2017 SENATE HUMAN SERVICES

SB 2202

2017 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2202
2/1/2017
Job Number 27726

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature rsmonson

Explanation or reason for introduction of bill/resolution:

A bill relating to clinical laboratory practice exemptions and board membership

Minutes:

#1	Bruce Pritschet, ND Board of Laboratory Practice
#2	Shelly Peterson, NDLTCA
#3	Rebecca LaFavor, Edgewood Vista and Village
#4	Bruce Murry, NDACP
#5	Jerry Jurena, ND Hospital Assoc.

V-Chair Larsen opened the hearing on SB 2202.

Chair J. Lee introduced the bill at the request of the director of the clinical laboratory program at UND.

Bruce Pritschet (2:00-6:35) (Member of the ND Board of Laboratory Practice) presented testimony in favor of SB 2202 which included amendments. Please see attachment #1.

Senator Heckaman: What are you looking at for a timeframe of length of training? Are you going to leave it up to long term to provide their own training?

Bruce Pritschet: The board started working on this a long time ago. An online training process has already been developed but because we didn't have what we needed in the law to implement it, we are trying to get this amendment.

Senator Heckaman: You haven't been using it yet but will be shortly?

Bruce Pritschet confirmed they would like to start using it shortly.

Chair J. Lee: Will that be available through the Department of Health or another source?

Bruce Pritschet responded that it would be available online for anyone who wants to take it.

Chair J. Lee: Have you had complaints or concerns about those doing glucose monitoring in long term care facilities and skilled facilities?

Bruce Pritschet: I wouldn't say complaints but they are not currently following the law. The law requires the testing to be under the supervision of a licensed med tech or a licensed clinical lab professional. That's not happening.

Chair J. Lee: I don't know of many skilled care facilities that hire a med tech or a licensed professional lab person.

Bruce Pritschet: They don't have to hire them. They just have to be under their supervision and it doesn't take an on-site presence.

Senator Kreun: What are we protecting if we've got all these exemptions?

Bruce Pritschet: The exemption just lists the testing methods that can be done under the supervision of someone licensed by the board by an individual that isn't licensed by the board. It actually opens up testing to people that may not be licensed by the board because they do not meet the qualifications of a clinical lab professional. They can do those tests listed in 96 if they're under supervision.

Senator Kreun: So a person testing for diabetes is not required to go through this process?

Bruce Pritschet: Currently the law requires that they be under the supervision of someone licensed by the board if they're going to do whole blood glucose testing.

Senator Kreun: Would that be specific to long term care patients?

Bruce Pritschet: No, it's not specific to long term care. It would be for anyone that is providing a whole blood glucose test that's not on themselves or their family but being provided for someone else.

Chair J. Lee: It could be done to children in school or day care if they are diabetic.

Chair J. Lee: If phlebotomists are exempted – doing a venal puncture is a bigger deal than poking someone in the finger.

Bruce Pritschet: The difference is, one is testing and the phlebotomists are not testing. They are just obtaining the sample. The actual result from the glucose test done by the other individuals is used to adjust insulin for diabetics. That becomes one of the concerns the board has, to protect the public from erroneous results. The other is the infection control that is necessary in the use of devices when they are used for different patients.

Shelly Peterson, President ND Long Term Care Association (12:55-25:00) testified in opposition of SB 2202. See attached testimony #2.

Rebecca LaFavor, Director Clinical Services, Edgewood Vista and Village (25:30-29:55) testified in opposition. Please see attachment #3.

Chair J. Lee: I assume you're fine with section 2. We're just talking about the testing in section 1. What do they do in schools and group homes?

Rebecca LaFavor: I don't have a child in school. I would assume there is someone who does it for those children but I'm not sure who that person is.

Shelly Peterson said that, for her son, teachers and coaches were very helpful.

Senator Kreun: Are these your procedures you designed for your facility?

Rebecca LaFavor: Yes, but most of us use a program out of Minot State which is the medication assistant one training program. A lot of those policies started with that program.

Senator Kreun: You implement these just for your facility. Somebody else might not use this exact program?

Rebecca LaFavor said that was correct.

Chair J. Lee: That would be the primary one out of Minot State, wouldn't it?

Rebecca LaFavor: Most of the basic care's in ND use the Minot State.

Bruce Murray (32:45-35:15) (Executive Director of the ND Association of Community Providers) provided testimony in opposition. Please see attachment #4.

Jerry Jurena (35:40-36:25) (President of the ND Hospital Association) testified in opposition. Please see attachment #5.

Stacey Pfenning: (Executive Director, Board of Nursing) According to 54-05 of the ND administrative code nursing delegations is an integral portion of standards of practice for nursing at the RN, LPN, and Advanced Practice nursing levels. If you refer to that it will answer question on delegation. According to the exemption on nursing, it appears that nurses duly and currently licensed to practice nursing and practicing within their scope of nursing license are exempt from 43-48-03. It appears that this would still be within nursing scope of practice.

Chair J. Lee: But can they delegate?

Stacey Pfenning: The nurses can delegate to unlicensed assistant personnel. They are registered so that is within the scope of practice for all levels of nursing. The nurses hold the ultimate accountability for what is delegated. Often they delegate things that are maybe not within the training of the UAP but then that UAP must be trained and have evidence of competency.

Chair J. Lee: You are comfortable with the process as far as the health and safety of the patients are concerned?

Stacey Pfenning: We have had no safety issues. We'd be happy to work with the Dept. of Health and Clinical Pathology if there is another option.

Chair J. Lee: If we need to clarify the language which allows what's going on, I would be fine with that discussion.

Chair J. Lee closed the public hearing on SB 2202.

2017 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2202
2/1/2017
Job Number 27753

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature RMonson

Explanation or reason for introduction of bill/resolution:

A bill relating to clinical laboratory practice exemptions and board membership.

Minutes:

Chair J. Lee brought the committee to order for committee work on SB 2202.

Senator Anderson: Maybe we can just strike out the line in the law that says they have to be under the supervision of somebody from the clinical laboratory board. I'm comfortable letting the nurses take care of their supervision. I think, because of that section in the law, the clinical laboratory board feels that there is something illegal going on. One way to fix that is to remove the language that says they have to supervise all these people. I'm not sure just leaving section 2 will solve the problem for them as far as looking at other people doing something illegal. Stacey Pfenning did say part of the nurse practice act allows delegation.

Senator Kreun: We didn't cover all the unintended consequences that will take place if we go through with this. We haven't worked out anything with the private sector workforce, schools, or day cares. This is nothing more than a solution looking for a problem other than what Sen. Anderson was talking about.

Senator Anderson: He referred to the testimony from Bruce Pritschet. Page 1 shows the section of the law which they think is telling them that what these other people are doing is illegal. Another option is what most states have done. Most states have simply recognized the Clinical Laboratory Improvement Act exemptions. Then they don't come under clinical laboratory board. Our board has never recognized CLIA so that might take a little more research. That's why I'm comfortable with just removing section 1 and leaving it at that for now. But we haven't solved the problem across the board.

Senator Anderson: If Dr. Pfenning is correct that the nurses can supervise these people, at least that solves the immediate problem in the long term care facilities, basic care facilities, and assistant living facilities. It doesn't solve the problem in schools or in your facility where someone needs to help an individual do their blood sugar test so they can get the right insulin dose. In those cases, exempting all the CLIA tests would solve that problem.

Chair J. Lee: Mr. Jeruna mentioned that 26 members of the hospital association have long term facilities as part of their facilities. She pointed out that the basic care and assisted living facilities do not have 24/7 nursing staff. They are residential models. That makes a difference having supervision by a nurse. We haven't resolved that, I hate to put a study section in there because it's so narrow. We need to look at all the areas of this.

Senator Anderson: One of the reasons I bring up the approach of CLIA is that when the pharmacists wanted to do the finger stick tests in the pharmacies, the clinical laboratory board insisted that we list the specific tests the pharmacists were authorized to do. (06:00)

Senator Kreun: What precipitated this? The law? He said he is opposed to this and shared examples of his need to work with parents and administer medications as needed in a for profit daycare (08:15). I don't want to minimize care, but if you don't have responsible people it doesn't matter.
(10:35) There was some discussion that small schools don't have nurses or full time nurses. **Senator Kreun** pointed out that you have to have responsible people. If you don't have responsible people, certification isn't going to make a bit of difference.

Senator Piepkorn: We're all probably on the same page, but how do we go about fixing it?

V-Chair Larsen: What resonated with me was, why do we need to change the process, when the process works. **He moved a Do Not Pass on SB 2202.**

Senator Kreun: Seconded the motion.

Chair J. Lee: We really do need to change section 2, just for pathology, I don't disagree with Senator Larsen but right now we probably are violating the law.

Senator Anderson: I need to do some more research but it looks like the language we talked about changing is in the rule 96-02-10. I think that's the rules adopted by the clinical laboratory board. We can change legislation but we can't change the rule.

Discussion continued on changing the legislation to say that "any individual administering those tests is exempt from the clinical laboratory boards practice act".

(16:00) There was a short discussion on who makes up the clinical laboratory board.

V-Chair Larsen and Senator Kreun withdrew their motion of Do Not Pass.

Chair J. Lee adjourned the meeting.

2017 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2202
2/6/2017
Job Number 27926

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature DMonson

Explanation or reason for introduction of bill/resolution:

A bill relating to clinical laboratory practice exemptions and board membership.

Minutes: 1 attachment

Senator Anderson offered an amendment for SB2202. (Attachment #1 2/6/17) He reviewed with the committee that there was discussion on this bill that maybe they should just kill it. But he explained that there is a part of section 2 they should keep and that there was a general disagreement with lines 10-18 on page 2. He explained the purpose of the amendment (01:30). He suggested eliminating lines 10-18 on page 2 and, after line 9, 14 from his proposed amendment .01001 would become 13.

Chair J. Lee reviewed what Senator Anderson had suggested. She then explained the bill to the nurses in the room (4:27-5:55).

Senator Kreun: This still exempts schools and daycare?

Chair J. Lee: We should be ok now?

Senator Anderson: This language should fix all that.

Senator Anderson made a motion to adopt the amendment 17.0769.01002.

V-Chair Larsen seconded the motion.

Roll call vote 7-0-0. **Amendment adopted**.

Senator Anderson moved a **Do Pass as Amended**.

Senator Kreun seconded the motion.

Roll Call Vote 7-0-0. **Motion carried**.

Senator Anderson will be the carrier.

