by us and every other state where they seek licensure. Estimated cost to the expected 115 sterile and non- sterile compounders who see licensure in North Dakota is \$230,000.

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

The cost directly to the North Dakota Board of Pharmacy will be minimal, as inspections will be conducted by the National Association of Boards of Pharmacy and made available to all states through their portal.

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

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