



State of North Dakota  
Jack Dalrymple, Governor

OFFICE OF THE EXECUTIVE DIRECTOR  
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## *STATE BOARD OF PHARMACY*

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Mark J. Hardy, PharmD, R.Ph.  
Executive Director

**Monday – September 15<sup>th</sup>, 2014**  
**Administrative Rules Committee**  
**Roughrider Room – State Capitol Building**

Chairman Devlin, members of the Administrative Rules Committee, thank you for the Opportunity to discuss the following rule changes with you.

I will answer your questions as a group, and then as we go through the rules page by page, I will elaborate the differences between one and the other.

1. There is only one of these rules that was impacted by a legislative change, through the passage of Senate Bill 2342, which specifically codified the fees under the Wholesale Distributor section NDCC 43-15.3-12. These fees are exactly the same at Senate Bill 2342 which was passed by the Sixty-third Legislative Assembly and signed into law by Governor Dalrymple.
2. There are no rules related to Federal changes in statute or legislation.
3. I have included in the packets the Public Hearing Notice, as well as the hearing record and a copy of the minutes where these rules were considered and adopted by the Board of Pharmacy. As is the general policy of this Board of Pharmacy, we usually go through a fairly extensive process with the profession and interested parties, before developing a rule to the extent that we have a public hearing. We actually held the public hearing during the North Dakota Pharmacists Convention, at which many pharmacists and interested parties were in attendance to voice their support or concerns, relative to these rules. The hearing lasted about an hour and a half, addressing each and every rule to give them an opportunity to voice their opinions.
4. At the rule hearing, there were a fair amount of comments on a few of these rules. Consideration of these comments is included in the packet, along with the written comments that were received. There were revisions made based on the comments.
5. The approximate cost of giving notice and holding hearings on these rules is \$3,131.80
6. I will address each of the rules in turn:

On your page 21 & 22, chapter 61-02-01-18 – Policy and Procedure Manual Required – this rule will require pharmacies to develop and maintain a policy and procedure manual regarding the operation of their pharmacy, depending on the particular practice of each pharmacy. There are currently several areas in our rules that require pharmacies to have a policy and procedure manual for certain tasks. We added reference to the new rule section in each of the sections of our rules where a Policy and Procedure manual is required. The intention is that the pharmacy would have one manual detailing the policy and procedures for all activities in the pharmacy. On page 23 - 61-02-06-04 – Written policy and procedures – On page 24- 61-02-07.1-12 – Technicians checking technicians; page 26 -61-03-02-03 – Physical requirements of provider pharmacy licensed on premises or other pharmacy; page 31 61-04-11-08 Policy and procedure manual; page 32 - 61-06-01-05 – Drug distribution and control also reference policy and procedure manuals. The Board of Pharmacy feels that a Policy and Procedure Manual is necessary, to ensure continuity of care. Should the staff change, there is a manual to guide the locating of pertinent records and also gives them an opportunity to examine and adjust the policy and procedures of the pharmacy based on issues they may encounter in the operation of pharmacy on a regular basis.

You may note in some of the regulatory analysis that there was also a rule which would have required a continuous quality improvement protocol be implemented in pharmacies. However, after an opinion from the Attorney General's Office, which stated that a law would need to be enacted to protect the discover of the continuous quality related events tracked in a program, the Board decided to withdraw the rule until such time as we could explore legislation to protect quality related event reporting from a subpoena court order. We intend to pursue a quality improvement rule at a future date.

On Page 28 –chapter 61-04-02-01 – Physician exemption. This rule clarifies some confusion that exists with the current rule regarding an exemption for practitioners to dispense to their patients in the short-term situations. It expands the ability of the practitioner to dispense specific items in the rule. You will note that it still does not exempt those practitioners who regularly engage in dispensing from being consistent in the labeling, counseling and profile recordkeeping that we all can expect to receive at a pharmacy.

On page 29-30 – chapter 61-04-08 Collaborative Agreements we simply modified to allow multiple pharmacists and physicians to be on the form. The original form in the rule only allowed one pharmacist and physician to sign and this was impractical to utilize. Currently, most Collaborative Agreements are between multiple pharmacists and physicians. Collaborative Agreements are now common practice in our health systems.

On page 35-36 – chapter 61-08-01 Administrative inspection – this rule requires an inspection of an out-of-state pharmacy to be licensed to serve patients in North Dakota. Our current practice is to accept the Inspection or Compliance Report of the Board of the state in which the pharmacy is actually physically located. However, it has increasingly come to our attention, based on some of the concerns surrounding the compounding issues, specifically the meningitis tragedy of the New England Compounding Center a few years ago; we have some states that obviously do not conduct inspections/compliance visitations regularly enough or with a vigorous inspection to account for the complex processes of compounding.

This rule allows us to mandate that an Out-of-State Pharmacy that ships compounded prescriptions into North Dakota conduct a qualified inspection once a year under 3(a). If the pharmacy does not conduct compounding, an inspection must be completed every two years under 3(b).

The National Association of Boards of Pharmacy [NABP] has a Verified Pharmacy Program, in which they would conduct inspection / compliance visitations on pharmacies and provide the results to both the pharmacy and the state Boards of Pharmacy, so that a thorough inspection is conducted regularly. We did add that the Verified Pharmacy Program [VPPs] would be an approved third-party inspection process and we currently see many out-of-state pharmacies going through this process, especially in states where minimal to no inspection occurs on a regular basis. For your information, our pharmacies typically are inspected every year.

Under 3.(c) Rogue internet pharmacies continue to be a major concern with counterfeit prescription medication, which puts the public at risk. Nearly all of the sites we encounter are rogue and do not hold any license to practice pharmacy. However, there are legitimate internet pharmacy practices soliciting prescriptions on the internet. This rule requires them to go through a compliance program provided by a Verified Internet Pharmacy Practice Site or VIPPS. For those specializing in providing veterinary medicine there is a program called Vet VIPPS. These compliance programs are not specific to North Dakota, but provide a pharmacy that wishes licensure in many states an approved uniform inspection to provide to multiple Boards of Pharmacy. This provides a level of safety to our residents that the pharmacies which are licensed are safe and well vetted to provide their prescription medication.

We will notify the current Out-of-State Pharmacy permit holders in such a way to ensure they can readily comply with this requirement.

On page 27-38 chapter 61-11-01 Fees - You will see that we have inserted the fees consistent with Senate Bill 2342 as passed by the Sixty-third Legislative Assembly. The increase in fees will cover the deficits the Board endure in operating the Prescription Drug Monitoring Program [PDMP].

And lastly, on page 39-40 - chapter 61-12-01 – Prescription Drug Monitoring Program, this updates the software standard for which pharmacies report controlled prescriptions to the PDMP database. Chapter 61-12-01-04 – Required use for certain dispensing situations – This section is new and requires a dispenser to access and view a patient's PDMP report before dispensing a pain or anxiety medication when the patient is new to the pharmacy, receiving the medication for long term or abuse is suspected.

7. As I indicated, a regulatory analysis was prepared for two of the rules and anticipated to cost more than \$50,000 across the state of North Dakota. They are chapter 61-08-01 -the requirement for Out-of-State Pharmacies to have an inspection and the Continuous Quality Improvement Rule.

However, the Continuous Quality Improvement Rule was not moved forward at the opinion of the Attorney General's Office and therefore will not have the economic impact as indicated in the regulatory analysis.

8. A regulatory analysis or economic impact statement on small entities was not required and was not issued.
9. We do anticipate these rules will have a fiscal effect on the Board of Pharmacy. I did attach a fiscal note, which had been attached to Senate Bill 2342, which mirrors the changes in Chapter 61-11 Fees. The rest of the rules will have no significant financial impact on the Board of Pharmacy.
10. No constitutional takings assessment was prepared as this did not apply.
11. None of these rules were adopted as emergency rules.