ET
2-6-17
p. 1 of 1

17.0769.01002
Title.02000

Adopted by the Human Services Committee

February 6, 2017

PROPOSED AMENDMENTS TO SENATE BILL NO. 2202

Page 2, line 10, remove "An individual who performs tests and uses methods identified by rules adopted by the"

Page 2, replace lines 11 through 18 with "Personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a et seq.]."

Renumber accordingly

Date: 2/6 2017

Roll Call Vote #: 1

2017 SENATE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 2202

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 17.0769.01002

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 Sen. Anderson Seconded By Sen. Larsen

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee (Chairman)	X		Senator Joan Heckaman	X	
Senator Oley Larsen (Vice-Chair)	X		Senator Merrill Piepkorn	X	
Senator Howard C. Anderson, Jr.	X				
Senator David A. Clemens	X				
Senator Curt Kreun	X				

Total (Yes) 7 No 0

Absent 0

Floor Assignment _____

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

Date: 2/6 2017

Roll Call Vote #: 2

2017 SENATE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 2202

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 17.0769.01002

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 Sen. Anderson Seconded By Sen. Kreun

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee (Chairman)	X		Senator Joan Heckaman	X	
Senator Oley Larsen (Vice-Chair)	X		Senator Merrill Piepkorn	X	
Senator Howard C. Anderson, Jr.	X				
Senator David A. Clemens	X				
Senator Curt Kreun	X				

Total (Yes) 7 No 0

Absent 0

Floor Assignment Sen. Anderson

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

REPORT OF STANDING COMMITTEE

SB 2202: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2202 was placed on the Sixth order on the calendar.

Page 2, line 10, remove "An individual who performs tests and uses methods identified by rules adopted by the"

Page 2, replace lines 11 through 18 with "Personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a et seq.]."

Renumber accordingly

2017 HOUSE INDUSTRY, BUSINESS AND LABOR

SB 2202

2017 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Peace Garden Room, State Capitol

SB 2202
3/14/2017
29170

☐ Subcommittee
☐ Conference Committee

Ellen LeTang

Explanation or reason for introduction of bill/resolution:

Clinical laboratory practice exemptions & board membership.

Minutes: Attachements 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

Chairman Keiser: Opens the hearing of SB 2202.

Senator Lee ~ District 13-Fargo: Attachment 1.

4:40

Chairman Keiser: Anyone else here to testify in support, opposition position to SB 2202?

Sam Matthey ~ Chairman of the Clinical Process Board: Attachment 2.

7:00

Chairman Keiser: What the senate did was to put in the exemption based on the clinical laboratory improvement act & that has 1,000 different tests in that act. Your organization thinks that it's too broad. You want to limit it solely to whole blood group & not urine testing or any of the other tests.

Matthey: Yes & in our administrative rules, we have gone through & have some exempt tests we have waived. We feel they are fool proof enough for people to do under the supervision of a licensed person.

Rep Ruby: Can you explain the licensing requirement?

Matthey: You need a 2 or 4-year degree & a certification by a national certifying agency to perform a moderate or high complexity testing lab test. Nursing & pharmacy can perform lab tests. We are not trying to limit health care or licensed professionals, it's the people who don't have any qualifications or medical background.

Rep Kasper: What was the need for this bill?

Matthey: What the board originally proposed was in order for bedside glucose testing who weren't licensed, to do a certification training & exam that was provided through UND. We had a fee of $25 to cover UND's fees. I think that the long care & other hospital associations felt that the cost would fall on them. They didn't want to bear those costs.

Rep Kasper: Is this a cost issue or lack of personnel?

Matthey: Our law says that people can do waive testing under the supervision by someone who is licensed. There are only about a 1,000 licensed clinical lab people in the state, where there are 30,000 people doing bedside glucose testing. We couldn't possible supervise all of them.

Rep Becker: What is the minimum amount of training requirement of the waive provision?

Matthey: It's really under the supervision of a licensed personnel. Anyone can do the waive test.

Rep Becker: This technically takes away the supervision?

Matthey: By a licensed lab person.

Rep Becker: There are about 1,000 waive tests. Give me a handful of the most concerning that should not be concerned about?

Matthey: One of my other board members will give a demonstration on that.

Dr Mark Koponen, MD ~ ND Board of Clinical Laboratory Practice: Attachment 3.

16:30

Rep Lefor: In your opinion, the compromise you are asking is full blood glucose. Would you rather kill the bill or do you think this amendment is a good thing forward rather than a compromise?

Dr Koponen: It's a good thing. We want people who are trained, basics of laboratory testing, quality control, quality assurance & get a feel for what is a good or bad result. We are setting up a system of quality control so that the results are meaningful & tests properly performed.

Rep Lefor: You would rather have this bill with the amendment because testing whole blood glucose in this fashion is preferable to killing this bill?

Dr Koponen: Yes.

Rep Becker: The study, in the methods, they are not assessing the errors complications & mistakes. Does this study address those types of things?

Dr Koponen: They do. You need a system of quality control so they understand the concept of laboratory testing.

Dr Ruth Paur ~ Member of the ND Board of Laboratory Practice & Chair of the Medical Laboratory Science Department in the ND School of Medicine & Health Sciences: Attachment 4.

28:10

Rep Becker: I hate to disagree with the agreeable people. The concern is a misinterpretation, not a miss reporting. The test is not very good because of a false positive rate of 40 some percent. My concern is the person who is conducting the test is not the person who interpreters the test. The person who orders the test, is the person who interprets the test. Therefore, the consumer, is not adversely affected by someone who is not trained to the degree that you would like trained. They simply report the test back to the person who orders it.

Paur: They are done by some individual & then given back to individuals that determine how much insulin they get. We would like to see the glucose as the addendum instead of all of them.

Rep Kasper: The test is done. In all circumstances after the test is done, where are the results reported to?

Paur: It doesn't have to be given to anyone in particular, it can be to the individual.

Rep Kasper: To the individual who orders it?

Paur: Yes.

Rep Kasper: Who determine that the test is going to be done in the first place?

Paur: It could be the patient.

Rep Kasper: Are you suggesting that places in ND would spring up that would do these tests without them being ordered by a medical provider?

Paur: Yes.

Rep Kasper: Without being interpreted by a medical provider & it's happening in other states?

Paur: Yes.

Rep Kasper: They are not being supervised at all?

Paur: Hopefully they are under the supervision of a credited lab, but if they are not, this CLIA amendment could allow your barber to do it.

Rep Bosch: I did the test on someone, it tested positive & the information would go to the doctor. He would prescribe some medicine but wouldn't they question that test? Help me understand the position you would do with that?

Paur: The doctor knows that an epidemic is started. They know that it's only correct about 53% of the time. After a time, they quit ordering it.

Rep Kasper: Who orders the test & who gets the results?

Dr Koponen: It is my understanding that the physician does not need to order the exam or test. Part of the bill is that if this is going to be provided in a health care setting, that there be a system of quality control & assurances.

Rep Kasper: This bill does not require that?

Dr Koponen: Correct.

Rep Ruby: If a place pops up where you can get these tests & they did it 10 times a week? It's not going to have a negative effect because they are not getting any drugs, treatment or anything, they are just wasting their money. If they want to know it they need to go to a doctor, no matter how many tests are done, I see no harm.

Paur: We will have somebody talking about the number of test that are on the waive test. There is a waive test for HIV. They are oversensitive which gives a lot of false positive.

Chairman Keiser: It's the false negatives that would be the problem for the patient.

Paur: It depends upon what they do with the information. They could commit suicide for the false information.

Rep Dobervich: Are you familiar with a lab called "Any lab test now"?

Paur: Yes.

Rep Dobervich: Is that similar to the type of lab he was describing?

Sam Matthey: It's referred as a retail lab, you pick out the test, pay for it, get your blood drawn & it's sent to a large commercial industrial lab for testing. Not quite the same thing.

Rep Louser: I'm looking at it procedural as to what happened in the Senate. The bill carrier mentioned that there was a meeting with the Senate & it didn't happen, so they just did this. What happened in the process in the Senate that could have fixed this?

Paur: We could have come up with a compromise earlier.

Rep Louser: Coming up with a compromise is the amendment that you are proposing?

Paur: Yes.

Rep Louser: That is what we may hear tomorrow?

Paur: That is what I brought up & what Dr Matthey brought up was the compromise also.

Rep Becker: The supervision for the technicians, is that direct or indirect?

Paur: We are hoping that the long term care facilities will continue with their supervision.

Chairman Keiser: That didn't answer the question.

Rep Becker: We have been talking about the safety because the technicians are supervised by someone with full training. In any type of these situations where we have a supervisory role in allowing someone to perform certain duties. Is it direct supervision or indirect? If it's indirect supervision, is it on site or off site?

Paur: I believe it can be either.

Sam Matthey: Are you talking current or proposed by SB 2202?

Rep Becker: I'm referring to the practice right now. I would like an assessment of supervision currently.

Sam Matthey: We've seen it direct & indirectly. Our preference would be that it be direct supervision but we have had some circumstances where the person supervising has been a traveling test.

Rep Becker: We currently have a situation where the supervision is at the discretion of the supervisor. My understanding is that the supervisor need not be on site at all.

Matthey: Correct.

Rep Becker: Does the board at their discretion have the ability to say that this person needs on site supervision, this person direct supervision, this person is indirect off site supervision?

Matthey: The board does not go out & survey. That's why we want a certification exam & test.

Bridget Weidner ~ Clinical Laboratory Improvement Amendments (CILIA) program manager for ND Dept of Health, Division of Health Facilities: Attachment 5.

49:10

Rep Becker: That survey you did showing 43% of the laboratories were noncompliant with regulatory requirements & 42% were noncompliant with laboratory best practices. That is not good, but that's with current law. Having the requirement of under supervision isn't doing anything.

Weidner: The point of the statistics in my testimony was to show the percent of noncompliance. We are currently requiring supervision of waive tests by somebody who is licensed by the board. If we are already having that level of noncompliance. I would hate to see what the worth of outcomes there are when we now open the test. The biggest issue we see is a lot of people do not follow the manufacturer's instructions & to think that anyone out there in the street could now choose to do one of these tests.

Rep Ruby: If the issue is people not being properly trained to do the test. This is narrowed to waive tests, why is there such a list of tests that make the waive status?

Weidner: The FDA considers what is waived. There are definite consequences when it's not done correctly.

Rep Becker: Consumer safety, we could argue that we should make all tests be required to be done by someone with the education rather than being supervised. You've done this survey; we've been presented a test & what we are talking about is not following best practices. You have the opportunity to identify instances in which consumers have been harmed. This would make it easy for the committee to say, we can't have the bill as presented. We have not heard of any examples of how patients have been harmed. Do you have any?

