

Walstad, John M.

From: Anderson, Howard
Sent: Friday, February 28, 2014 4:37 PM
To: Walstad, John M.
Cc: Alan Yan Jr.; Amanda Volochenko; Angela Scharnowske; Bonnie Thom; Centralrx@daktel.com; Chase Peterson; Dave Olig; 'David Lindell'; 'Dewey'; Diane Halvorson; Diane Halvorson; 'Eileen'; Fran G Gronberg; Gary Dewhirst; Gayle Ziegler; Hanel, Harvey J.; Jenna Midgarden; 'Jenna Wahlstrom'; Jeremy Grindeland; Joyce, Brendan; 'Judy Swisher'; Justin Stubstad; Katie Miller; 'Laurel Haroldson (E-mail)'; 'Mark Hardy'; Michael Fisher; Michelle.Mckay@ndsu.edu; Paul Jilek; 'Rick Detwiller'; Sierra Roecker; Trisha Oss; tyler.j.haugen.3@my.ndsu.edu
Subject: Rule Hearing 4-5-2014
Attachments: Regulatory Analysis - Rules for April 5, 2014 Hearing.doc; 61-02-01-01 Class L Pharmacy Permit.docx; 61-02-01-18 Continuous Quality 61-02-01-19 Policy Procedure 2-13-2014 Revision.doc; 61-04-02 Physician Exemption Revision.doc; 61-04-08-07 Collaborative Agreement Signature page.doc; 61-08 Inspections Rule for Out of State Pharmacies.docx; 61-11 - Fees - revision from legislature.doc; 61-12-01 -02 ASAP Version 4.2 Dispenser Reporting [PDMP].doc; 61-12 PDMP Use Requirements for Pharmacies.docx; Abbreviated Notice 4-5-2014 Hearing.doc; Fiscal Note for 4-5-2014 Rules.doc; Full Notice 4-5-2014 Hearing.doc

February 28, 2014

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

Dear Mr. Walstad:

As required by NDCC 28-32-10(1) enclosed are the Notice of Intent to Adopt or Amend Administrative Rules, the Regulatory Analysis, Fiscal Note and a copy of the proposed rules:

1. Revise N.D. Admin. Code Chapter 61-02-01 Pharmacy Permits to add a Class L permit for automated dispensing devices in Nursing Homes.
2. Create two new sections to N.D. Admin. Code Chapter 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement for retail pharmacies.
3. Revise N.D. Admin. Code Article 61-11 to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session.
4. Revise N.D. Admin. Code Chapter 61-04-02 Physician Exemption to expand the exemption.
5. Revise N.D. Admin. Code Chapter 61-04-08 Limited Prescriptive Practices to clarify the signature requirements and form.
6. Revise N.D. Admin. Code Chapter 61-08-01-08 to require inspection or accreditation of out-of-state pharmacies.
7. Revise N.D. Admin. Code Chapter 61-12 Prescription Drug Monitoring Program to designate the submission standard for data submitted by dispensers and requires accessing the program in certain circumstances by pharmacies.

Sincerely,

Howard C. Anderson Jr, R.Ph.

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

Howard C. Anderson, Jr., R.Ph.
Executive Director
North Dakota Board of Pharmacy
1906 E. Broadway Ave.
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State of North Dakota

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

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.

Howard C Anderson, Jr, R.Ph.
Executive Director Prepared February 28, 2014



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**BOARD OF PHARMACY
State of North Dakota**

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www.nodakpharmacy.com

Jack Dalrymple, Governor

**Mark J. Hardy, PharmD, R.Ph.
Assistant Executive Director
Howard C. Anderson, Jr, R.Ph.
Executive Director**

Fiscal Note Required by NDCC 28-32-08.2 Relative to the adoption of:

1. Revise N.D. Admin. Code Chapter 61-02-01 Pharmacy Permits to add a Class L permit for automated dispensing devices in Nursing Homes.
 - a. This rule will have no fiscal impact on the Board of Pharmacy or the State of North Dakota
 2. Create two new sections to N.D. Admin. Code Chapter 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement for retail pharmacies.
 - a. This rule will have no fiscal impact on the Board of Pharmacy or the State of North Dakota, as compliance will be part of our regular inspections of pharmacies.
 3. Revise N.D. Admin. Code Article 61-11 to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session.
 - a. This rule is expected to increase revenue for the board of Pharmacy by \$171,600 per year beginning July 1, 2014, which will be used to operate the Prescription Drug Monitoring Program and other board functions including a Controlled Substance take back program. The programing has already been done and cost approximately \$4000.
 4. Revise N.D. Admin. Code Chapter 61-04-02 Physician Exemption to expand the exemption.
 - a. This rule will have no fiscal impact on the Board of Pharmacy or the State of North Dakota
 5. Revise N.D. Admin. Code Chapter 61-04-08 Limited Prescriptive Practices to clarify the signature requirements and form.
 - a. This rule will have no fiscal impact on the Board of Pharmacy or the State of North Dakota
 6. Revise N.D. Admin. Code Chapter 61-08-01-08 to require inspection or accreditation of out-of-state pharmacies.
 - a. This rule will have little fiscal impact on the Board of Pharmacy or the State of North Dakota as the pharmacy applying for licensure will pay the costs of the inspections, although we may lose 20 to 30 licensees at \$175 each (\$3500 to \$5250) annually.
- Revise N.D. Admin. Code Chapter 61-12 Prescription Drug Monitoring Program to designate the submission standard for data submitted by dispensers and requires accessing the program in certain circumstances by pharmacies.
- a. This rule will have no fiscal impact on the Board of Pharmacy or the State of North Dakota.

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

Full Notice

**NOTICE OF INTENT TO ADOPT, and AMEND ADMINISTRATIVE
RULES RELATING TO THE PRACTICE OF PHARMACY AND
WHOLESALERS**

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed new rules and amendments to, N.D. Admin. Code Chapters: 61-02-01 Pharmacy Permits to add a Class L; 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement ; 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 61-08-01 Requirements for Out-Of-State Pharmacies; Chapter 61-12-01 Prescription Drug Monitoring Program to designate the submission standard and require accessing the program in certain circumstances by pharmacies at:

**The Ramada Plaza Suites 1635 42nd St SW, Fargo, ND, 58103
Saturday, April 5, 2014 from 4:00-5:00 P.M in the Crystal
Ballroom.**

1. Revise N.D. Admin. Code Chapter 61-02-01 Pharmacy Permits to add a Class L permit for automated dispensing devices in Nursing Homes.
2. Create two new sections to N.D. Admin. Code Chapter 61-02-01 to add a Continuous Quality Improvement and Policy and Procedure Requirement for retail pharmacies.
3. Revise N.D. Admin. Code Article 61-11 to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session.
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6. Revise N.D. Admin. Code Chapter 61-08-01-08 to require inspection or accreditation of out-of-state pharmacies.

7. Revise N.D. Admin. Code Chapter 61-12 Prescription Drug Monitoring Program to designate the submission standard for data submitted by dispensers and require accessing the program in certain circumstances by pharmacies.

These rules are expected to have a cumulative cost on licensees in excess of \$50,000 and this is addressed in our regulatory analysis. There is no taking of real property involved in these regulatory actions.

The proposed rules may be reviewed at the office of the ND State Board of Pharmacy – 1906 E Broadway – Bismarck ND 58501. A copy of the proposed rules and/or a regulatory analysis may be requested by writing P O Box 1354 Bismarck ND 58502-1354, calling 701-328-9535, or by e mail at ndboph@btinet.net. The proposed rules and regulatory analysis are also on the board's web site at www.nodakpharmacy.com. Written or oral comments on the proposed rules sent to the above address, e mail or telephone number and received by April 16th, 2014 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 28th day of February, 2014.

Howard C. Anderson, Jr, RPh.
Executive Director

Abbreviated Notice

**NOTICE OF INTENT TO ADOPT, and AMEND ADMINISTRATIVE
RULES RELATING TO THE PRACTICE OF PHARMACY AND
WHOLESALERS**

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Board of Pharmacy at the above telephone number or address at least two weeks (14 days) prior to the public hearing.

Dated this 28th day of February, 2014.

Howard C. Anderson, Jr, RPh.
Executive Director