Respectfully,

Mark J. Hardy, PharmD

**CHAPTER 43-15.3  
WHOLESALE DRUG PEDIGREE**

**43-15.3-12. Fees.**

The board shall charge and collect the following fees under this chapter:

- Chain drug warehouse \$200
- Chain pharmacy warehouse \$200
- Durable medical equipment distributor, medical gas distributor, or both \$200
- Durable medical equipment retailer, medical gas retailer and distributor, or  
both \$300
- Hospital offsite warehouse \$200
- Jobber or broker \$400
- Manufacturer \$400
- Medical gas retailer, durable medical equipment retailer, or both \$200
- Medical gas durable medical equipment distributor and retailer \$300
- Own label distributor \$400
- Pharmacy distributor \$200
- Private label distributor \$400
- Repackager \$400
- Reverse distributor \$200
- Third-party logistic provider \$400
- Veterinary-only distributor \$200
- Virtual manufacturer \$400
- Virtual wholesaler or distributor \$400
- Wholesaler or distributor \$400

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 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.
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 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](mailto:ndboph@btinet.net). The proposed rules and regulatory analysis are also on the board's web site at [www.nodakpharmacy.com](http://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 28<sup>th</sup> 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  
WHOLESALEERS**

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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 28<sup>th</sup> day of February, 2014.

Howard C. Anderson, Jr, RPh.  
Executive Director

## Agenda April 17, 2014

Consideration of final approval of the rules is:

**April 17<sup>th</sup>, 2014 at 7:30 PM via conference call**

**Thursday April 17<sup>th</sup>, 2014 at 7:30 PM CDST**

Speakerphone located at:

ND Board of Pharmacy Office - 1906 East Broadway – Conference Room

**Call 1-800-423-1988 - Conference #1634598**

**Under the Name: Mark Hardy**

Call to order – President Diane Halvorson

Review of rules set for rule hearing on April 5, 2014 during the Pharmacy Convention:

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.

On Thursday April 17, 2014 at 7:30 PM the North Dakota State Board of Pharmacy held a conference call meeting.

The meeting was called to order by President Halvorson at 7:30 PM. Executive Director Hardy was in the Board of Pharmacy Conference Room. Present on the telephone conference call were Board Members: Pharmacist Gary W Dewhirst; Pharmacist Laurel Haroldson; Pharmacist Gayle D Ziegler; Pharmacist Shane Wendel; Public Member Fran Gronberg; and Diane M. Halvorson, RPhTech. Also on the call was Howard C Anderson, Jr Pharmacist and Michelle Mack from Express Scripts

Absent from the call was Pharmacist Bonnie J Thom.

The agenda was posted on the door of the Board of Pharmacy Office – Located at 1906 E Broadway Ave in Bismarck, ND 58501.

Comments were received during the Rule Hearing held at the NDPhA convention and also in the comment period commencing on April 16, 2014. The comments received on the rules were sent via email to the Board members for their considerations.

Board members discussed the various rules and comments received.

**It was moved by Pharmacist Dewhirst and seconded by Public Member Gronberg that we approve 61-02-01 Pharmacy Permits to add a Class L permit for automated dispensing devices in Nursing Homes. All Board Members present voted aye – the motion carried.**

It was moved by Pharmacist Wendel and seconded by Pharmacist Haroldson that we approve the creation of 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. All Board Members present voted aye – the motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Haroldson that we approve N.D. Admin. Code Article 61-11 to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session. All Board Members present voted aye – the motion carried.

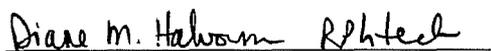
It was moved by Pharmacist Ziegler and seconded by Public Member Gronberg that we approve N.D. Admin. Code Chapter 61-04-02 Physician Exemption to expand the exemption. All Board Members present voted aye – the motion carried.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Wendel that we approve N.D. Admin. Code Chapter 61-04-08 Limited Prescriptive Practices to clarify the signature requirements and form. All Board Members present voted aye – the motion carried.

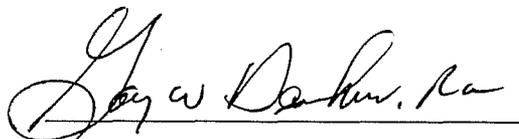
It was moved by Pharmacist Dewhirst and seconded by Pharmacist Wendel that we approve N.D. Admin. Code Chapter 61-08-01-08 to require inspection or accreditation of out-of-state pharmacies. All Board Members present voted aye – the motion carried.

It was moved by Public Member Gronberg and seconded by Pharmacist Ziegler that we approve 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. All Board Members present voted aye – the motion carried.

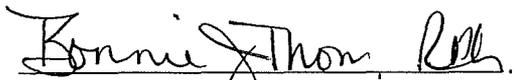
President Halvorson asked about other business. There being no further business – the meeting adjourned.



Diane M. Halvorson, RPhTech.  
President



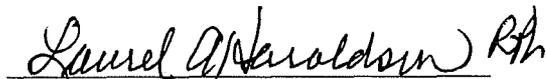
Gary W. Dewhirst, R.Ph.  
Senior Member



Member  
Bonnie J. Thom, R.Ph.



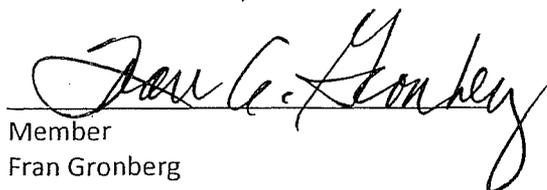
Member  
Gayle D. Ziegler, R.Ph.



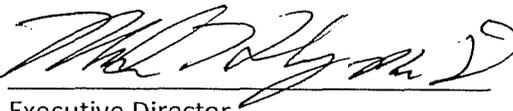
Member  
Laurel A. Haroldson, R.Ph.



Member  
Shane R. Wendel, R.Ph.



Member  
Fran Gronberg



Executive Director  
Mark J. Hardy, PharmD

**Monday April 28<sup>th</sup>, 2014**

**Meeting Conference Call Meeting**

Agenda - Monday April 28<sup>th</sup>, 2014 - 8:30 PM  
ND Board of Pharmacy Office 1906 East Broadway – Conference Room

CALL – 1-800-423-1988 Under the Name: MARK HARDY  
Conference # 1637537

Topic: Article 61-02-01- New Rules being considered  
Chapter 61-02-01-18 Continuous Quality Improvement  
Attorney General's Opinion on 61-02-01-18 Continuous Quality Improvement –  
potential resending of CQI portion of the rule

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President Halvorson called the meeting to order via teleconference at 8:38PM.

Present on the teleconference meeting were President Diane Halvorson, RPhTech, Fran Gronberg, Public Member; Laurel Haroldson, RPh; Gary Dewhirst, RPh; Bonnie Thom, RPh; Howard Anderson Jr, RPh, and Executive Director Mark Hardy, PharmD.

Not present on the teleconference were members Shane Wendel, RPh and Gayle Ziegler, RPh.

Executive Director Hardy explained the reason for the meeting and referenced the Attorney General opinion sent via email to the Board Members. Pharmacist Anderson provided the context of a conversation had with the Assistant Attorney General Edward Erickson on the legal issues with the Continuous Quality Improvement portion of the rule and provided options to the Board Members.

The issue is outlined below in a portion of an email received from Mr. Erickson:

*Earlier today we discussed proposed new NDAC 61-02-01-18, concerning continuous quality improvement for pharmacies. In my review of the Board's proposed rules for legality, I noticed that this rule included provisions protecting a pharmacy's self-audit and quality control information from subpoenas or court discovery. This provision is much different, legally, from a pharmacist's duties regarding patient confidentiality because the Board's rule would be regulating the courts instead of pharmacists.*

*These provisions require clear statutory authority. Authority to bind the courts is not contained in the Pharmacy Practice Act. We discussed NDCC chapter 23-34, which provides subpoena and discovery protection for peer reviews for certain institutions and physicians. It had been your intent to have proposed NDAC 61-02-01-18 come under these laws. However, as we discussed, chapter 23-34 does not apply to pharmacies, and this law would have to be amended before the Board could use it as authority for a rule such as proposed NDAC 61-02-01-18.*

Board members agreed that we do not want to implement a requirement to collect Quality Related Events with the implications that it could be discoverable.