Weidner: When we talk about surveys, we are talking about on site surveys. Explains & gives examples of what they do for testing. The question about the examples of negative outcome, I don't specifically have any for the certificate of waiver tests. If you allow all these tests without any supervision, they don't even have the knowledge to know what they are doing is not a waive test.

Rep Kasper: Currently these waive test laboratories, are they under the supervision with the ND Dept of Health?

Weidner: The ND Dept of Health does oversee all the laboratories that have certificates. They do any type of test, they have oversite. The certificate of waiver, has the lowest level of oversight & that is a requirement only that they follow manufacturer's instructions. We only do surveys of them based on what CMS tells us to do. Currently that includes only complaints.

Rep Kasper: How many clinics would be out of your supervision if this bill passes?

Weidner: They would still all be under our jurisdiction.

Rep Kasper: How many laboratories in ND would be exempt?

Weidner: All of them would be potentially affected.

Rep Kasper: You said, anyone who is authorized can order a CLIA test. Under current ND law, it does not define authorized. So anyone can walk & ask. They have the test done & it can be reported to themselves. This seems to be an area that should have been looked

at in the past to correct. Was there discussion with the Dept of Health to tighten up some of these areas?

Weidner: We have not addressed that & suggested putting something in law. What we have done is required laboratories to determine their own policies who they feel is qualified.

Rep Kasper: What is the price of the patient versus the doctor ordering the test?

Weidner: I don't have an answer to that question.

Shelly Peterson ~ President of the ND Long Term Care Association (NDLTCA): Attachment 6.

1:09:50

Melissa Hauer ~ General Council for the ND Hospital Association: Attachment 7. Passes out Jerry Jurena's written testimony. He couldn't be here & he is the President of the ND Hospital Association.

Rebecca LaFavored-MSN RN ~Clinical Services Director, Edgewood Vista & Village: Attachment 8. We support the boards position with the amendment.

Dr Brooke Solberg ~ Associate Professor in the Dept of Medical Laboratory Science at UND & ND Licensed, Certified & Practicing Medical Laboratory Scientist for Altru: Attachment 9.

1:17:30

Amanda Peterson ~ ASCP Certified & ND State Licensed Medical Laboratory Scientist: Attachment 10.

1:22:10

Chairman Keiser: Anyone else here to testify in opposition, neutral position? Closes the hearing.

2017 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Peace Garden Room, State Capitol

SB 2202
3/15/2017
29206

☐ Subcommittee
☐ Conference Committee

Ellen LeTang

Explanation or reason for introduction of bill/resolution:

Clinical laboratory practice exemptions & board membership.

Minutes:

Chairman Keiser: Opens the hearing of SB 2202.

Chairman Keiser: What are the wishes of the committee?

Rep Becker: Moves a Do Pass

Rep Beadle: Second.

Chairman Keiser: Discussion?

Rep Ruby: The Food & Drug Administration puts a lot these tests as waived. What is the reasoning for someone not being able to do it? One group says it's waived & the other says we don't want less trained people doing all these because they are properly certified. Does anybody have answers or reasons why is the FDA has waived the tests?

Rep Kasper: The only one who was in favor was the bill sponsor. All the rest of the professionals that know what's going on in the medical industry were against including people. I would oppose the motion but support the amendment if there was one.

Chairman Keiser: I did talk to Senator Lee & Senator Anderson. Senator Lee likes the original bill & Senator Anderson said he doesn't oppose the amended bill. Do with it what you wish.

Rep Becker: The way I'm viewing it & the reason for my motion, is just weighing the testimony. Listening to the evidence & what we have are waived test. The reason they are waived is because it involves extraordinarily little complexity.

I was looking at the studies & surveys. There is no evidence of anyone being harmed. There is a concern about requiring supervision but we received testimony that there really are not

necessarily being supervised that much. You could be several hundred miles away & be under supervision. Which means, what we are being told is problematic is already occurring.

I looked for specific reasons why we should require the supervision. It's already not occurring; we didn't see any problems with it & the only reason I come up with is its job security. I'm not suggesting that that's their motivation.

Chairman Keiser: Further discussion?

Roll call was taken for a Do Pass on SB 2202 with 6 yes, 8 no, 0 absent. Motion failed.

Chairman Keiser: Motion failed, any other further action on this bill?

Rep Kasper: Moves the amendment that was distributed to the committee yesterday.

Vice Chairman Sukut: Second.

Chairman Keiser: Further discussion on the amendment?

Rep Louser: Moving the amendment would have one waived test in ND when the FDA has 26,000?

Chairman Keiser: Yes.

Rep Kasper: Looking at Bridget Weidner's testimony from yesterday. When it was 1st enacted if was 127 waived tests. Now there are 26,000.

Roll call was taken on the amendment with 11 yes, 3 no, 0 absent, motion carried.

Chairman Keiser: The amendment is adopted & we have engrossed SB 2202 as amended, what are the wishes of the committee?

Rep Becker: Moves a Do Pass as Amended.

Rep Bosch: Second.

Chairman Keiser: Further discussion?

Roll call was taken on SB 2202 for a Do Pass as Amended with 14 yes, 0 no, 0 absent & Rep Boschee is the carrier.

3/15/17 DC

17.0769.02001
Title.03000

Adopted by the Industry, Business and Labor Committee

March 15, 2017

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2202

Page 2, line 10, after "performing" insert "whole blood glucose"

Renumber accordingly

Date: Mar, 15, 2017

Roll Call Vote #: 1

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2202

House Industry, Business and Labor **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 Becker **Seconded By** Rep Beadle

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser		X	Rep Laning	X	
Vice Chairman Sukut		X	Rep Lefor		X
Rep Beadle	X		Rep Louser	X	
Rep R Becker	X		Rep O'Brien		X
Rep Bosch		X	Rep Ruby	X	
Rep C Johnson	X		Rep Boschee		X
Rep Kasper		X	Rep Dobervich		X

Total (Yes) 6 No 8

Absent 0

Floor Assignment

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

Motion failed

Date: Mar 15, 2017

Roll Call Vote #: 2

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. HB 2202

House Industry, Business and Labor **Committee**

☐ **Subcommittee**

Amendment LC# or Description: 17.0769.02001

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 Kasper **Seconded By** Rep Sukut

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	X		Rep Laning	X	
Vice Chairman Sukut	X		Rep Lefor	X	
Rep Beadle	X		Rep Louser		X
Rep R Becker		X	Rep O'Brien	X	
Rep Bosch	X		Rep Ruby	X	
Rep C Johnson		X	Rep Boschee	X	
Rep Kasper	X		Rep Dobervich	X	

Total (Yes) 11 No 3

Absent 0

Floor Assignment _____

Date: Mar 15, 2017

Roll Call Vote #: 3

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2202

House Industry, Business and Labor **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 Becker **Seconded By** Rep Bosch

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	X		Rep Laning	X	
Vice Chairman Sukut	X		Rep Lefor	X	
Rep Beadle	X		Rep Louser	X	
Rep R Becker	X		Rep O'Brien	X	
Rep Bosch	X		Rep Ruby	X	
Rep C Johnson	X		Rep Boschee	X	
Rep Kasper	X		Rep Dobervich	X	

Total (Yes) 14 No 0

Absent 0

Floor Assignment Boschee

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

REPORT OF STANDING COMMITTEE

SB 2202, as engrossed: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (14 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed SB 2202 was placed on the Sixth order on the calendar.

Page 2, line 10, after "performing" insert "whole blood glucose"

Renumber accordingly

2017 TESTIMONY

SB 2202

2202
Attach #1
2/1

Testimony: Senate Bill No. 2202

Madame Chair and members of the Senate Human Services Committee, My name is Bruce Pritschet, a member of the North Dakota Board of Laboratory Practice and I am here in support of Senate Bill 2202.

Section 1. Amendment. Section 43-48-03 of the North Dakota Century Code

It is generally assumed that individuals completing bed-side testing for patients, such as whole blood glucose testing, in long term care facilities are complying with the appropriate laws related to this testing. I have attached the following document: Chapter 96-02-10 Exemption from Licensure.

> 96-02-10-01. Exempt tests and methods. An individual, **supervised by an individual licensed by the board,** performing the following food and drug administration-waived tests and using the following methods, is exempt from the provision of North Dakota Century Code Chapter 43-48:
>
> 6. Whole blood glucose by an accepted single analyte method.

The reality of the bed-side testing for patients in long term care facilities and many other healthcare setting like Basic Care and Assisted Living facilities is that the testing is not being supervised by an individual licensed by the board. We need to work together to solve this problem in a positive way to promote quality healthcare for our long term care citizens. Under ND Century Code 43-48-03 Exemptions, Bill No. 2202 Section 1 Amendment , page 2 line 10, #13, initiates a solution:

> An individual who performs tests and uses methods identified by rules adopted by the board after having completed any training required by the board and successfully passed a certifying exam administered by the board or by an entity the board appoints for the tests performed and methods used. To be exempt initially under this section, the individual shall complete all required training and pass the certifying exam within the time periods the board requires for the tests performed and methods used. To continue exemption status, the individual shall successfully complete any required training and pass the certifying exam for the tests performed and methods used as often as the board requires.

2202
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The amendment is created to:

- protect the health of North Dakota citizens who are dependent on others to correctly complete and report test results that impact their care,
- utilize the already available staff at long term care facilities,
- alleviate the costs of a long term care facility hiring an individual licensed by the board to supervise the testing,
- allow the board to train and certify that the staff performing this bed-side testing is complying with appropriate testing methods, infection control standards of practice, documentation, and quality control in a cost effective way,
- charge a minimal fee for a certificate to cover the cost of creating and delivering on-line training, administering a certifying exam, issuing the certificate, and maintaining the database,
- accommodate new testing methods for bed side testing as they are developed and approved.

Section 2. Amendment Subsection 2 of section 43-48-05 of the North Dakota Century Code

In this amendment the board is trying to:

- clarify the language to better specify that the physician would be a pathologist in the state. A pathologist is a physician who is a specialist in clinical laboratory medicine and has historically been appointed to the Board of Clinical Laboratory Practice.
- The current law requires the Board to solicit three candidate names of possible pathologist board members from the ND pathology organization. This ND organization no longer exists and therefore cannot submit possible candidates' names to the governor for appoint to the board.
- clarify the language. All of the board members are nominated and sent to the governor for appointment. The current wording makes it appear that only the physician is.

I would be happy to answer any questions from the committee.

