2015 SENATE HUMAN SERVICES

SB 2121

2015 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2121
1/28/2015
22728

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature Donald Mueller

Explanation or reason for introduction of bill/resolution:

Relating to medical peer review records.

Minutes:

Attach #1: Testimony by Sen. Howard Anderson
Attach #2: Chapter 61-02-01 Pharmacy Permits
Attach #3: Testimony by Mark Hardy

Senator Howard Anderson, Jr. introduced SB 2121 to the committee (attach #1). Also provided Chapter 61-02-01 Pharmacy Permits (attach #2). (end 3:38)

Senator Warner it does not provide any immunity in criminal law?

Senator Howard Anderson, Jr. think it still provide protection under criminal law, however, when prosecutor has a case he is making one specific case based on the facts. It would be rare for a prosecutor to say give me all the background in the other areas you made because it is not pertinent to the case. Protect his records from discovery, not the records subject to the case, obviously. The same thing would be true before the board of pharmacy. If the board gets a complaint, and decides to proceed with the complaint of their own against that pharmacy, then the records of that case would be public once the case is done. Also quality assurance reports would be available for inspections that board of pharmacy is doing what they should be doing. Pharmacy board is interested in improving practice, not intended to ding them - improve practice.

Chairman Judy Lee the section of statute is on Medical Peer Review records. Isn't that pretty limiting in a sense that it wouldn't necessarily provide protections in other areas, such as a criminal complaint. Chairman Judy Lee asked for attorney in the room to provide some guidance.

Senator Howard Anderson, Jr. it's not in the board of pharmacy. The attorney general's office stated this would be the best place to solve this problem.

Chairman Judy Lee it suggests to her that it only relates to peer review records.

Senator Howard Anderson, Jr. the intent is quality reviews are peer review records. Each pharmacy reports to those to a federally qualified quality assurance group which then protects them under federal law.

Chairman Judy Lee said Senator Warner does it give protection in a criminal case. I'm not seeing that this would give the protection in criminal cases, but only quality assurance part.

Mr. John Olson, attorney, representing pharmacy and board of medical examiners, testified. Peer review, it is quality assurance, want to incentivize the profession to have free and open discussions. For board of medical examiners, they have that protection. Their statute states that the board itself can have access to the peer review records. Those peer review records are not available in any discovery, civil or criminal. That doesn't apply to other sources or duties of other members of the profession that have direct knowledge of violations of those disciplinary acts that govern pharmacists or doctors. There not relieved of their duty to report. Mr. Olson does not have the precise answer of who will have access to the records.

Chairman Judy Lee thinks that it is limited to a peer review. Femi will clarify with attorney general office.

Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy, testified IN FAVOR of SB 2121, (attach #3) (10:28-13:10)

No questions.

OPPOSITON TO SB 2121
No opposing testimony

NEUTRAL TO SB 2121

No Neutral testimony

Closed Public Hearing

2015 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2121
2/2/2015
23021

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature Donald Mueller

Explanation or reason for introduction of bill/resolution:

Relating to medical peer review records.

Minutes: "Click to enter attachment information."

"Click here to type your minutes"
These are minutes from the Senate Human Services Committee on February 2, 2015.

(2:35 discussion begins)
Senator Howard Anderson, Jr. indicated that he had talked with Mark Hardy, who was checking with things with Attorney General's office. We don't need all the protections of the medical board. Dr. Hardy indicated we should go with what is written.

Senator Howard Anderson, Jr. recommended a DO PASS on SB 2121. The motion was seconded by **Senator Axness**.

Roll Call Vote
6 Yes, 0 No, 0 Absent. Motion pasess

Senator Axness will carry the bill to the floor.

Date: 02/02 2015
Roll Call Vote #: 1

2015 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. SB2121

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description:

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐

Motion Made By Anderson Seconded By Axness

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee (Chairman)	✓		Senator Tyler Axness	✓	
Senator Oley Larson (V-Chair)	✓		Senator John M. Warner	✓	
Senator Howard C. Anderson, Jr.	✓				
Senator Dick Dever	✓				

Total (Yes) 6 No 0

Absent 0

Floor Assignment Axness

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2121: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2121 was placed on the Eleventh order on the calendar.