Board members also recommended the Board look at the statutory changes that could be made during the next session before we move forward with this rule in the future.

***It was moved by Pharmacist Dewhirst to rescind the proposed rule in its entirety contained in NDAC 61-02-01-18 related to a continuous quality improvement program. Public Member Gronberg seconded the motion. All member present voted Aye. Motion carried.***

***It was moved by Pharmacist Thom to adjourn the teleconference meeting. It was seconded by Pharmacist Haroldson. All members present voted Aye. The teleconference ended at 8:55PM***

*Diane M. Halvorson RPhTech*  
Diane M. Halvorson, RPhTech.  
President

*Bonnie J. Thom, R.Ph.*  
Member  
Bonnie J. Thom, R.Ph.

*Laurel A. Haroldson RPh*  
Member  
Laurel A. Haroldson, R.Ph

*Fran Gronberg*  
Member  
Fran Gronberg

*Gary W. Dewhirst, R.Ph.*  
Gary W. Dewhirst, R.Ph.  
Senior Member

*Gayle D. Ziegler R.Ph.*  
Member  
Gayle D. Ziegler, R.Ph.

*Shane R. Wendel R.Ph.*  
Member  
Shane R. Wendel, R.Ph.

*Mark J. Hardy PharmD*  
Executive Director  
Mark J. Hardy, PharmD

Consideration of Comments for April 5, 2014 rule hearing. President Halvorson called the meeting to order at 4:10PM.

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.**

No Comments Received

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.**

Jesse Breidenbach and Robert Biberdorf – Sanford has its own internal program for capturing Quality Related Events and Errors. Wondering if this will be adequate for the section 61-02-01-18-02 (2b)

**Board Response – By how it currently reads that would not meet the requirement unless it is a PSO listed as a AHRQ.**

Jesse Breidenbach – Felt that if they had an internal program that addressed that tracked Quality Related Events it should be sufficient and it shouldn't need to be a PSO.  
Joel Aukes – Agreed with Jesse

**Board Response – The Board agrees that an internal program would be sufficient as long as events are tracked and evaluated. Upon inspection the Board's inspector will check the program to ensure use and evaluation. Therefore 61-02-01-18-02 section 2, b & c will be modified to:**

**b. The pharmacy reports incidents, near misses and unsafe events through either:**

**i. a contracted Patient Safety Organization (PSO) that is listed as an Agency for Health Research and Quality (AHRQ) on www.ahrq.com whose primary mission is pharmacy continuous quality improvement; or,**

**ii. an internal program to the pharmacy which is acceptable to the Board where proper documentation and evaluation can be completed**

David Olig – Feels this rule is just another mandate and is unnecessary as pharmacies will not utilize.

**Board Response- The Board disagrees with Pharmacist Olig's comments as CQI is an important process to assure practices are continually being evaluated to make improvements for the patients safety. The Board has heard good comments from those pharmacies implementing such a system in identifying shortfalls in workflow. Utilization of a pharmacy's CQI program will be addressed during regular inspections to ensure use and evaluation of reports.**

Dacotah Yokom - Email through Gayle Ziegler 4/15/14, asked about discussion on the time frame for follow-up. In one section it says 30 days and in another it says 7 days. Is one for internal documentation and the other for reporting or should they match? She is also wondering how pharmacies will be held accountable to this time frame by the board?

**Board Response** - The two dates address different things. The 30 days is for reporting to the PSO (or in the case of the hospital to their company wide internal system) and may need to be gleaned from the QRE (internal reporting) which is required within seven days, as it will likely be forgotten about shortly after that and missed altogether.

Within seven days it needs to show up in the QRE reporting system and within 30 days be reported to the PSO or the internal company system, if it qualifies as reportable. Not everything needs to go on to the PSO, such as the tech pulling the wrong bottle, realizing it and getting the correct one.

In regard to the enforcement by the Board, it will mostly be monitored upon inspection or checked based upon a complaint. The Board expects reporting done as soon as possible to make sure it is accurately documented.

Keith Horner – St Alexius – Attached

**Board Response** – Similar comments received and adjustments made to rule to allow internal program be used.

3. **Revise N.D. Admin. Code Article 61-11 to list the fees required by Senate Bill 2342, adopted in the 2013 legislative session.**

No Comments Received

4. **Revise N.D. Admin. Code Chapter 61-04-02 Physician Exemption to expand the exemption.**

Robert Biberdorf – Questioned whether we are serving the public by allowing practitioners to dispense.

Dave Olig – Felt opening this exemption is not necessary

Jeff Lindoo – Explained that MN workers compensation is having issues around physician dispensing

**Board Response** – There is currently language in the ND Century Code which specifically allows physicians to dispense. This rule is intended to better define what practitioners can dispense and when they must perform the packaging, labeling, consulting and recordkeeping standards consistent with a pharmacy.

Harvey Hanel – Asked for the 14 day supply of initial maintenance therapy by changed to 10 days to attempt to limit the pre-packaged medications being dispensed.

**Board Response** – The Board agrees with Pharmacist Hanel's comment and will adjust the section from fourteen to ten day supply of initial therapy of a maintenance medication....

Dave Olig – Commented that it should be limited to be 3 days as no patient is more than 3 days away from a pharmacy.

**Board Response** – the Board agrees with Dave that is should be limited but 10 days is a reasonable amount

Jeff Lindoo – Felt that we could grant practitioners full dispensing authority if pharmacists get full prescribing authority

Jordan Wolf – Expressed concern with exemption from practitioners to the consultation requirement

**Board Response** – The Board of Medical Examiners is going to expect the practitioner to be responsible for ensuring the patient is informed about the medication.

Sanford Health –Comments received in support of proposed rules. Attached at end of document

**5. Revise N.D. Admin. Code Chapter 61-04-08 Limited Prescriptive Practices to clarify the signature requirements and form.**

No Comments Received

**6. Revise N.D. Admin. Code Chapter 61-08-01-08 to require inspection or accreditation of out-of-state pharmacies.**

Dennis McAllister representing Express Scripts – Spoke about his experiences and other states' stance on the PIC being licensed in state where prescriptions are sent to the patient. Dennis has submitted written comments regarding the rule which are attached

**Re: Comments on Proposed Amendments to Chapter 68-08-01 Requirements for Out-of-State Pharmacies Erik Woehrmann Received via e mail April 16, 2014**

CVS Caremark appreciates the opportunity to submit comments for your consideration regarding Chapter 68-08-01 Requirements for Out-of-State Pharmacies.

**61-08-01-08(c)** The pharmacist in charge or another pharmacist responsible for the North Dakota patients must be licensed in North Dakota.

CVS Caremark opposes this section of the proposed rule. Requiring the resident pharmacist-in-charge (PIC) or another pharmacist to be licensed in North Dakota will not add further assurances of regulatory compliance or understanding of North Dakota State Board of Pharmacy laws and rules to those of the current nonresident pharmacy licensure, but may result in potential administrative non-compliance and interruptions to patient care. The requirement of a nonresident PIC can be overly burdensome and time consuming due to licensing reciprocity delays if unforeseen staff changes leave a pharmacy without a nonresident PIC. The 3 - 6 month reciprocity process places the pharmacy and its patients in a compromising situation. We do not feel that this additional requirement benefits the patient or provides additional accountability for the Board. Through the current non-resident pharmacy license, the pharmacy agrees to comply with applicable laws and rules and has a strong incentive to comply based on its multistate patient base and business model.

**Board Response** – We agree with Pharmacist McAllister and Mr. Woehrmann and the requirement for the PIC of an out-of-state pharmacy to be licensed here has been removed.