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CHAPTER 96-02-10
EXEMPTION FROM LICENSURE

Section
96-02-10-01 Exempt Tests and Methods
96-02-10-01.1 Exempt Test and Method
96-02-10-02 Supervision

96-02-10-01. Exempt tests and methods.

An individual, supervised by an individual licensed by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Any of the following tests by nonautomated or automated urinalysis by dipstick:
   a. Bilirubin.
   b. Blood.
   c. Glucose.
   d. Ketone.
   e. Leukocyte.
   f. Nitrate.
   g. Potential of hydrogen (pH).
   h. Protein.
   i. Specific gravity.
   j. Urobilinogen.
2. Fecal occult blood by any accepted method.
3. Ovulation test by visual color comparison.
4. Qualitative urine pregnancy test by visual color comparison.
5. Erythrocyte sedimentation rate by any accepted nonautomated method.
6. Whole blood glucose by any accepted single analyte method.
7. Spun microhematocrit by any accepted method.
8. Hemoglobin by single analyte instrument or manual copper sulfate method.
9. Any of the following tests by immunoassay using a rapid test device that detects antibodies or antigens:
   a. Helicobacter pylori.
   b. Influenza.
   c. Mononucleosis.
   d. Streptococcus group A.

Pg. 3

2202
#1
2/1

e. Hepatitis C virus.

f. Respiratory syncytial virus.

10. Prothrombin time international normalized ratio by mechanical endpoint.

11. Antibodies to human immunodeficiency virus types 1 and 2 by clearview complete HIV 1/2 assay.

History: Effective January 1, 2006; amended effective January 1, 2008; April 1, 2012; April 1, 2013.
General Authority: NDCC 43-48-03, 43-48-04
Law Implemented: NDCC 43-48-03

96-02-10-01.1. Exempt test and method.

An individual, supervised by an individual licensed by the board, performing total protein tests by Reichert digital refractometer, is exempt from the provisions of North Dakota Century Code chapter 43-48.

History: Effective January 1, 2010.
General Authority: NDCC 43-48-03, 43-48-04
Law Implemented: NDCC 43-48-03

96-02-10-02. Supervision.

As used in subsection 9 of North Dakota Century Code section 43-48-03 and North Dakota Administrative Code sections 96-02-10-01 and 96-02-10-01.1, "supervised" means the following:

1. The supervisor shall identify the individuals being supervised on a form provided by the board and shall promptly notify the board of any changes to the information provided.

2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.

3. The supervisor shall:

   a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.

   b. Not allow an individual supervised to start or continue performing tests until the individual has been properly trained and demonstrated competency.

   c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon request.

4. The supervisor shall regularly monitor and be available to consult with the individuals being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

History: Effective January 1, 2006; amended effective January 1, 2010.
General Authority: NDCC 43-48-04
Law Implemented: NDCC 43-48-03

SB 2202
Attach #2
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Testimony on SB 2202

Senate Human Services Committee

February 1, 2017

Good morning Chairman Lee and members of the Senate Human Services Committee. My name is Shelly Peterson, President of the North Dakota Long Term Care Association (NDLTCA). We represent 210 assisted living, basic care and nursing facilities in North Dakota. We are here today to enter into discussion on SB 2202 and propose a different solution. We appreciate the efforts of the North Dakota Board of Clinical Laboratory Practice and the solution of creating a certification course, certifying exam and registration process, but we think a simpler and safe solution already exists.

Assisted living, basic care and nursing facilities employ well over 12,000 individuals and care annually for over 16,000 North Dakotans. Numerous individuals cared for in long term care facilities are diabetic and require various levels of assistance throughout the day.

In assisted living, forty-two percent of tenants have impaired mental status ranging from mild confusion to forgetfulness to a mental health diagnosis. Forty-seven percent of tenants need full assistance with medication administration. These tenants on average take 10.4 over the counter and prescription medications daily. Many could probably take care of their own blood sugars, but their arthritic hands or poor eye sight cause them to seek assistance. Sometimes the mild confusion, doesn't allow them with confidence to monitor this vital component of their health so it is turned over to the facility.

In basic care, we see more cognitive and physical limitations. Eighty percent of residents have impaired mental status ranging from early stage dementia to disorientation. Ninety-five percent of all residents need full medication administration.

Residents in both assisted living and basic care have stable medical conditions, but undoubtedly are dealing with chronic health issues and aging is becoming more evident.

Up until May 2014, the task of blood glucose testing though the use of various devices has been done by nurses and those under their supervision; nurse assistants, certified nurse assistants, medication assistant I and medication assistant II's. Attached is a handout detailing the scope of delegated medication administration for medication assistant I & II. Under this system the nurse is ultimately responsible to assure those under her supervision are properly trained, including demonstration of continued competency (annually).

In most states, blood glucose testing is a nursing task and delegated as such. As you know, checking blood sugars is a vital piece of information to assure those who are diabetic are within acceptable ranges and if not, interventions are made.

In May 2014 we became aware through a posting on the Board of Nursing website that nurses, according to NDCC Clinical Laboratory Personnel 43-48-03 Exemptions, may perform certain laboratory tests but nurses could not delegate laboratory tests to UAP or other unlicensed persons.

That posting disrupted the care and services to individuals living in basic care, assisted living, and nursing facilities causing statewide confusion and panic, especially in settings where a nurse is not required to be present 24/7, in our basic case and assisted living setting.

We reached out to the Board of Clinical Laboratory Practice and they indicated this was a lab test under their authority and as such nurses could perform this test, but others under their delegated authority could not. They indicated a licensed lab professional must supervise the testing and competence of an individual performing this test. We reached out to various hospital and clinic labs and almost universally they refused to fulfill this testing/supervision role. Their concern was

2202
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they were not comfortable, nor did they feel competent and the entity they worked for had concerns on liability. "How can I supervise people not in my lab, I see once a year and have no idea if they are following the correct protocol." Thus, we found ourselves in a very difficult situation.

We understood the reluctance of lab professionals.

NDCC 43-48 & NDAD 96-02-10-10 supervision for them meant:

1. The supervisor shall identify the individuals being supervised on a form provided by the board and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
   a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.
   b. Not allow an individual supervised to start to continue performing tests until the individual has been properly trained and demonstrated competency.
   c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon requests.
4. The supervisor shall regularly monitor and be available to consult with the individual being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

On July 14, 2014 the Board of Nursing reconsidered and rescinded their position, opening the door again for nurses and those under their delegation to complete this vital function. They did this out of concern for safety, as a gap was occurring when labs could not fulfill this statewide need. CNA's, nurse aides, medication assistants I & II's are still doing this function today, under the delegation of a nurse. Based upon a recent statewide survey, lab professionals are still not training, testing and supervising this function, nurses are. It is working and working well.

2202
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Thus we recognize something needs to change as the statute says this is a lab responsibility.

Once the labs decided this wasn't a role they could fulfill, we were told the clinical practice lab was working on a solution. We did propose a solution to the Clinical Practice Board on July 8, 2014. We requested that they remove whole blood glucose testing by blood glucose monitoring system, as a test that must be completed, supervised or delegated by a lab professional.

The solution proposed in SB 2202 is costly. Nurse assistants and medication aides I & II already pay a fee to be on the health department's register. Requiring thousands of individuals to complete training and testing and continued certification for one small but vital test should not be the one and only solution.

Attached please see our letter to the Clinical Practice Board. I wish we would have been aware the Clinical Practice Board was proposing this option. They have put a lot of work into this issue. Having those who are impacted by this issue at the table may have resulted in more options for compliance. We believe the best option that is safe, proven and cost effective, assuring all residents in our care get the monitoring and intervention they depend on is having this specific test exempt from the oversight of the Clinical Practice Board and under the preview of a nurse. This is also the practice of most states.

Thank you for your consideration of our perspective. I would be happy to answer any questions you may have.

Shelly Peterson, President
North Dakota Long Term Care Association
1900 North 11th Street
Bismarck, ND 58501
(701) 222-0660

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North Dakota Department of Health

Medication Assistant I

Scope of Delegated Medication Administration Statement

Registry Requirements:

- Must hold a current registration on the ND Department of Health Nurse Aide Registry as a Nurse Aide or Certified Nurse Aide prior to entry into the Medication Assistant I Training Program ,
- Must have completed a medication assistant I training and competency program (study and clinical practice in the administration of routine, regularly scheduled medications which meets the department's requirements), and
- Must hold a current registration on the department's registry as a Medication Assistant I.

Required Licensed Nurse Supervision and Delegation:

- May perform medication administration that has been delegated and supervised by a licensed nurse, consistent with completion of a department approved training program, scope of practice defined by regulation, and facility policies and procedures.
- May not perform medication administration if not under the supervision and delegation of a nurse.

Settings where a Medication Assistant I <u>can be employed</u> to provide delegated medication administration:

- Settings where the licensed nurse is <u>not</u> regularly scheduled including Assisted Living Facilities and Basic Care Facilities, however, none of the settings listed in the next section.
- If considering employment in a setting other than Basic Care or Assisted Living, contact the Department of Health to determine if it is an allowable setting for a Medication Assistant I to work in.

Settings where a Medication Assistant I <u>cannot be employed to provide medication administration</u>:

- Skilled Nursing Facilities,
- Acute Care setting,
- Clinics,
- Home Health Agency setting, and
- Private Home setting.

Medication administration that may be delegated to a Medication Assistant I who is supervised by a nurse include:

- Routine, regularly scheduled medication for individuals or groups of individuals with stable conditions which are administered on a routine basis and do not require determination of need, drug calculation, or dosage conversion.
- A stable patient is a patient the registered nurse has determined to have a predictable, non-fluctuating, and consistent clinical and behavioral status, and may have fluctuations that are expected with planned interventions.

Routine, regularly scheduled medications may be delegated by a licensed nurse to a Medication Assistant I for administration to individuals or groups of individuals with stable, predictable conditions via the following routes according to facility policies and procedures:

- Oral, sublingual, and buccal medications;
- Eye medications;
- Ear medications;
- Nasal medications;
- Rectal medications and enemas;
- Vaginal medications;
- Skin ointments, topical medications, including patches and transdermal medications;
- Metered hand-held inhalants; and
- Unit dose nebulizers.

<u>When specifically delegated by a licensed nurse to a Medication Assistant I for a specific</u> patient with a stable predictable condition, regularly scheduled medications via the additional following routes:

- Gastrostomy;
- Jejunostomy;
- Subcutaneous; and
- Premeasured injectable medication for allergic reactions.