2015 HOUSE HUMAN SERVICES

SB 2121

2015 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

SB 2121
2/18/2015
Job #24052

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

Relating to medical peer review records.

Minutes: Testimonies 1-2

Chairman Weisz opened the hearing on SB 2121.

Sen. Howard Anderson: Introduced and testified in support of the bill. (See Testimony #1)

3:39
Chairman Weisz: Basically you are putting them in a definition area which would put them in with the physicians etc.

Sen. Anderson: That is correct.

Rep. Porter: On page 2 on the top, the current definition seems to already include pharmacists and anyone else licensed or certified to provide health care services. Is there a reason why outside of physicians we are going to singly list a pharmacist and not leave it the way it is? I'm thinking we should leave it as anyone who is licensed to provide the services.

Sen. Anderson: That came from the Attorney General's office. I think that is there because some people are in private practice.

Rep. Porter: On the second page the definition of a provider is anybody who is licensed in the state. That encompasses everyone. If we start adding more to it then it will start to be a pig pile where everyone is going to want their license profession listed to be covered under this.

Sen. Anderson: I can't say I delved into that issue related to this. Perhaps Dr. Hardy has more information.

Chairman Weisz: I think Rep. Porter makes a point. We will have Dr. Hardy explain.

8:20
Dr. Mark Hardy: Executive Director of the ND State Board of Pharmacy testified in support of the bill. (See Testimony #2) (10:08) To answer Rep. Porter's question, why I have that in the second page of the bill. We ran it through the Attorney General's Office and that was there recommendation to add it. I see your point. We wouldn't oppose if you and the committee feel you should take it out. It still accomplishes the purpose if we leave pharmacist and pharmacy on page 1 of the bill.

NO OPPOSITION

Chairman Weisz closed the hearing.

Chairman Weisz: Let's take up SB 2121.

Rep. Porter: I move an amendment, on page 2, line 1 to remove the underscored words "a pharmacist".

Rep. Seibel: Second.

Rep. Muscha: Haven't we also been changing person to individual on other bills?

Chairman Weisz: There is a difference. It would stay person in this case because individual means to an actual person where person can mean an entity also. I don't think you want to change it.

Rep. Porter: Some of these are professional corporations.

Rep. Oversen: On page 1, doesn't health care organizations cover the corporate side of the term person and provider is actually referring to individual (inaudible)? That is how I would read that.

Chairman Weisz: It is two separate definitions.

Rep. Oversen: If council didn't think it was a problem we are fine.

Rep. Fehr: I'm going to resist the motion. I don't think the motion helps or improves the bill any.

Rep. Porter: I think if you pick individual people you are going to hear other professions say they want to be listed too. I think it is dangerous as lawyers sit down with a Judge and looking at it and saying we don't know if you qualify as another person as the legislature is already naming individual practices.

VOICE VOTE: MOTION CARRIED

Rep. Seibel: I Move a Do Pass As Amended on SB 2121

Rep. Fehr: Second.

ROLL CALL VOTE: 13 y 0 n 0 absent.

MOTION CARRIED

Bill Carrier: Rep. Seibel

15.0459.01001
Title.02000

Adopted by the Human Services Committee 2/23/15

February 18, 2015

PROPOSED AMENDMENTS TO SENATE BILL NO. 2121

Page 2, line 1, remove ", a pharmacist,"

Renumber accordingly

Date: 2-18-15
Roll Call Vote #: 1

2015 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2121

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep. Porter Seconded By Rep. Seibel

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz			Rep. Mooney		
Vice-Chair Hofstad			Rep. Muscha		
Rep. Bert Anderson			Rep. Oversen		
Rep. Dick Anderson					
Rep. Rich S. Becker					
Rep. Damschen	Voice	Vote			
Rep. Fehr					
Rep. Kiefert					
Rep. Porter					
Rep. Seibel					
	Motion Carried				

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Page 2 line 1 remove "a pharmacist"

Date: 2-18-15
Roll Call Vote #: 2

2015 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2121

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep. Seibel Seconded By Rep. Fehr

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz	✓		Rep. Mooney	✓	
Vice-Chair Hofstad	✓		Rep. Muscha	✓	
Rep. Bert Anderson	✓		Rep. Oversen	✓	
Rep. Dick Anderson	✓				
Rep. Rich S. Becker	✓				
Rep. Damschen	✓				
Rep. Fehr	✓				
Rep. Kiefert	✓				
Rep. Porter	✓				
Rep. Seibel	✓				

Total (Yes) 13 No 0

Absent 0

Floor Assignment Rep. Seibel

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2121: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (13 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2121 was placed on the Sixth order on the calendar.