**61-08-01-08(d)** The facility shall be inspected in a manner and frequency prescribed by the Board:

- (1) For nonresident pharmacies that prepare and ship sterile and/or non-sterile compounded products into this state, the facility must be inspected at least once every 12 months by:
  - (i) The Board or its duly authorized agent; or

- (ii) A duly authorized agent of a third party approved by the Board which is the National Association of Boards of Pharmacy verified Pharmacy Program

CVS Caremark is concerned that the resident State Board of Pharmacy inspection is not allowed as an option. This is a blatant and unnecessary disregard for the resident State Board of Pharmacy and their requirements and may result in conflicting information for the pharmacy. The potential for multiple inspections by different agencies may result in an interruption of pharmacy practice.

CVS Caremark recommends allowing the resident State Board of Pharmacy inspection as an alternative.

**Board Response: The board disagrees with CVS Caremark. North Dakota had State inspections on file for the New England Compounding Center for the prior two years, both of which indicated no serious problems. This inspection by the National Association of Boards of Pharmacy will eliminate the variations from state to state, and the VPP inspection will come to be accepted by many states and actually make out of state licensure easier for most pharmacies.**

**61-08-01-08(d)** The facility shall be inspected in a manner and frequency prescribed by the Board:

- (1) For nonresident pharmacies that do not ship sterile and non-sterile compounded products into this state, the facility must be inspected at least once every 2 years by:
  - (i) The resident state board of pharmacy, if the resident board's inspection is substantially equivalent to the inspection in this state;
  - (ii) The Board or its duly authorized agent; or
  - (iii) A duly authorized agent of a third party approved by the Board, which if the National Association of Boards of Pharmacy verified Pharmacy Program

CVS Caremark requests clarification on the requirement that the resident State Board of Pharmacy inspection will be accepted "if the resident board's inspection is substantially equivalent to the inspection" in North Dakota. While we strongly support the acceptance of the resident state's inspection, there needs to be clarity for pharmacies as to what is required to be able to serve North Dakota patients from outside the State. A pharmacy must have a clear way to determine if its resident state inspection is going to be deemed acceptable to North Dakota as the pharmacy has little to no control over what a state chooses to inspect.

**Board Response: The board disagrees with CVS/Caremark. We will accept inspections by the National Association of Boards of Pharmacy and the VPP inspection will come to be accepted by many states and actually make out of state licensure easier for most pharmacies.**

**We have had language stating a similar inspection will be accepted for many years and have been able to accept most of them, however, if for example a state does not address non-sterile compounding in their inspection process, our board may decide to ask for another inspection. This issue has not been a problem for our out-of-state licensees in the past and should not be in the future. Some states provide only self inspections by the pharmacies themselves, and this is not adequate for serving North Dakota patients.**

Comments by Kerrin Prince , Compliance Specialist Supervisor of IWP e mailed asking if we accept the VPP inspection reports for licensure, which we answered that we will as soon as this rule is adopted.

**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 pharmacists.**

Dennis McAllister – Likes the New York Legislation which places burden of PDMP use on the practitioners.

Amber Olek – Asked about the capturing of prescriptions in the PDMP when dispensed after hours or for emergencies.

**Board Response** – **Dispensing is not very well reported by emergency rooms and needs to be more consistently reported. After hours dispensing by pharmacies is reported like all other dispensing.**

Shane Wendel – Felt this is a good draft of a guideline for use of the PDMP. It allows for professional judgment but gives guidance that use of the PDMP is needed in certain circumstances.

Mark Hardy – Presented a proposed addition to the rule to allow for technology enhancements with integration efforts of the PDMP into Electronic Health Records.

Justin Heiser – Asked questions of the workings of the NARxCheck system.

**Board Response** – **Agreed that the proposed addition (below) should be added to the rule.**

**4. For the purpose of compliance with Section 1, a report could be obtained through a PDMP integration with software or also a Board approved aggregate tool, for which the NARxCHECK will be an approved tool.**

**a. The National Association of Boards of Pharmacy Foundation's NARxCHECK service is a risk assessment tool for health care providers and pharmacists that accesses patient prescription information from prescription drug monitoring program (PDMP) databases, analyzes the data, and provides a risk-based score that includes PDMP data and graphical analysis to assist in prescribing and dispensing decisions.**

Jeff Lindoo – Should it be all controlled substances or limited to opiates as that is much of the concern with regards to current abuse trends.

**Board Response** – **Agreed that much of the abuse trends involve medication for pain and anxiety. Thus an addition should be made on section 1 line 2, for the treatment of pain or anxiety,**

Keith Horner – St Alexius – Concerned with requirement for all controlled substances and suggests modification to identify specific controlled classes as well as providing greater professional discretion to our pharmacists.

**Board Response** – **The Board agrees to modify the rule to be for those medications in the treatment of pain or anxiety. However the Board feels the current draft now provides a good guideline for the use of the PDMP while still allowing professional discretion once a relationship with a pharmacy has been established.**

## *Proposed Rule Comments by Express Scripts*

Comment on proposed rule amendments to N.D. Admin. Code Chapter 61-08-01-08

*(c) The pharmacist in charge or another pharmacist responsible for the North Dakota patients must be licensed in North Dakota.*

### **Express Scripts:**

Express Scripts is opposed to this section of the proposed rule. Having the pharmacist in charge (PIC) or another pharmacist, licensed in North Dakota will do little to ensure regulatory compliance and knowledge of the North Dakota Board of Pharmacy rules as opposed to the current non-resident pharmacy license. Non-resident pharmacies are almost always part of a larger company that services clients through health plans or government contracts. The non-resident pharmacy license is a critical element of their business, and compliance is of the highest priority. The non-resident permit gives the Board jurisdiction to discipline or revoke in the case of non-compliance. By virtue of having a non-resident pharmacy license, the pharmacy agrees to comply with North Dakota Statutes and Rules. Therefore, we believe the current non-resident license requirement in the state serves as a stronger incentive for compliance than would the proposed individual licensed PIC or pharmacist.

### **Express Scripts:**

At present, there are 10 states that require non-resident PIC licensure and several of these states are considering repealing this requirement. This is due to the fact the requirement does not increase jurisdiction and is an unnecessary burden to the business. Non-resident PIC licensure is administratively difficult, as changes in personnel can create compliance issues for pharmacies due to the 3-6 month reciprocity licensing process. In Arizona, we have had such a requirement for 11 years, and not once has the Board found that the Arizona licensed PIC should be disciplined. The Board has always found the permit holder responsible for non-compliance. With only 10 states that have the requirement, and 40 that do not, it is hard to find a compelling reason for such a rule.

### **Express Scripts:**

The current non-resident license in North Dakota requires that the PIC be named on the application and renewal, and that person is responsible to the Board for correspondence, complaint investigation, and response. We believe that this is sufficient for the Board to fulfill its mission to the citizens of North Dakota.

### **Express Scripts:**

In conclusion, requiring a non-resident license holder to have a North Dakota licensed pharmacist employed does not give the Board additional jurisdiction, and is an unnecessary administrative burden to business.

### **Response-**

**The Board agrees with this comments and the section has been removed.**



# St. Alexius Medical Center PrimeCare

April 16, 2014

## North Dakota Board of Pharmacy

1906 East Broadway Avenue

Bismarck, ND 58501

Phone: 701-328-9535

Fax: 701-328-9536

Executive Director Mark Hardy and members of the ND Board of Pharmacy:

St. Alexius Medical Center has reviewed the 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.

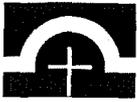
Please accept our comments and concerns relating to Chapters 61-02-01 and 61-12-01.

**Chapter 61-02-01.** Health Systems currently have continuous quality improvement programs in place to assist in detecting, documenting, assessing, improving, and preventing unsafe practices and conditions within the Health System. Joint Commission, as well as other accrediting agencies, require the implementation, collection and analysis of data, and where necessary the modifications of practice and policy to improve patient safety and outcomes. St. Alexius Medical Center Pharmacy participates in this process. We take no issue with the requirement of establishing a CQI Program. Our concern is that this chapter also requires a contract with a Patient Safety Organization (PSO) that is listed as an Agency for Health Research and Quality (AHRQ) on [www.ahrq.org](http://www.ahrq.org). This requirement may be interpreted to require data collected to be reported to an above listed and approved agency. This exceeds what is currently required by accrediting agencies and is of concern to the Medical Center. St. Alexius Medical is opposed to Chapter 61-02-01 as it is currently written.