A Medication Assistant I <u>may not administer medications via the following routes</u>:

- Central lines;
- Colostomy;
- Intramuscular injection;

2202
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A Medication Assistant I may not administer medications via the following routes (Cont.):

- Intravenous;
- Intravenous lock;
- Intrathecal;
- Nasogastric tube;
- Nonmetered inhaler;
- Intradermal;
- Non-unit dose aerosol or nebulizer; or
- Uretheral catheter.

A Medication Assistant I may not administer the following kinds of medications:

- Barium and other diagnostic contrast media;
- Chemotherapeutic agents except oral maintenance chemotherapy; or
- Through any medication pumps, or assume responsibility for medication pumps, including patient-controlled analgesia.

A Medication Assistant I cannot be delegated the decision to administer a pro re nata (PRN) medication in situations where an onsite assessment of the patient is needed prior to administration.

- For example, if a chemical restraint (medication) is needed for a documented emergency or to prevent injury to the resident or others, the chemical restraint must be authorized and documented by a physician for a limited period of time and the chemical restrain must be administered by a licensed nurse or physician.
- Some situations allow administration of PRN medications without directly involving the licensed nurse prior to each administration based on the following:
  - The decision regarding whether an onsite assessment is required is at the discretion of the licensed nurse.
  - Written parameters specific to an individual patient's care must be written by the licensed nurse for use by the Medication Assistant I when an onsite assessment is not required prior to administration of a medication. The written parameters: 1) Supplement the physician's PRN order; and 2) Provide the medication assistant with guidelines that are specific regarding the PRN medication.

A Medication Assistant I, or other individual on the department's registry, may not perform the following acts even if delegated by a licensed nurse:

- Conversion or calculation of medication dosage;
- Assessment of patient need for or response to medications; and
- Nursing judgment regarding the administration of pro re nata medications.

Specific Delegation of Medication Administration from a licensed nurse to a Medication Assistant I must comply with department regulation and facility policies and procedures. (Please note the four additional routes of medication administration that can be delegated through specific delegation by the licensed nurse.) The delegation must be for the delivery of a specific drug to a specific patient, and include the following steps:

1. The Medication Assistant I must receive a copy of the facility policies and procedures to follow regarding specific delegation.
2. The Medication Assistant is taught by the licensed nurse for each specific patient's medication administration with both verbal and written instructions (beyond the physicians order). The specific instructions include: a)The medication trade name and generic name; b) The purpose of the medication; c) Signs and symptoms of common side effects, warnings, and precautions; d) Route and frequency of administration; and e) Instructions under which circumstances to contact the licensed nurse or licensed health care provider.
3. The Medication Assistant I must be observed by a licensed nurse administering the medication to the specific patient until competency is demonstrated.
4. Areas the Medication Assistant I must be verified to be competent include: a) Knows the six rights for each medication for the specific patient, including the right patient, right medication, right dosage, right route, right time, and right documentation; b) Knows the name of the medication and common dosage; c) Knows the signs and symptoms of side effects for each medication; d) Knows when to contact the licensed nurse; e) Can administer the medication properly to the patient; and f) Documents medication administration according to organization policy.
5. Documentation that the Medication Assistant I has received the training related to specific delegation of medication administration for each patient must be maintained and updated when further instruction is received as necessary to implement a change.

Regulatory sources:

- NDCC Chapters 23-44 and 50-10.2
- NDAC ARTICLE 33-43
- Link to Applicable Rules: http://www.ndhealth.gov/HF/PDF_files/Nurse%20Aide%20Registry/Medication_Rules_10-22-2012.pdf

Effective Date: July 1, 2011

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North Dakota Department of Health
Medication Assistant II
Scope of Delegated Medication Administration Statement

Registry Requirements:

- Must hold a current registration on the ND Department of Health Nurse Aide Registry as a Certified Nurse Aide prior to entry into the Medication Assistant II training and competency program,
- Must have completed a medication assistant II training and competency program (study and clinical practice in the administration of routine, regularly scheduled medications which meets the department's requirements), and
- Must hold a current registration on the department's registry as a Medication Assistant II.

Required Licensed Nurse Supervision and Delegation:

- May perform medication administration that has been delegated and supervised by a licensed nurse, consistent with completion of a department approved training program, scope of practice defined by regulation, and facility policies and procedures.
- May not perform medication administration if not under the supervision and delegation of a nurse.

Settings where a Medication Assistant II <u>can be employed</u> to provide <u>delegated</u> medication administration:

- Settings where the licensed nurse is either scheduled regularly or not regularly including Skilled Nursing Facilities, Assisted Living Facilities and Basic Care Facilities, however, none of the settings listed in the next section.
- If considering employment in a setting other than Nursing Facility, Basic Care Facility, or Assisted Living, contact the Department of Health to determine if it is an allowable setting for a Medication Assistant II to work in.

Settings where a Medication Assistant II <u>cannot be employed to provide medication administration</u>:

- Acute Care setting,
- Clinics,
- Home Health Agency setting, and
- Private Home setting.

Medication administration that may be delegated to a Medication Assistant II who is supervised by a nurse include:

- Routine, regularly scheduled medication for individuals or groups of individuals with stable conditions which are administered on a routine basis and do not require determination of need, drug calculation, or dosage conversion.
- A stable patient is a patient the registered nurse has determined to have a predictable, non-fluctuating, and consistent clinical and behavioral status, and may have fluctuations that are expected with planned interventions.

Routine, regularly scheduled medications may be delegated by a licensed nurse to a Medication Assistant II for administration to individuals or groups of individuals with stable, predictable conditions via the following routes according to facility policy and procedures:

- Oral, sublingual, and buccal medications;
- Eye medications;
- Ear medications;
- Nasal medications;
- Rectal medications and enemas;
- Vaginal medications;
- Skin ointments, topical medications, including patches and transdermal medications;
- Metered hand-held inhalants; and
- Unit dose nebulizers.

<u>When specifically delegated by a licensed nurse to a Medication Assistant II for a specific</u> patient with a stable predictable condition, regularly scheduled medications via the additional following routes:

- Gastrostomy;
- Jejunostomy;
- Subcutaneous; and
- Premeasured injectable medication for allergic reactions.

A Medication Assistant II <u>may not administer medications via the following routes</u>:

- Central lines;
- Colostomy;
- Intramuscular injection;
- Intravenous;
- Intravenous lock;

2202
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A Medication Assistant II may not administer medications via the following routes (Cont.):

- Intrathecal;
- Nasogastric tube;
- Nonmetered inhaler;
- Intradermal;
- Non-unit dose aerosol or nebulizer; or
- Uretheral catheter.

A Medication Assistant II may not administer the following kinds of medications:

- Barium and other diagnostic contrast media;
- Chemotherapeutic agents except oral maintenance chemotherapy; or
- Through any medication pumps, or assume responsibility for medication pumps, including patient-controlled analgesia.

A Medication Assistant II cannot be delegated the decision to administer a pro re nata (PRN) medication in situations where an onsite assessment of the patient is needed prior to administration.

- For example, if a chemical restraint (medication) is needed for a documented emergency or to prevent injury to the resident or others, the chemical restraint must be authorized and documented by a physician for a limited period of time and the chemical restraint must be administered by a licensed nurse or physician.
- Some situations allow administration of PRN medications without directly involving the licensed nurse prior to each administration based on the following:
  - The decision regarding whether an onsite assessment is required is at the discretion of the licensed nurse.
  - Written parameters specific to an individual patient's care must be written by the licensed nurse for use by the Medication Assistant II when an onsite assessment is not required prior to administration of a medication. The written parameters: 1) Supplement the physician's PRN order; and 2) Provide the medication assistant with guidelines that are specific regarding the PRN medication.

A Medication Assistant II, or other individual on the department's registry, may not perform the following acts even if delegated by a licensed nurse:

- Conversion or calculation of medication dosage;
- Assessment of patient need for or response to medications; and
- Nursing judgment regarding the administration of PRN medications.

Specific Delegation of Medication Administration from a licensed nurse to a Medication Assistant II must comply with department regulation and facility policies and procedures. (Please note the four additional routes of medication administration that can be delegated through specific delegation by the licensed nurse.) The delegation must be for the delivery of a specific drug to a specific patient, and include the following steps:

1. The Medication Assistant II must receive a copy of the facility policies and procedures to follow regarding specific delegation.
2. The Medication Assistant II is taught by the licensed nurse for each specific patient's medication administration with both verbal and written instructions (beyond the physicians order). The specific instructions include: a)The medication trade name and generic name; b) The purpose of the medication; c) Signs and symptoms of common side effects, warnings, and precautions; d) Route and frequency of administration; and e) Instructions under which circumstances to contact the licensed nurse or licensed health care provider.
3. The Medication Assistant II must be observed by a licensed nurse administering the medication to the specific patient until competency is demonstrated.
4. Areas the Medication Assistant II must be verified to be competent include: a) Knows the six rights for each medication for the specific patient, including the right patient, right medication, right dosage, right route, right time, and right documentation; b) Knows the name of the medication and common dosage; c) Knows the signs and symptoms of side effects for each medication; d) Knows when to contact the licensed nurse; e) Can administer the medication properly to the patient; and f) Documents medication administration according to organization policy.
5. Documentation that the Medication Assistant II has received the training related to specific delegation of medication administration for each patient must be maintained and updated when further instruction is received as necessary to implement a change.

Regulatory sources:

- NDCC Chapters 23-44 and 50-10.2
- NDAC ARTICLE 33-43
- Link to Applicable Rules: http://ndhealth.gov/HF/PDF_files/Nurse%20Aide%20Registry/Medication_Rules_10-22-2012.pdf

Effective Date: July 1, 2011

2202
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Shelly

From: Shelly
Sent: Wednesday, June 04, 2014 3:13 PM
Subject: Blood glucose testing
Attachments: NDLTCA_20140604_095912.pdf

THIS IS BEING SENT TO ALL MEMBERS ON OUR LIST SERVE:
Attached please see a notice listed on the Board of Nursing website and an email from Bruce Pritschet regarding who can perform whole blood glucose monitoring on residents and tenants. This issue has surfaced because of the ND Board of Clinical lab practice, who determines the qualifications of who can perform and supervise lab tests, has indicated nurses can perform the test, but cannot delegate this lab test to unlicensed persons. The use of a whole blood glucose monitoring device is a lab test. Although a nurse can perform the whole blood glucose testing, as they and other professionals are exempt from licensing for lab testing, they cannot supervise others (nurse aides, CNAs, medication aides). See the email from Bruce Pritschet, who is a member of the ND Board of Clinical Laboratory Practice.
Even if you have a CLIA certificate this will not exempt you from this issue. The CLIA certificate is a federal issue and the licensing of clinical laboratory personnel is a state issue. One suggestion for complying would be to hire or contract with a licensed clinical lab professional to observe and determine competency of any of your staff that complete this lab test. This determination of competence would need to be completed annually and would need to be completed by a laboratory professional (Medical Technologist or medical laboratory technician). Currently there are about 1100 lab professionals in ND.
This issue cannot be changed administratively and we may want to consider legislation to allow this task to be delegated by a nurse. The other option for compliance would be for the nurse to complete the task or of course the resident or tenant, which doesn't seem very practical.
This is something nurses have been supervising and delegating for years, however apparently it is against the ND Clinical Lab practice act. I will put this issue on the agenda of our Legislative committee. Let me know if this is a concern of yours so we can better determine the impact.