Page 2, line 1, remove ", a pharmacist,"

Renumber accordingly

2015 TESTIMONY

SB 2121

OH#22728 Attach #1 SB 2121 01/28/15

Testimony of Howard C. Anderson Jr. on Senate Bill No. 2121

January 28, 2015, before the Senate Human Services Committee, Senator Judy Lee Chair.

Chair Lee and members of the Senate Human Services. While I was still director of the Board of Pharmacy we proposed a rule to require all of our pharmacies to have a Quality Assurance Program. The rule went through the hearing process with a few tweaks but no opposition, however when it went to the Attorney General's office for review, they said we could not grant protection from discovery via rule and suggested these changes in the medical peer review statute necessary to accomplish this. Therefore you see this bill before you.

As background, our Hospital Pharmacies have Quality Assurance programs and our telepharmacies have quality assurance programs, but the board is reluctant to require it of all pharmacies without this protection. There is always the risk that a lawyer proceeding in a civil case will seek to subpoena your quality assurance reports, which you are keeping to improve the care of all your patients, to point out that you have other errors and thus must be generally careless, when that may not be true at all.

These simple additions to the Medical Peer Review statutes will accomplish our goal and we can proceed with the rule. The quality assurance programs will still be open for inspection by the Board of Pharmacy to help pharmacies improve their operations and reduce errors and near misses to the lowest level possible.

I have included a copy of the rule we intended to adopt for your reference.

Sincerely,

Howard

Attach #2
SB 2124
01/28/15
J#22728

CHAPTER 61-02-01 PHARMACY PERMITS

Final Copy

Section

61-02-01-01 Permit Required
61-02-01-02 Application for Permit
61-02-01-03 Pharmaceutical Compounding Standards
61-02-01-04 Permit Not Transferable
61-02-01-05 Change of Ownership
61-02-01-06 Affidavit of Ownership
61-02-01-07 Renewal of Permits
61-02-01-08 Change of Location
61-02-01-09 Permit for Heirs at Law of Pharmacist
61-02-01-10 Pharmacist-in-Charge -Requirement - Definitions - Duties
61-02-01-11 Pharmacist-in-Charge - Termination of Service
61-02-01-12 Posting of Permit
61-02-01-13 Pharmacist on Duty
61-02-01-14 Limitation on Rent
61-02-01-15 Closing a Pharmacy
61-02-01-16 Transfer of Controlled Substances When Selling a Business
61-02-01-17 Identification
~~61-02-01-18 Continuous Quality Improvement~~
61-02-01-19 Policy and Procedure Manual Required

~~61-02-01-18 Continuous Quality Improvement~~

~~61-02-01-18-01 Definitions: In this chapter, unless the context or subject matter otherwise requires:~~

1. ~~"Actively Reports" means reporting all dispensing errors and analysis of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.~~

2. ~~"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.~~

3. ~~"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:~~

   a. ~~Variation from the prescriber's prescription drug order, including, but not limited to:~~

      i. ~~Incorrect drug;~~

      ii. ~~Incorrect drug strength;~~

2.12

iii. Incorrect dosage form;

iv. Incorrect patient; or

v. Inadequate or incorrect packaging, labeling, or directions.

b. Failure to exercise professional judgment in identifying and managing:

i. Therapeutic duplication;

ii. Drug-disease contraindications, if known;

iii. Drug-drug interactions, if known;

iv. Incorrect drug dosage or duration of drug treatment; interactions;

v. A clinically significant, avoidable delay in therapy; or

vi. Any other significant, actual or potential problem with a patient's drug therapy.

c. Delivery of a drug to the incorrect patient.

d. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

i. Incorrect drug;

ii. Incorrect drug strength;

iii. Incorrect dosage form; or

iv. nadequate or incorrect packaging or labeling.

4. "Incident" A patient safety event that reached the patient, whether or not the patient was harmed.