*"Let all be received as Christ."*

900 East Broadway • PO Box 5510 • Bismarck, ND 58506-5510

Tel. (701) 530-7000 • Fax (701) 530-8984 • TDD (701) 530-5555 • [st.alexius.org](http://st.alexius.org)



# St. Alexius Medical Center PrimeCare

**Chapter 61-12-01.** Chapter 61-12-01 appears to place additional requirements on anyone that is licensed to dispense **any form of controlled substance**. This proposed regulation would require pharmacies to generate a report from the Prescription Drug Monitoring Program (PDMP) once a year for each and every patient that receives a controlled substance from the licensed pharmacy. As written, it appears to require pharmacies generate a report for every pediatric patient receiving codeine containing products all the way to geriatric patients receiving Lyrica. While we all agree that diversion and misuse of controlled substances must be addressed, we question whether this specific regulation is a prudent use of our professional resources. We suggest that the ND Board of Pharmacy consider revising this chapter to identify specific control classes as well as providing greater professional discretion to our pharmacists. St. Alexius Medical Center is opposed to Chapter 61-12-01 as it is currently written.

Thank you for your time and attention to these comments.

Sincerely,

Keith Horner, PharmD MPA

Director of Pharmacy and Clinical Informatics

*"Let all be received as Christ."*

900 East Broadway • PO Box 5510 • Bismarck, ND 58506-5510

Tel. (701) 530-7000 • Fax (701) 530-8984 • TDD (701) 530-5555 • [st.alexius.org](http://st.alexius.org)

## Howard Anderson

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**From:** Files, Brian <Brian.Files@caremark.com>  
**Sent:** Wednesday, April 16, 2014 2:52 PM  
**To:** mhardy@btinet.net; ndboph@btinet.net; ndboph@btinet.net  
**Cc:** Files Brian; Woehrmann, Erik M.; Mesaros, Jeffrey  
**Subject:** Comments on Proposed Amendments to Chapter 68-08-01 Requirements for Out-of-State Pharmacies  
**Attachments:** 2014 ND Non-Resident PIC Comment- CVS Caremark Comment.doc; CVS Comment on Proposed Amendments to Chapter 68-08-01 Requirem.pdf

Dear Mr. Hardy:

CVS Caremark appreciates the opportunity to submit comments for your consideration regarding Chapter 68-08-01 Requirements for Out-of-State Pharmacies. Per the deadline of April 16, 2014, I respectfully submit the attached comments on behalf of CVS Caremark.

Please acknowledge receipt of this information.

Thank you!

Best,

**Brian Files** | CVS Caremark | Director, Public Policy | T: 202.772.3512 | M: 202.372.7179 | 1300 I St., NW, Washington DC 20005  
| [brian.files@cvscaremark.com](mailto:brian.files@cvscaremark.com)

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April 16, 2014

Mark Hardy, RPh  
Executive Director  
North Dakota State Board of Pharmacy  
1906 E. Broadway  
Bismarck, North Dakota 58501

**Re: Comments on Proposed Amendments to Chapter 68-08-01 Requirements for Out-of-State Pharmacies**

Dear Mr. Hardy:

CVS Caremark appreciates the opportunity to submit comments for your consideration regarding Chapter 68-08-01 Requirements for Out-of-State Pharmacies.

**61-08-01-08(c)** The pharmacist in charge or another pharmacist responsible for the North Dakota patients must be licensed in North Dakota.

CVS Caremark opposes this section of the proposed rule. Requiring the resident pharmacist-in-charge (PIC) or another pharmacist to be licensed in North Dakota will not add further assurances of regulatory compliance or understanding of North Dakota State Board of Pharmacy laws and rules to those of the current nonresident pharmacy licensure, but may result in potential administrative non-compliance and interruptions to patient care. The requirement of a nonresident PIC can be overly burdensome and time consuming due to licensing reciprocity delays if unforeseen staff changes leave a pharmacy without a nonresident PIC. The 3 - 6 month reciprocity process places the pharmacy and its patients in a compromising situation. We do not feel that this additional requirement benefits the patient or provides additional accountability for the Board. Through the current non-resident pharmacy license, the pharmacy agrees to comply with applicable laws and rules and has a strong incentive to comply based on its multistate patient base and business model.

**61-08-01-08(d)** The facility shall be inspected in a manner and frequency prescribed by the Board:

- (1) For nonresident pharmacies that prepare and ship sterile and/or non-sterile compounded products into this state, the facility must be inspected at least once every 12 months by:
  - (i) The Board or its duly authorized agent; or
  - (ii) A duly authorized agent of a third party approved by the Board which is the National Association of Boards of Pharmacy verified Pharmacy Program

CVS Caremark is concerned that the resident State Board of Pharmacy inspection is not allowed as an option. This is a blatant and unnecessary disregard for the resident State Board of Pharmacy and their requirements and may result in conflicting information for the pharmacy. The potential for multiple inspections by different agencies may result in an interruption of pharmacy practice.

CVS Caremark recommends allowing the resident State Board of Pharmacy inspection as an alternative.

**61-08-01-08(d)** The facility shall be inspected in a manner and frequency prescribed by the Board:

- (2) For nonresident pharmacies that do not ship sterile and non-sterile compounded products into this state, the facility must be inspected at least once every 2 years by:
  - (i) The resident state board of pharmacy, if the resident board's inspection is substantially equivalent to the inspection in this state;
  - (ii) The Board or its duly authorized agent; or
  - (iii) A duly authorized agent of a third party approved by the Board, which if the National Association of Boards of Pharmacy verified Pharmacy Program

CVS Caremark requests clarification on the requirement that the resident State Board of Pharmacy inspection will be accepted "if the resident board's inspection is substantially equivalent to the inspection" in North Dakota. While we strongly support the acceptance of the resident state's inspection, there needs to be clarity for pharmacies as to what is required to be able to serve North Dakota patients from outside the State. A pharmacy must have a clear way to determine if its resident state inspection is going to be deemed acceptable to North Dakota as the pharmacy has little to no control over what a state chooses to inspect.

CVS Caremark appreciates the opportunity to submit comments for the proposed regulation. If you have any questions, please contact Brian Files, Director of Policy, at 202.772.3500.

Sincerely,

Erik Woehrmann  
Senior Director, Government Affairs

RECEIVED

APR 09 2014

SANFORD  
HEALTH

Sanford Health  
Occupational Medicine Clinic

sanfordhealth.org

April 4, 2014

Dear Board Members:

The Bakken Oil Field's incredible growth has created a demand for medical services that existing local resources cannot serve alone. A key to maintaining positive quality of life for the region's residents and workers includes ensuring high quality and readily available healthcare services.

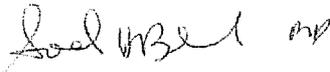
As Sanford expands medical coverage in the Bakken Oil Field, the proposal to revise the administrative rule regarding physician exemption for dispensing medications will greatly benefit these underserved workers.

In our plan to reach these individuals, we have faced many obstacles. The changes to the administrative rules that will allow our providers to dispense medications to complete a course of antibiotics, start a pack of pre-packaged medications or provide up to a 14-day supply of initial therapy of a maintenance medication that needs to be started urgently, will be of great help.

I support these changes, as I believe it will improve the medical care we will be able to provide for the oil workers in western North Dakota.

Thank you.