Shelly Peterson, President
North Dakota Long Term Care Association
1900 N 11th St
Bismarck, ND 58501
(701) 222-0660
Cell: (701) 220-1992
Fax: (701) 223-0977
www.ndltca.org

2202
#2
2/1

North Dakota
Board of Nursing

Articles / General

Blood Glucose Testing

5/19/2014

This memo is intended to remind nurses that according to NDCC Clinical Laboratory Personnel 43-48-03 Exemptions. (2) Nurses duly and currently licensed to practice nursing and practicing within the scope of nursing license means that nurses may perform certain laboratory tests but nurses **cannot** delegate laboratory tests to UAPs or other unlicensed persons.

Pg. 10

2202 #2 2/11

North Dakota Board of Nursing
Meeting Minutes – July 17, 2014

AGENDA	ACTION
5.2-3 Dakota Nursing Program – Programmatic Changes	*Discussion:* Julie Traynor, Chair of the Dakota Nursing Program was present via phone. The program had worked with a consultant to review and revise their mission, philosophy, program outcomes and student learning outcomes. Traynor reviewed each with the board.
	Motion: J. Christianson, seconded by C. Christianson to: **ACCEPT THE DAKOTA NURSING PROGRAM NOTIFICATION OF MAJOR PROGRAMMATIC CHANGES AS THE PROGRAM HAS FULL APROVAL FROM THE ND BOARD OF NURSING AND THE PROGRAMMATIC CHANGES ARE IN COMPLIANCE WITH NDAC 54-03.2-06-02.**
	Roll call vote: C Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
5.3-1 Status of Policy: Continuing Education Providers request to be displayed on website & Continuing Education online (NEC)	*Discussion:* The NEC reviewed a current policy for entities such as CE provider to have their website link posted on the board website. With the website revision, the site no longer has a "links" section and the committee discussed whether it should be added. Currently staff have been referring these requests to the ND Center for Nursing. The committee agreed providers should not be posted on the board of nursing website and should be referred to the ND Center for Nursing and suggested the board post the information on where this information can be found on the Center for Nursing website.
	Motion from the Nursing Education Committee: **RECOMMENDS THE BOARD ARCHIVE THE POLICY REGARDING CE PROVIDER REQUESTS FOR DISPLAY ON THE NDBON WEBSITE AND REFER REQUESTS TO THE ND CENTER FOR NURSING.**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
	Discussion: A second policy titled "Continuing Education Online" also applies to the same situation and staff request this policy by archived as well.
	Motion: J. Christianson, seconded by Price to: **ARCHIVE THE DOCUMENT TITLED "CONTINUING EDUCATION ONLINE".**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
5.4-1 New Policy for Programmatic Changes (NEC)	*Discussion:* Staff developed new guidelines for Major Programmatic Changes that define what changes require prior approval by the board and require a motion for approval, which changes need to be submitted to the board for notification, and changes that do not require board notification. The NEC made recommendations for clarification at what point an increase in enrollment becomes a programmatic change, and that a degree change within a program would be a programmatic change. Staff added additional clarification since the committee met and requests a motion for approval of the current document.
	Motion: J. Christianson, seconded by C. Christianson that: **THE BOARD ADOPT THE NEW PROPOSED GUIDELINES TITLED "MAJOR PROGRAMMATIC CHANGES" WITH REVISIONS TO CLARIFY #5 UNDER SECTION 1 AND CLARIFY #2 IN SECTION III.**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
5.4-4 Nursing Education Loan Awards FY 2014-2015	*Discussion:* The NEC reviewed 53 applicants for nursing education loans under blind review. The full amount of award to each applicant was above the available funding. The committee reviewed an option to award all applicants 80% of the maximum amount or to award applicants a set amount by degree with graduate loans receiving a greater percentage of the funding. The committee recommended to the board to accept the 80% of maximum option.
	Motion from the Nursing Education Committee: **RECOMMENDS THAT ACCORDING TO NDAC 54-04.1 NURSING EDUCATION LOANS THE BOARD APPROVE THE ATTACHED INDIVIDUALS FOR THE NURSING EDUCATION LOAN FOR A TOTAL AWARDED OF $92,510.**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
6.1 Update on whole blood glucose testing – delegation to unlicensed persons	*Discussion:* Char Christianson reviewed a history of the issue that ND Board of Clinical Laboratory Practice (NDBCLP) had directed that nurses could not delegate Blood Glucose testing to a UAP or other unlicensed personnel and that the training for those procedures would need to be done by someone licensed under the NDBCLP. After discussing the issue at the March & May board meetings, the board posted the directive on the board of nursing website, and it has since generated many questions. It has been discovered that most laboratory personnel will not train UAP/CNAs for blood glucose monitoring, and this has a huge impact on schools and DD facilities where nurses are not regularly scheduled. At the request of NDBCLP, representatives of the Long Term Care Association, the NDBON, and the Department of Health have been meeting to resolve the issue. It was noted that the Board of Nursing has not been made aware of any safety issues or concerns. NDBCLP has discussed the rule revisions and will work with the board to find a solution.
	Motion: C. Christianson, seconded by Hanson to: **RECONSIDER THE DIRECTIVE FROM THE MAY 2014 & MARCH 2014 BOARD MEETING RELATED TO THE EXEMPTION IN NDCC 43-48-03 (2) THAT ALLOWS NURSES DULY AND CURRENTLY LICENSED TO PRACTICE NURSING AND PRACTICING WITHIN THE SCOPE OF THE NURSING LICENSE (TO COMPLETE WAIVED LABORATORY TESTS).**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.

pg. 11

AGENDA	ACTION
6.1 Update on whole blood glucose testing – delegation to unlicensed persons (cont.)	*Motion:* C. Christianson, seconded by Holth to: **DIRECT STAFF TO WORK WITH THE NDBCLP REGARDING CHAPTER 43-48-03-02 EXEMPTIONS THAT ALLOWS NURSES TO COMPLETE WAIVED LABORATORY TESTS AS THEY HAVE IN THE PAST AND DELEGATE TO UNLICENSED ASSISTIVE PERSONS UNTIL CLARIFICATION CAN BE WORKED OUT WITH THE BOARD OF CLINICAL LABORATORY PRACTICE.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, absent; Price, yes; Rustvang, yes; Schmalz, yes. 8 yes, 1 no, 0 absent. Motion carried.
7.1-1 DARP Charting – response from ND Department of Health	In the course of a recently reviewed Potential Violation Report against a licensee, it was noted that DARP charting (Data/Action/Response/Plan) was done by the unlicensed person. An anonymous call was also received in December 2013 related to the same issue at a different facility and the appropriateness of nurse aides charting in the nurse's notes. Staff sent a letter to the ND Department of Health related to the concerns. A response from Bridget Weidner, Program Manager at the Division of Health Facilities was reviewed and indicates they found no evidence of inappropriate charting in the information provided.
7.1-2 Delegation of medication administration and nursing tasks to Direct Support Professionals (see agenda item 12.12)	Staff have been meeting with representative of the DD facilities related to Nurse Delegation, looking at case studies of individuals who are residents and reviewing what tasks can be delegated and what tasks cannot be delegated. The board reviewed the minutes of the meetings.
7.1-3 NPC Subcommittee – Aesthetic Cosmetic and Dermatological Procedures by License Nurses Practice Statement (draft)	*Discussion:* The Nurse Practice Committee convened a subcommittee to review the practice statement entitled "Aesthetic Cosmetic and Dermatological Procedures by Licensed Nurses". The subcommittee suggested some revisions to the practice statement to add clarification in regards to knowledge and education. *Motion:* Schmalz, seconded by C. Christianson to: **APPROVE THE REVISED PRACTICE STATEMENT "AESTHETIC COSMETIC AND DERMATOLOGICAL PROCEDURES BY LICENSED NURSES" AND DISTRIBUTE TO STAKEHOLDERS.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
7.2-1 APRN Compact Statue discussion – Bergeson	*Discussion:* Brian Bergeson, SAAG for the board was present via phone for this agenda item. NCSBN has been working on an interstate licensure compact for advanced practice registered nurses for the last three years. Bergeson stated that the difference between the proposed APRN compact and the RN compact is that there is an Interstate Commission for APRN Compact Administrators who would be responsible for administering the compact and review and revise rules as necessary, and all states would agree the commission rulemaking would have the status of law. The RN compact contains more local control and the APRN compact would promote uniformity throughout the states. ND Nurse Practices Act and rules currently are consistent with the proposed APRN compact model rules. It is the obligation of the nurse to know and follow the practice act and requirements of the state in which they are practicing. The NCSBN Delegate assembly will vote on the APRN compact rules and the delegates would like direction as to how the board would like them to vote. *Motion:* C. Christianson, seconded by Schmalz to: **SUPPORT APRN COMPACT STATUTE AND RULES FOR VOTING PURPOSES AT THE NATIONAL COUNCIL STATE BOARD OF NURSING DELEGATE ASSEMBLY.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
7.2-2 APRN Compact Rules	The board reviewed the proposed APRN Compact Rules.
7.2-3 Key Elements of the APRN Compact	The board reviewed key elements of the APRN Compacts.
7.2-4 APRN Compact to Delegate Assembly	The board reviewed a NCSBN memo related to proposed revisions to the APRN compact that will be voted on at Delegate Assembly.
7.2-5 2014 State of Consensus Conference – Grandfathering Guidelines	*Discussion:* The board reviewed proposed guidelines for grandfathering APRNs by Endorsement during implementation of the APRN compact. Schmalz reviewed discussions at the APRN Roundtable and rationale for the scenarios. *Motion:* J. Christianson, seconded by Price to: **ADOPT THE GUIDELINES FOR GRANDFATHERING APRNS BY ENDORSEMENT CONSISTENT WITH THE APRN CONSENSUS MODEL.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
7.3-2 Model Policy for the Appropriate Use of Telemedicine	The board reviewed a report of the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup titled "Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
7.4-1 Administrative Rule Promulgation	The board reviewed numerous health care bill proposals for the upcoming legislative session.