5. "Near Miss" A patient safety event that did not or could not have reached the patient.

6. "Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

7. "Unsafe Condition" Any circumstance that increases the probability of a patient safety event.

61-02-01-18-02 Continuous Quality Improvement Program

1. Each pharmacy permittee shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions.

2. A pharmacy permittee meets the requirements if they meet the following:

   a. Maintains and complies with the policies and procedures as noted in (4);

   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

3. At a minimum, a CQI Program shall include provisions to:

   a. Designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

   b. Initiate documentation of incidents, near misses, and unsafe conditions as soon as possible, but no more than seven days, after determining their occurrence;

4. Policies and Procedures in compliance with 61-02-01-19 and must include.

   a. Train all pharmacy personnel in relevant phases of the CQI program;

   b. Identify and document reportable incidents and near misses and unsafe events;

   c. Minimize the impact of incidents and near misses and unsafe events on patients;

2.4

d. Analyze data collected to assess the causes and any contributing factors relating to incidents and near misses and unsafe events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce incidents and near misses and unsafe events; and

f. Periodically, but at least quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

5. Quality Self-Audit

a. Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of incidents, near misses, and unsafe conditions has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.

6. Protection from Discovery

a. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.

b. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are confidential and shall not be released, distributed or communicated in any manner, except as provided by these rule or the permitee's policies and procedures. Recognizing the importance of sharing information with staff , experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permitee's quality program in any manner shall not compromise the confidentiality and privilege of such information.

c. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated solely as a component of a pharmacy's ongoing quality assurance program and maintained solely for that program.

7. The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

8. ~~An analysis or summary of findings, produced within six months of submission, shall be evidence of compliance with the records and data collection provisions. A permittee shall not be required to produce data, charts, error reports or findings collected and used in compiling an analysis summary.~~

9. ~~Not withstanding paragraphs (6) and (8), If pharmacy is reporting to a Patient Safety Organization whose primary mission is continuous quality improvement all data and records are privileged and confidential as provided in the 2005 Patient Safety and Quality Improvement Act of 2005 and implementing regulations.~~

61-02-01-19 Policy and Procedure Manual Required

1. Each Pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacies operations. The policy and procedure manual must be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis
    a. Inspection Procedures including
        i. Location of Controlled substance records including
            1. Location of current biennial inventory
            2. Wholesale records of receipt and sale of controlled substances
            3. DEA 222 forms, both paper and electronic, executed or not.
            4. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances
            5. Power of attorney forms if granted and termination forms if executed
        ii. Location of most recent inspection forms by the board of pharmacy, accreditation agencies or the FDA, if applicable

History: Effective July 1, 1990. Amended July 1, 2014

2. **General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)
3. **Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-02-06-04. Written policy and procedures. Written policy and procedures must be available electronically or in hard copy format ~~at each computer location~~, detailing responsibilities of each pharmacist relative to the operation of the computer and its records.

History: Effective July 1, 1990.Amended July 1, 2014
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-02-07.1-12 – Technicians Checking Technicians Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the

2.6

preparation of a prescription or order for dispensing or administration may be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under the following conditions:

1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice, included in the policy and procedure manual required under 61-02-01-19.
    a. Training for the specific activity is reflected in a written policy.
    b. A record of the individuals trained is maintained in the pharmacy for two years.
2. The pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product, including:
    a. Recording any quality related events leading up to the final dispensing or administration of the drug prepared, and
    b. Recording any errors which actually reach the patient as a result of these activities.
    c. Specific limits of acceptable quality related event levels before reassessment is required.
    d. Consideration must be made for high risk medications on the Institute for Safe Medication Practices (ISMP) list and specific monitoring, review and quality assurance parameters must be instituted if any of these products are included in the Pharmacy's Technician-Checking-Technicians Program.
3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.
4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.
5. As always, the pharmacist-in-charge and the permit holder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

History: Effective January 1, 2009, Amended July `1,2014

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-03

61-03-02-03. Physical requirements of provider pharmacy licensed on premises or other pharmacy.

Attach #3
SB 2121
01/28/15
J#22728

State of North Dakota
Jack Dalrymple, Governor

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STATE BOARD OF PHARMACY

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

Senate Bill 2121 – Medical Peer Review Records
Senate Human Services Committee – Red River Room
11:00 AM - Wednesday – January 28, 2015

Chairperson Lee, members of the Senate Human Services Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak with you today about SB2121, relative to medical peer review records.