Sincerely,



Joel Blanchard, MD  
Medical Director  
Sanford Occupational Medicine Clinic  
2603 E. Broadway Ave.  
Bismarck, ND 58501

2603 E. Broadway Ave  
Bismarck, ND 58501  
(701) 339-5222 • (800) 419-5222

1231 West Villard St., Suite A  
Dickinson, ND 58601  
(701) 225-7575 • (800) 723-2638

201 21st Ave. Southeast  
Minot, ND 58701  
(701) 839-5942 • (800) 595-8310

Our Mission:  
Dedicated to the work of  
health and healing

## Howard Anderson

---

**From:** Howard Anderson <ndboph@btinet.net>  
**Sent:** Friday, March 21, 2014 9:51 AM  
**To:** 'Kerrin Prince'  
**Cc:** 'Bolin, Joshua'  
**Subject:** RE: North Dakota inspection report requirements

Dear Kerrin Prince:

We will accept the VPP inspection. We actually have a rule in the process to require it. You can find the proposed rule at <https://www.nodakpharmacy.com/pdfs/61-08inspectionsRule4oosPharmacies.pdf>

The rule hearing is set for April 5<sup>th</sup>. The notice is on our web site.

We would welcome your comments.

Sincerely,

Howard

Howard C. Anderson, Jr., R.Ph.  
Executive Director  
North Dakota Board of Pharmacy  
1906 E. Broadway Ave.  
P.O. Box 1354  
Bismarck, ND 58502-1354  
Phone (701) 328-9535  
Fax (701) 328-9536  
Web site [www.nodakpharmacy.com](http://www.nodakpharmacy.com)

---

**From:** Kerrin Prince [<mailto:kprince@iwpharmacy.com>]  
**Sent:** Thursday, March 20, 2014 9:02 AM  
**To:** 'ndboph@btinet.net'  
**Subject:** North Dakota inspection report requirements

Good Morning,

According to North Dakota's Application for Permit or Renewal, it states a copy of the latest inspection report is a required document to be submitted with the application. Does the North Dakota Board of Pharmacy accept inspections performed by NABP's Verified Pharmacy Program (VPP) or do the inspections have to be performed by the regulatory or licensing agency of our resident state?

Any assistance you could provide would be greatly appreciated.

Sincerely,

**Kerrin Prince, Compliance Specialist Supervisor**

PO Box 338, Methuen, MA 01844-0338 | Toll free: 888-321-7945, Ext. 3014 | Cell: 978-987-2184

## Howard Anderson

---

**From:** Mcallister, Dennis (WDC) <Dennis\_McAllister@express-scripts.com>  
**Sent:** Friday, March 14, 2014 4:00 PM  
**To:** 'Howard Anderson'  
**Subject:** Comments on proposed rule.  
**Attachments:** ND BOP NR PIC Comments (2).docx

Howard,

Thanks for the time to chat this week. Here are the ESI comments on the proposed rule for Non-resident PIC licensure. I also will be at the hearing to supplement for the board.

See you in April!

Dennis

Dennis K. McAllister R.Ph.,D.Ph., FASHP  
Senior Director, Pharmacy Regulatory Affairs  
Express Scripts  
[dennis\\_mcallister@express-scripts.com](mailto:dennis_mcallister@express-scripts.com)  
602-513-2759 (Cell)  
(AZ Time Zone)

March 14, 2014

Howard Anderson, RPh.  
Executive Director  
North Dakota State Board of Pharmacy  
1906 E. Broadway Avenue  
Bismarck, ND 58501-1354

Re: Comment on proposed rule amendments to N.D. Admin. Code Chapter 61-08-01-08

Dear Howard and Members of the Board of Pharmacy,

I am sending this letter in my capacity as Senior Director of Pharmacy Regulatory Affairs for Express Scripts. I would like to comment on the proposed rule that a non-resident pharmacy have a pharmacist who is licensed in North Dakota.

**(c) The pharmacist in charge or another pharmacist responsible for the North Dakota patients must be licensed in North Dakota.**

Express Scripts is opposed to this section of the proposed rule. Having the pharmacist in charge (PIC) or another pharmacist, licensed in North Dakota will do little to ensure regulatory compliance and knowledge of the North Dakota Board of Pharmacy rules as opposed to the current non-resident pharmacy license. Non-resident pharmacies are almost always part of a larger company that services clients through health plans or government contracts. The non-resident pharmacy license is a critical element of their business, and compliance is of the highest priority. The non-resident permit gives the Board jurisdiction to discipline or revoke in the case of non-compliance. By virtue of having a non-resident pharmacy license, the pharmacy agrees to comply with North Dakota Statutes and Rules. Therefore, we believe the current non-resident license requirement in the state serves as a stronger incentive for compliance than would the proposed individual licensed PIC or pharmacist.

At present, there are 10 states that require non-resident PIC licensure and several of these states are considering repealing this requirement. This is due to the fact the requirement does not increase jurisdiction and is an unnecessary burden to the business. Non-resident PIC licensure is administratively difficult, as changes in personnel can create compliance issues for pharmacies due to the 3-6 month reciprocity licensing process. In Arizona, we have had such a requirement for 11 years, and not once has the Board found that the Arizona licensed PIC should be disciplined. The Board has always found the permit holder responsible for non-compliance. With only 10

states that have the requirement, and 40 that do not, it is hard to find a compelling reason for such a rule.

The current non-resident license in North Dakota requires that the PIC be named on the application and renewal, and that person is responsible to the Board for correspondence, complaint investigation, and response. We believe that this is sufficient for the Board to fulfill its mission to the citizens of North Dakota.

In conclusion, requiring a non-resident license holder to have a North Dakota licensed pharmacist employed does not give the Board additional jurisdiction, and is an unnecessary administrative burden to business.

Thank you for the opportunity to address the Board of Pharmacy on the proposed rule.

Respectfully,

Dennis McAllister, R.Ph., FASHP  
Senior Directory of Pharmacy Regulatory Affairs  
Cell: 602-513-2759  
Email: [dennis\\_mcallister@express-scripts.com](mailto:dennis_mcallister@express-scripts.com)



2122104

**The Commonwealth of Massachusetts**  
 Executive Office of Health and Human Services  
 Department of Public Health  
 For the Board of Registration in Pharmacy  
 239 Causeway St. Suite 400  
 Boston, MA 02108-4619  
 617 727 6091

MITT ROMNEY  
GOVERNOR

KERRY HEALEY  
LIEUTENANT GOVERNOR

RONALD PRESTON  
SECRETARY

CHRISTINE C. FERGUSON  
COMMISSIONER

Compounding Pharmacy Inspection (G.L. c. 94C S. 11) date: 2-20-04

# reg tech. 1  
 # cert. Tech 4  
 # rph 2

**PREMISES I.D.**

- 1) Corporation Name New England Compounding Inc
- 2) DBA Name New England Comp
- 3) Address 101 Liberty St Store Number - City / Town Frammingham Ma  
 Zip Code 01602
- 4) Telephone Number 800 944 6322 Fax Number 888 820 1616
- 5) Registrant BARRY COBBIN License Number 21239
- 6) Massachusetts Control Substance # 2898 DEA # -  
 Expiration Date 12/07 Expiration Date -
- 7) Pharmacy hours of operation M-F 9-5 Sat. no Sun. no

**REFERENCES SOURCES**

- 1) Rules and Regulations Board of Pharmacy 247 CMR (Y)
- 2) FDA Guidelines 795 480 1206 → USP (Y) N disc
- 3) USP Guidelines some some sterile 1104 (Y) N
- 4) Facts and Comparisons (latest edition) (Y) N  
 Updates inserted (Y) N  
 CD Rom versions: Y N Updated quarterly (Y) N
- 5) USP / DI Volume 1 Volume 2 Y N
- 6) American Hospital Formulary Service Drug Information (Y) N NA
- 7) American Medical Association Drug Evaluations Y N NA
- 8) Gold Standard Y (N) Updated quarterly Y N NA
- 9) Mosby's Drug Consult Y N
- 10) M.L.I.D. (latest version) Y N