2202 2 #2 2/2

pg. 12

2202
#2
2/1

SUPERVISION OF UNLICENSED PERSONNEL PERFORMING EXEMPTED TESTS FORM

North Dakota Board of Clinical Laboratory Practice
1/2006

Name of Licensee	
License Number	Work Telephone Number
Place of Employment	

As used in subsection 9 of North Dakota Century Code section 43-48-03 and section 96-02-10-01, "supervised" means the following:

1. The supervisor shall identify the individuals being supervised on a form provided by the board, and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
    a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.
    b. Not allow an individual supervised to start or continue performing tests until the individual has been properly trained and demonstrated competency.
    c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon request.
4. The supervisor shall regularly monitor and be available to consult with the individuals being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

List the following for each unlicensed personnel under your supervision:

Name	Background	Tests performed

Facility where exempted tests are being performed:

_____

Is there a plan in place for training and annual competency for the individuals listed above?

□ Yes □ No

Signature of Licensee_____ Date_____

Return completed form to: North Dakota Board of Clinical Laboratory Practice – PO Box 4103 – Bismarck, ND 58502

2202
#2
2/1

North Dakota
Long Term Care
ASSOCIATION

Shelly E. Peterson, *President* • *email:* shelly@ndltca.org

July 8, 2014

Sandra Matthey, Chair
North Dakota Board of Clinical Laboratory Practice
PO Box 4103
Bismarck, ND 58502-4103

Dear Sandra:

My name is Shelly Peterson, President of the North Dakota Long Term Care Association (NDLTCA). We represent eighty (80) licensed nursing facilities, sixty-five (65) licensed basic care facilities and sixty-four (64) licensed assisted living facilities. Together these long term care facilities employee around 15,000 individuals and care annually for over 19,000 individuals. Thank you for the opportunity to meet and discuss with you the issue of blood glucose testing and the requirements under NDCC 43-48-03 and NDAC 96-02-10-01.

Numerous individuals cared for in long term care facilities are diabetic. Those in assisted living facilities are fairly independent and many care for their own blood sugars, while those in skilled nursing facilities require continuous nursing care and close monitoring.

Currently the task of conducting the blood glucose testing through the use of various devices has been done by nurses and those under their supervision: nurse assistants, Certified Nurse Aide's (C.N.A.'s) and Certified Medication Assistant's (C.M.A.'s). We realize through a recent posting on the Board of Nursing web site and our seeking information from your board that nurses cannot and should not have been delegating this task to those under their authority and supervision. We recently sent information to our members informing them of the need to have a licensed lab professional supervise the testing and competency of an individual performing this lab test.

As we understand from NDCC 43-48-03 and NDAC 96-02-10-01 supervision means the following:

1. The supervisor shall identify the individuals being supervised on a form provided by the board, and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
    a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.

(701) 222.0660 • *fax:* (701) 223.0977 • 1900 North 11th Street, Bismarck, ND 58501 • *Web site:* www.ndltca.org

b. Not allow an individual supervised to start to continue performing tests until the individual has been properly trained and demonstrated competency.
c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon request.

4. The supervisor shall regularly monitor and be available to consult with the individual being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

Recently we hosted a telephone call on this issue and were most appreciative to have three members of the North Dakota Board of Clinical Laboratory Practice, Kathy Pepple, Sherry Melby and Bruce Pritschet participating in the call. As well as Dr. Constance B. Kalanek and Patricia Hill of the North Dakota Board of Nursing. We appreciated both state boards participating in this education session.

I am here to request that you remove whole blood glucose testing by blood glucose monitoring systems, as a test that must be completed, supervised or delegated by a lab professional.

In making this recommendation we ask that you consider the following:

1. The current practice of delegation and supervision by a nurse has been a safe, secure process. We believe the public is well protected.
2. C.N.A. turnover in nursing facilities is 58% (2012 data). This rapid rate of turnover would require numerous contact by lab professionals for competency testing and supervision.
3. Currently there are a number of glucose monitoring systems, with each resident and tenant selecting their choice or Medicaid requiring a certain device. As multiple devices are used in long term care facilities the lab professional would need to competency test and "supervise" on each device. This extra layer of professional oversight is adding costs, costs that will be added to each resident/tenant bill.
4. We have heard from one major health system lab, some rural hospital/clinic labs, and one independent lab that they will not provide the competency testing and supervisor to long term care nursing personnel because of the "liability" concerns. Compliance with the clinical lab requirement is becoming difficult for many because labs are reluctant to fulfill this role.

In conclusion we believe the practice of having blood glucose testing systems under the supervision and delegation of a nurse is safe practice. Clinical labs have some valid concerns and need guidance on the liability and supervision issues. To assure those thousands of individuals in long term care facilities get the care and services they need we ask that you implement an emergency rule to resolve this issue.

2202
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Thank you for listening to our concerns. We commit to working with you to assure public safety and continued care for our frail diabetic residents living in a long term care facility.

Sincerely,

Shelly Peterson

Shelly Peterson
President

SEP/pjt

Testimony Senate Bill 2202

Rebecca LaFavor MSN RN
Clinical Services Director
Edgewood Vista and Village

Rebecca's resume

- I have been a nurse for 19 years
- I have been the Clinical Services Director at Edgewood for 4 years
- My responsibilities include:
  - Training personal care attendants (PCA) and certified nurse assistants (CNA)
    - This training includes caring for the elderly with personal cares, such as activities of daily living (bathing, dressing, bathroom assistance, etc.)
  - Developing quality care programs and monitoring care of residents
  - In-house training for staff to be able to pass medication to residents

Medication Assistant I

- Training includes:
- 4 hours self study
- 4 hours classroom training
- Nurse supervised on-the-floor training for minimum of 4 hours, (can be up to 16 hours if needed)
- Afterwards, nursing manager provides follow up with the new medication aid:
  - Four times weekly
  - Three times monthly
  - Quarterly, thereafter
  - This follow up included watching all routes of medication administration and the specific delegated tasks, including blood glucose testing and insulin injections

Medication Assistance I

- The Medication Assistance trained staff are the only caregivers allowed to complete blood glucose testing at Edgewood
- In four years working at Edgewood, our nursing department has not had safety issues related to inaccurately completing a blood glucose test
- The PCA/CNA medication aids work with several different blood glucose machines and during all the follow ups not one has put a resident at risk with this type of testing.

Please vote no on Senate bill 2202

SB 2202
Attach #4
2/1

Senate Human Services Committee
Senator Judy Lee, Chairman
NDACP Testimony, February 1, 2017
Senate Bill 2202

Good morning, Chairman Lee and members of the Senate Human Services Committee. I am Bruce Murry, Executive Director of the North Dakota Association of Community Providers (NDACP). NDACP is the membership organization of 31 licensed providers of services to North Dakotans with developmental disabilities (DD).

I have consulted our association's Nursing Affiliation Group, which raised serious concerns. NDACP opposes SB 2202 unless it can be amended to address the following problems:

- DD nurses have successfully delegated blood glucose testing to properly trained direct support professionals for decades without negative outcomes.
- Community providers have developed a teaching curriculum that includes competency testing by a nurse.
- Some agencies need to perform training on a weekly basis to accommodate new staff members.
- When DD nurses asked lab professionals to provide the training and delegation, they were unwilling.
- DD nurses serve an aging population with increasing health care needs, creating great pressure upon their time and availability;
- DD nurses, like all nurses, are in short supply.
- Thousands of places where people with DD are served have no routine access to nursing care. These include residences and workplaces in rural, small town, and city settings.

2202
#4
2/1

- Blocking safe nursing delegation of this simple test will require unreasonable congregation of people served because of shortages in nursing staff, violating the civil rights and best interests of the people we serve. People with DD want to get on with their day, and not wait to go to work until they can see a nurse.
- Requiring agencies to hire lab technicians or more nurses to complete this simple test will cost at least hundreds of thousands of dollars within the DD system alone (assuming 9.3% incidence of diabetes in population served (CDC), once daily tests, 20 tests per hour, and $30 hourly cost to employ a nurse), in addition to any registration costs.

Please leave regulation of nurse delegation of tasks within their scope of practice to the Board of Nursing.

We support the amendments requested by the North Dakota Long Term Care Association.

Thank you for your time and consideration this morning.

2202
Attach #5
2/1

NDHA
North Dakota Hospital Association Est. 1934

Vision
The North Dakota Hospital Association will take an active leadership role in major Healthcare issues.

Mission
The North Dakota Hospital Association exists to advance the health status of persons served by the membership.

Testimony: 2017 SB 2202
Senate Human Services Committee
Senator Judy Lee, Chairman
February 1, 2017

Good morning Chairman Lee and Members of the Senate Human Services Committee. I am Jerry E. Jurena, President of the North Dakota Hospital Association. I am here to testify regarding 2017 Senate Bill 2202 and ask that you give this bill in its current form a **Do Not Pass** recommendation.

While we agree with the intent of the bill to provide some regulation of those who perform clinical laboratory tests, which includes blood glucose testing, we would like to see the flexibility of allowing nurse supervision rather than mandating training and passage of a certifying exam. Specifically, NDHA requests that you remove whole blood glucose testing by blood glucose monitoring systems as a test that must be completed, supervised, or delegated by a lab professional. We believe that nurse delegation and supervision of this limited testing has worked well and shows that this task may be safely and appropriately delegated by a nurse to nurse assistants, Certified Nurse Aides (CNA), and Certified Medication Assistants (CMA).

We oppose this bill and ask that, unless the bill is amended, you give it a **Do Not Pass** recommendation.

I would be happy to try to answer any questions you may have. Thank you.

Respectfully Submitted,

Jerry E. Jurena, President
North Dakota Hospital Association

PO Box 7340 Bismarck, ND 58507-7340 Phone 701 224-9732 Fax 701 224-9529

SB 2202
Attach #1
2/6

17.0769.01001
Title.

Prepared by the Legislative Council staff for
Senator Anderson
February 3, 2017

PROPOSED AMENDMENTS TO SENATE BILL NO. 2202

Page 2, after line 18, insert:

"14. Personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a et seq.]."

Renumber accordingly

Mar 14, 2017

SB 2202

House Industry Business and Labor Committee

Senator Judy Lee

SB 2202 was requested by the ND Board of Laboratory Practice to require special training and certification at a cost of $25 of all people who are doing simple laboratory tests, such as glucose monitoring.