In 2013 and 2014, the Board of Pharmacy worked on a rule that would require pharmacies to implement a continuous quality improvement program, which would track and monitor errors or quality related events in the pharmacy. As my attachments will show, we held a rule hearing and planned to move forward with the adoption of a rule after collecting input from the profession during the annual *North Dakota Pharmacist Association Convention.* However, once we submitted the proposed rule to the Attorney General's office for review, the concern was raised that we could not adopt a version that would protect the pharmacies reported information from subpoenas or court discovery.

Upon review of the Attorney General's opinion, the Board of Pharmacy decided to withdraw the proposed rule, as we did not intend to require our pharmacies to report to a system that could potentially be used punitively against their practice. The attached April 28th, 2014 conference call meeting minutes will show – we rescinded the rule. The Attorney General's opinion provided their suggestions as to what statutory changes would be required to achieve our goal, which resulted in Senate Bill 2121 before you.

If Senate Bill 2121 passes, we will look to promulgating a rule of Continuous Quality Improvement programs accordingly. The Board of Pharmacy feels having a Continuous Quality Improvement program is an important component of review for pharmacies to ensure that the highest quality of patient care can be administered to our North Dakota citizens by our pharmacies.

Again, I thank you for the opportunity to speak on this bill and will be happy to answer any questions you may have.

3.V

Monday April 28th, 2014 **Meeting Conference Call Meeting**

Agenda - Monday April 28th, 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.
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

#1

Testimony of Howard C. Anderson Jr. on Senate Bill No. 2121

February 18, 2015, before the House Human Services Committee, Representative Robin Weisz Chairman.

Chairman Weisz and members of the House Human Services Committee. While I was still director of the Board of Pharmacy we proposed a rule to require all of our pharmacies to have a Quality Assurance Program. The rule went through the hearing process with a few tweaks but no opposition, however when it went to the Attorney General's office for review, they said we could not grant protection from discovery via rule and suggested some changes in the medical peer review statute necessary to accomplish this. Therefore you see this bill before you.

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These simple additions to the Medical Peer Review statute will accomplish our goal and we can proceed with the rule. The quality assurance programs will still be open for inspection by the Board of Pharmacy to help pharmacies improve their operations and reduce errors and near misses to the lowest level possible.

Sincerely,

Howard

State of North Dakota
Jack Dalrymple, Governor

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

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Senate Bill 2121 – Medical Peer Review Records
House Human Services Committee – Fort Union Room
9:00 AM - Wednesday – February 18, 2015

Chairperson Weisz members of the House Human Services Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak with you today about SB2121, relative to medical peer review records.

In 2013 and 2014, the Board of Pharmacy worked on a rule that would require pharmacies to implement a continuous quality improvement program, which would track and monitor errors or quality related events in the pharmacy. As my attachment will show, we held a rule hearing and planned to move forward with the adoption of a rule after collecting input from the profession during the annual *North Dakota Pharmacist Association Convention.* However, once we submitted the proposed rule to the Attorney General's office for review, the concern was raised that we could not adopt a version that would protect the Quality Assurance tracked information from a subpoena or court discovery.

Upon review of the Attorney General's opinion, the Board of Pharmacy decided to withdraw the proposed rule, as we did not intend to require our pharmacies to report to a system that could potentially be used punitively against their practice. The attached April 28th, 2014 conference call meeting minutes will show – we rescinded the rule. The Attorney General's opinion provided their suggestions as to what statutory changes would be required to achieve our goal, which resulted in Senate Bill 2121 before you.

If Senate Bill 2121 passes, we will look to promulgating a rule of Continuous Quality Improvement programs accordingly. The Board of Pharmacy feels having a Continuous Quality Improvement program is an important component of review for pharmacies to ensure quality related events are tracked and monitored for potential improvements. Having such a program will ascertain the highest quality of patient care can be administered to our North Dakota citizens by our pharmacies.

Again, I thank you for the opportunity to speak on this bill and will be happy to answer any questions you may have.

Monday April 28th, 2014 **Meeting Conference Call Meeting**

Agenda - Monday April 28th, 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.
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