**EQUIPMENT**

- 1) Sufficient Equipment (Y) N
- 2) Balance information: Torsion balance / scale and weights. Seal Date: na  
 Electronic balance analytical Seal Date: 9-03  
 Scale with print out: (Y) N Seal Date: 3
- 3) Number of Sinks in pharmacy location: clean room / primary / clean room (Y) N
- 4) Hot and Cold running water (Y) N

powder container hoods - HEPTA  
hormones - sulfa

Chris Conigliano - General Manager cx 633

5) Computer Software Name PK (PKA) Support Number 800 331 2698

6) Label Compliance  
Legend label compliant with interchange  Y  N NA  
7) Written copy of Policy & Procedures Manual on location related to the handling of Medication Errors  Y  N

**O.B.R.A**

1) Counseling Sign (11" x 14") posted:  Y  N  
2) Designated Confidential Counseling Area  Y  N  
3) Drive Up Window: Y  N Sign Posted: Y  N  
4) Counseling offer is offered by:  Pharmacist  Reg. Tech.  Certified Tech Intern / Student / Grad. Pharmacist?  
5) Record maintained of Offer to Counsel  Y  N  
6) Monographs used?  All prescriptions  New prescriptions only  
7) Prospective DUR on new prescriptions?  Y  N  
Conducted by:  Pharmacists?  Certified Tech?  Reg. Tech? Intern / Student / Grad. Pharmacist

**E.D.T.**

1) Random Sampling of Purported Prescriptions: DEA # Correct  Y  N  
2) Identifier of Recipient on Rx.  Y  N  
3) Transmitting by Computer on time? Disc  Y  N  
4) Counseling or Intervention Book - in computer practice  Y  N  
5) Patient Drug Regimen Review completed prior to dispensing medication.  Y  N

**RECORD KEEPING**

1) Biennial Inventory Readily Retrievable  Y  N  
Date of last inventory: 9/17/03  
2) Date of Last Change of Manager na  Y  N  
3) 222 Forms Sampling Compliant Y  N  
4) Power of Attorney on File  Y  N  
Located where: \_\_\_\_\_  
5) Perpetual Inventory Schedule II  Y  N Date Last Reconciled: 9/7 days  
Date of Inspection: 8/20/03  
6) Schedule III through Schedule IV controlled substances dispersed through the pharmacy?  Y  N  
7) Controlled substances in Schedule II locked and stored in the pharmacy  Y  N  
8) Controlled substance deliveries are delivered directly to the pharmacy dept.  Y  N  
9) Biennial Inventory readily retrievable?  Y  N  
Last Inventory date, 9/17/03  
10) Inventory taken for Change of pharmacy manager  Y  N  
Date taken na Name of Incoming pharmacist na  
Name of Outgoing pharmacist \_\_\_\_\_  
11) Procedures in practice to validate controlled substance prescription  Y  N  
12) Computerized records of distribution by schedule  Y  N  
a) Signed daily by pharmacist  Y  N  
b) Central Record Keeping Authority  Y  N  
13) Schedule II prescriptions are segregated  Y  N  
14) Schedule III, IV, and V prescriptions maintained in a separate file  Y  N  
15) Schedule VI prescriptions and syringes and instruments filed together  Y  N

HPP TRAINING Facility

**CODE OF PROFESSIONAL CONDUCT – 247 CMR 9.01**

- 1) Patient Confidentiality (Y) N
- 2) Corresponding Responsibility: making sure prescription is for a legitimate use in usual course of practice. (Y) N
- 3) Doctor Shoppers as it relates to OBRA (Y) N
- 4) Faxing of Prescriptions (Y) N
  - a) plain paper fax (Y) N
  - b) location of fax: Pharmacy (Y) N
  - c) accept Schedule II fax prescriptions for reference? (Y) N
- 5) Prescribers signature is on face of prescription faxed (Y) N
- 6) Faxed prescription or drug order is marked Electronically Transmitted RX (Y) N
- 7) Fax includes the identification number of the sending facsimile machine (Y) N
- 8) Record maintained for transferring prescriptions (Y) N
  - Computerized record: YN Hard copy log (N)
- 9) Emergency authorized prescriptions in Schedule II accepted? (Y) N
  - a) Marked for authorization for emergency dispensing (Y) N
    - i.e. faxes: marked with both: Electronically transmitted RX and Authorization for Emergency Dispensing (Y) N
    - b) Written prescription is postmarked with in 7 days to pharmacy (Y) N
    - c) Non-compliant physicians reported to DPH and DEA? (Y) N
- 10) Copies of pharmacists license posted (Y) N
  - Copies of technicians licenses posted (Y) N
- 11) Names badges and titles noted (Y) N
- 12) Manager of record is responsible for (setting forth) policy & procedures (Y) N
  - a) staff is adequately trained (Y) N
  - b) technician manual on premises (Y) N
  - c) ratio pharmacists to technicians 4 : 1 (Y) N
- 13) Number of Students/ Interns \_\_\_\_\_ Reg. Pharm. techs 1 (Y) N
  - Pharmacists 1 (Y) N
  - Cert. Pharm. techs \_\_\_\_\_ (Y) N
- 14) After hours access to pharmacy? (Y) N
- 15) Evidence of security cameras (Y) N
- 16) Quarantine area for control substances in schedule II, III, IV, V recalls or expired product segregated from current inventory (Y) N
- 17) Quarantine area for schedule VI expired or recalled items (Y) N
- 18) Biohazard waste appropriately flagged (Y) N
- 19) Name of Reverse Distributor Clon Kentco telephone number 5088725000 (Y) N
  - date of last return: 11/1/07 (Y) N
- 20) JCAHO approved? (Y) N
- 21) Log noting re-packaging date, expiration date, lot number, manufacturer, expiration date size of packages, filled by and checked by? (Y) N
- 22) Current file of patients requesting Non Child Proof Caps? (NCPC) and is a release on file? computerized (Y) N
- 23) Repackaged unit dose log complete (Y) N
  - (Date, manufacturer, manuf. exp. date, lot number, quantity, tech prep, internal lot number, R.Ph verified and initialed) (N) +
- 24) Refrigerator cleanliness (Y) N
  - a) Temperature log (Y) N
    - Freezer log (Y) N
    - Freezer free of frost buildup (Y) N
  - b) Thermometer present? Temperature 39° (Y) N
  - c) Biological Refrigerator (Y) N
  - d) Employee Refrigerator (Y) N

logged dispenser

- 25) Technician Training Manual on site  
 Last update 2/04 last in-service 2/19/04 (Y) N
- 26) Pharmacy and dispensing are, clean, organized, neat, adequate (Y) N
- 27) After hours access to pharmacy? (Y) N  
 Answering service Inhouse Telephone Number \_\_\_\_\_

**CIVAS PHARMACY (Central Intravenous Admixture Service) / Compounding Information:**

- 1) Clean room minimum of 72 sq. ft (Y) N
- 2) Clean room adjacent to prescription department (Y) N
- 3) Room under continual positive pressure (Y) N *Hood only*
- 4) CIVAS letter from Board posted  
 date of letter 3/99 (Y) N
- 5) Adequate Reference Standards (Y) N
- 6) Sterile Products: Laminar Flow Hood (name) Microsphere Expiration date \_\_\_\_\_  
 Vertical Flow Hood (name) \_\_\_\_\_ Expiration date \_\_\_\_\_  
 Served by: Scientific Air Analy telephone # 800-287-5252 8/31/04
- 7) Written Quality Assurance Guidelines to include aseptic technique, sterility, stability and endotoxins testing? (Y) N
- 8) Pharmacy will test and sterilize vials and stoppers for sterile products? Received (Y) N
- 9) Adequate Education in Sterile Products Last update 4 Last in-service 1/04
- 10) Batch log is initialed or signed by technician preparing the compound? (Y) N *Non-sterile only*
- 11) Quality controls in place (Y) N
- 12) Log for such controls in place? (Y) N
- a) Air Quality (Y) N
- b) Filters (Y) N
- c) Floors and Equipment cleaned (Y) N
- d) IV room and AnteRoom clean (Y) N *PCCA*
- 13) Computer Software Name PK Software Support Number 1-800-331-2488  
 Label Compliance: Compounding label: (Y) N/A  
 IV label (Y) N/A
- 14) All prescriptions are patient specific (Y) N
- 15) Compounding practices are in conformance with U.S. FDA guidelines (Y) N
- 16) All bulk compounding materials will be purchased from a U.S. Food and Drug approved manufacturer (Y) N
- 17) Certificates of analysis will remain filed on site and be readily retrievable (Y) N
- 18) Policy exists for how beyond use dates will be determined (Y) N
- 19) Batch log sheets will be kept on all compounded prescriptions compounded to include product name, expiration dates, manufacturers lot numbers, pharmacy lot numbers, name of patient / rx number, who calculated, who compounded, who verified the prescription (Y) N
- 20) Pharmacy will advertise the business as a compounder and not the specific products? (Y) N

**SUPPLIER INFORMATION**

- 1) PCCA 2) Spectrace 3) \_\_\_\_\_

**PHARMACIST ROSTER (List or see attach Roster)**

- 1) Lisa Cadben
- 2) Billy Cadben
- 3) \_\_\_\_\_
- 4) \_\_\_\_\_
- 5) \_\_\_\_\_

**Registered Technicians ROSTER (List or see attached Roster)**

- 1) \_\_\_\_\_
- 2) \_\_\_\_\_
- 3) \_\_\_\_\_
- 4) \_\_\_\_\_
- 5) \_\_\_\_\_

**Inspection Findings**

- 1) complaint. all concerns addressed
- 2) in complaint
- 3) \_\_\_\_\_

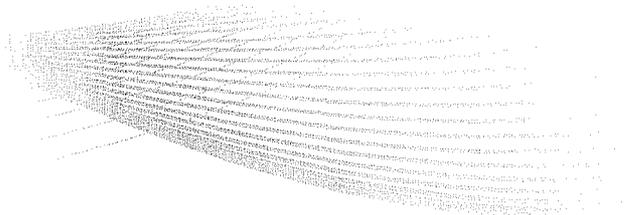
**PHARMACIST INTERVIEWED**

Signature [Signature] License Number 21239 Date 2/20/04

Investigator Assigned [Signature]

**Statutes / Regulations Cited:**

A = 21 USC                      B = 247 CMR                      C = 105 CMR    D = 94CL  
E = MGL 112 SEC 61            F = MGL C138 S 15L            G = MGL C 138 S 30 A



## Verified Pharmacy Program™

In the wake of the New England Compounding Center (NECC) tragedy, member state boards of pharmacy spoke out very clearly about the need to build regulatory uniformity among the states and enhance the services offered by the National Association of Boards of Pharmacy® (NABP®). Due to the strength and leadership of its member boards, NABP had a strong foundation to rapidly build and deploy services to assist member boards in their charge to protect the public health.

Building from a wide range of existing services – including license verification; the Electronic Licensure Transfer Program®; NABP Clearinghouse, which includes disciplinary information; accreditation; and inspection services – NABP developed the Verified Pharmacy Program™ (VPP™) to assist member boards in enhancing the licensure processes they already have in place.



### What Is VPP?

VPP, or the Verified Pharmacy Program, is an inspection service and information sharing network the boards of pharmacy may use to share critical inspection and licensing data with their fellow boards. Similar to the Electronic Licensure Transfer Program for pharmacists, VPP also facilitates what could be described as the nonresident pharmacy licensure transfer process.

### What Is VPP Meant to Accomplish?

VPP creates e-Profiles for each pharmacy and links these facility e-Profiles to key personnel e-Profiles, including those of the pharmacist-in-charge (PIC) in the state of domicile as well as any nonresident PICs.

The program is meant to enhance what the state boards of pharmacy are already doing in terms of determining qualifications for pharmacy licensure and ensure that the boards have complete and accurate information for making licensure decisions on nonresident pharmacies.

### What Does Recognizing and/or Requiring VPP Mean for the Boards?

The boards can recognize VPP and/or require that nonresident pharmacies apply through VPP when seeking to obtain or renew licensure. If an e-Profile

for the applicant does not already exist, one will be created and applicable alerts pertaining to that facility's disciplinary and inspection history will automatically be pushed to the board of pharmacy. Additionally, participating boards will have access to the e-Profiles and will have the capability to search for facilities by a variety of categories. The boards also have the ability to attach their own inspection reports and other documentation to the e-Profiles.

Recognizing and/or requiring VPP does not necessarily mean that the board is requiring that an inspection be conducted by NABP. When a VPP application from a pharmacy is received, NABP reviews and verifies the data submitted by the pharmacy. This includes any recent inspection reports, if available. Should an applicant submit a "qualified" inspection report and/or already have a qualified inspection report attached to the pharmacy e-Profile through the Inspection Clearinghouse, that pharmacy will not require a new inspection and all qualifying information will be pushed directly to the state board of pharmacy where the pharmacy is seeking licensure. In addition, the information will be provided to any other states where the pharmacy holds a license in order to provide supplemental data for the states to utilize when making licensing decisions.

If the applicant is found to not have a “qualified” inspection, an inspection will be scheduled through NABP. All VPP inspections are conducted by licensed pharmacists.

NABP provides all data directly to the applicable state boards of pharmacy and does not render any judgment on an applicant, as this authority is left to the state boards.

### **What Is a “Qualified” Inspection and What Inspection Forms Are Available?**

A qualified inspection is one that has been conducted within the past 18-24 months, if the facility provides routine retail pharmacy services, or within the past 12 months if it provides compounding services, and includes the appropriate modules of inspection standards depending on the services provided.

The simple presence of an inspection by the state of domicile does not necessarily mean the nonresident facility meets nonresident states’ requirements. Further, if a facility has been performing sterile compounding, it is possible that it may not have been subjected to a thorough compliance inspection by a properly trained inspector in many years, if ever.

NABP recently convened a task force to compile licensure standards that are consistent across the states with the purpose of structuring a uniform inspection form. Drawing from the expertise provided during the task force meeting, this form is under development and will assist in further defining a qualified inspection. The form will continue to evolve to meet the states’ needs. In addition, NABP has worked to develop uniform compounding inspection forms using elements of several different states’ inspection forms that inspect to United States Pharmacopeia Chapter <795> and Chapter <797> as a minimum standard for compounding. These will also evolve to further meet the needs identified by the member boards of pharmacy.

NABP is also exploring the possibility of forming specialized working groups to develop inspection form modules based on the varying types of pharmacy services.

The uniform, qualified inspections can also be coupled with self-reported facility information in order to identify sterile compounding facilities.

### **What Are the Fees for VPP?**

If recognizing and/or requiring VPP, and the board has the ability to pass the costs of an inspection along to the applicant/licensee, the board can direct nonresident pharmacies to NABP to begin the application process.

VPP applicants pay fees dependent on the type of pharmacy:

- Routine Retail: \$1,995
- Nonsterile Compounding or Large Mail Order: \$2,500
- Sterile Compounding or Institutional: \$3,000

If an applicant already has a resident state inspection deemed qualified through NABP processes, the applicant is refunded all but a \$500 processing fee. Pharmacies seeking licensure in multiple states will likely experience savings in inspection fees by avoiding costs associated with multiple state inspections.

For those states that must bear the costs of the inspections, NABP still recommends that states send their applicants through the VPP process and subsidize the inspection fee for the applicants. The Association may be able to work with the board on a discounted inspection fee.

The fees were developed based on estimates of NABP’s costs of performing inspections and other processing functions and are not intended to generate excess revenue. Any excess revenue will be used to support member boards of pharmacy through programs and services including, but not limited to, additional compliance training, the development of uniform inspection forms, and the development of other technology and tools to perform inspections.

**For more information or to apply for VPP, visit [www.nabp.net/programs/licensure/verified-pharmacy-program](http://www.nabp.net/programs/licensure/verified-pharmacy-program).**

**Or contact VPP staff via phone at 847/391-4406 or via e-mail at [vpp@nabp.net](mailto:vpp@nabp.net).**



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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 61** N.D. Admin. Code: 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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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.

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Howard C. Anderson Jr., R.Ph  
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