I introduced the bill at their request, but the testimony that was presented, and that I am confident you will hear today, led the Senate Human Services Committee to amend the bill. As you may know, many of the simple lab tests, whether a blood glucose test or a urine test, can be done very easily by someone who is taught how to do it, but does not need certification. We heard from the representatives of the ND Association of Community Providers, the Long Term Care Association, and the ND Hospital Association asking for a "do not pass" on the bill.

As our committee discussion progressed, Senator Howard Anderson suggested that we amend in the Clinical Laboratory Improvement Amendments (CLIA) which were adopted by CMS several years ago and which list the simple tests which can be done without extensive training.

A Certificate of Waiver (CW) permits a laboratory to perform only waived tests. Waived tests are so simple and accurate that little risk of error exists, when done correctly. Examples of waived tests include:

Certain testing methods for glucose and cholesterol

Fecal occult blood tests

Pregnancy tests

Some urine tests.

Routine on-site surveys are not required for a CW unless there is a complaint.

This seemed really sensible to the Senate Human Services committee, and I hope that IBL will consider it positively, too.

Matthey,Sam (Sandra)

From: Matthey,Sam (Sandra)
Sent: Monday, March 13, 2017 1:53 PM
To: 'gkeiser@nd.gov'; 'gsukut@nd.gov'; 'tbeadle@nd.gov'; 'rcbecker@nd.gov'; 'gdbosch@nd.gov'; 'jboschee@nd.gov'; 'gdobervich@nd.gov'; 'craigjohnson@nd.gov'; 'vrlaning@nd.gov'; 'jkasper@nd.gov'; 'mlefor@nd.gov'; 'sclouser@nd.gov'; 'eobrien@nd.gov'; 'druby@nd.gov'
Subject: SB 2202 and NDBCLP Proposed Amendment
Attachments: Bill Amendment 2202.docx; 17-0769-02000.pdf

Importance: High

Mar 14, 2017

SB 2202

Dear Members of the House Industry, Business, and Labor Legislative Branch,
I am currently Board Chair of the North Dakota Clinical Laboratory Practice Board, and we are very concerned with the amended language in Senate bill 2202 that exempts all waived testing from the Laboratory Licensure Law. The original intent of waived testing was simple one step testing that if performed incorrectly would have no impact on patient care. There were originally 8 waived tests and now the CLIA office in ND has printed 300 pages of waived tests (so thousands of waived tests) as manufacturers have produced these to broaden their market. Many do impact patient care if performed incorrectly. We have concern for public safety if anyone can perform these tests without some oversight by the ND Clinical Laboratory law, whose purpose is to protect the public.

Our proposal would be to amend Senate bill 2202 to exempt whole blood bedside glucose testing from the licensure law thus allowing this this testing to be done by nursing assistants and medical assistants in long term care facilities, schools, and other centers that are performing bedside glucose testing. This we feel is safer for the public than the broad effects of including all waived testing. Both the bill as revised by the Senate and the ND Board's proposed change are attached. I have also attached articles regarding standards for waived testing from both the Joint Commission and the College of American Pathologists as these are regulations we are held to in hospitals and laboratories.

http://www.jointcommission.org/assets/1/18/Waived_Testing_Source_Article.pdf

http://www.pointofcare.net/keypocc/Summary_of_Waived_Testing_Requirements.pdf

I would welcome further discussion of this topic if would like to contact me directly. I plan to attend the hearing tomorrow to address this in person.

Thank you for your consideration.
Sam Matthey
Board Chair
North Dakota Board of Clinical Laboratory Practice
701-234-2481

2

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2202

Page 2, line 10, after "performing" insert "whole-blood glucose"

Renumber accordingly

p2

17.0769.02000

Sixty-fifth
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED SENATE BILL NO. 2202

Introduced by

Senators J. Lee, Anderson, Meyer, Nelson

Representatives Porter, Delmore

A BILL for an Act to amend and reenact section 43-48-03 and subsection 2 of section 43-48-05 of the North Dakota Century Code, relating to clinical laboratory practice exemptions and board membership.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 43-48-03 of the North Dakota Century Code is amended and reenacted as follows:

43-48-03. Exemptions.

The provisions of this chapter do not apply to the following:

1. Physicians duly and currently licensed to practice medicine.
2. Nurses duly and currently licensed to practice nursing and practicing within the scope of the nursing license.
3. Persons performing clinical testing for teaching or research, provided that the results of any examination performed in such laboratories are not used in health maintenance, diagnosis, or treatment of disease.
4. Persons employed by the United States government, or ~~anya~~ a bureau, division, or agency thereof, and working in a licensed laboratory.
5. Any person in the pursuit of a supervised course of study leading to a degree at an accredited or educational program approved by the board.
6. Phlebotomy personnel performing phlebotomy procedures.
7. Persons performing testing for their own personal use and persons performing screening tests for mass screening under appropriate supervision.
8. Agents of the state or federal government performing hematological tests for anemia upon participants of the special supplemental food program for women, infants, and children.

9. An individual supervised by an individual ~~who is~~ licensed by the board and who performs tests and uses methods identified by rules adopted by the board.
10. Perfusionists performing clinical laboratory tests for hematology, coagulation, and chemistry during the course of a patient's perfusion procedures.
11. Personnel of the division of laboratory services of the state department of health participating in the centers for disease control and prevention's chemical terrorism toxic metals determination program.
12. A person licensed or registered under another chapter of this title and carrying out the therapy or practice for which the person is licensed or registered.
13. Personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a et seq.].

SECTION 2. AMENDMENT. Subsection 2 of section 43-48-05 of the North Dakota Century Code is amended and reenacted as follows:

2. The board must be composed of:
   a. One physician ~~recommended by the North Dakota pathology organization. The North Dakota pathology organization shall submit to the governor a list of physicians qualified to serve, such list to contain at least three names~~licensed to practice medicine in the state and qualified to practice as a pathologist.
   b. The following laboratory persons, whose names may be included on a list of such persons qualified to serve submitted to the governor by the North Dakota society for medical technology or other interested persons, such list to contain at least three names for each vacancy:
      (1) One administrative nonphysician clinical laboratory director;
      (2) One clinical laboratory scientist; and
      (3) One clinical laboratory technician.
   c. Two consumer members, each of whom must be a citizen of the United States, a resident of North Dakota for at least two years before the date of appointment, and a current resident of North Dakota.
   d. The state health officer or such officer's designee, ex officio.

Summary of Waived Testing Requirements*
CAP ACCREDITATION PROGRAMS

Reagents
- Lot-to-lot reagent confirmation of acceptability not required
- Follow manufacturer instructions

Competency
- Training must be completed prior to performing patient testing
- Competency must be assessed annually (semiannual competency not required for new waived testing personnel)
- May select which competency elements to assess

Correlation
- Initial correlation between waived instruments (eg, glucose meters) not required
- Correlation between waived instruments and main laboratory instrument not required
- Multi-instrument comparison not required

Quality Control
- Follow manufacturer instructions
- QC results must be judged acceptable and recorded prior to release of patient results
- If control results exceed tolerance limits, corrective action must be documented
- Internal control results need not be documented for instruments using such controls, if—and only if—an unacceptable instrument control automatically locks the instrument and prevents release of patient results
- Frequency of QC is defined by the manufacturer
- External controls run as required by manufacturer

Calibration and Calibration Verification
- Follow manufacturer instructions
- Calibration verification every six months not necessary unless required by manufacturer

Analytical Measurement Range (AMR)
- Follow manufacturer instructions
- Initial AMR validation and six-month interval verification not necessary unless required by manufacturer

Method Performance Specifications
- Verification not required EXCEPT for reference range
- Follow manufacturer's instructions for instrument setup and use

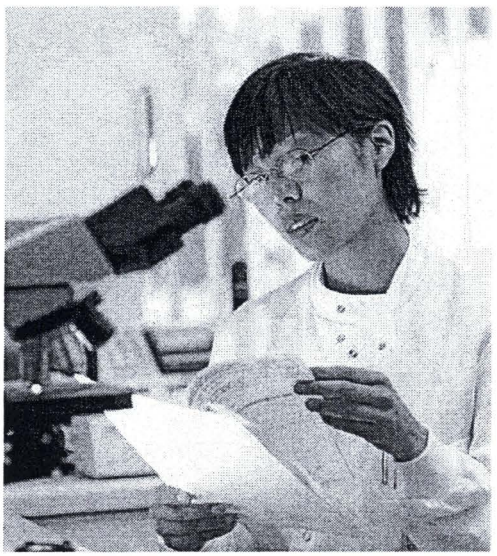
Other checklist requirements in areas of proficiency testing, instrument maintenance, procedure manuals, specimen handling, results reporting, and safety remain the same for waived and nonwaived testing.

*Inspection Checklist Edition 07/29/13. Waived testing is covered in the following Checklists: All Common, Point-of-Care, Chemistry, Hematology, Immunology, Microbiology, Urinalysis, and Limited Service. List of currently waived analytes can be found at accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm.

800-323-4040
accred@cap.org

p 5

5 Sure-Fire Methods
Complying with WT.03.01.01



Waived testing (WT) includes tests that meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) requirements for waived tests and are cleared by the U.S. Food and Drug Administration for home use. **Standard WT.03.01.01** applies to ambulatory health care, behavioral health care, home care, hospitals, laboratories, long term care, and office-based surgery. (*See* sidebar, opposite, for the entire standard). This standard was one of the 10 most problematic standards during the first half of 2011 for long term care organizations (16% of organizations noncompliant) and office-based surgery practices (17% of organizations noncompliant).

Reasons for Noncompliance

Organizations struggle with this standard for a number of reasons, including some related to process and some related to personnel. For example, one reason organizations are noncompliant with WT.03.01.01 is that they are not assessing health care provider competency. "People often assume if a provider is doing a test, that he or she knows how to do it, so the providers sometimes get overlooked during orientation and training and competency assessment," says Jay Afrow, D.M.D., M.H.A., surveyor, The Joint Commission.

Also, some organizations that do assess provider competency use only one method, Afrow says. "The standard gives organizations four assessment methods to choose from, and they are required to use two," he says.

According to John Gibson, M.A., M.T. (A.S.C.P.), D.L.M., associate director, Standards Interpretations Group, The Joint Commission, some organizations have trouble with Standard WT.03.01.01 because the individuals responsible for providing orientation and training and assessing competency do not always fully understand waived testing. "The person may not have a really good grasp of the technical areas in which problems can arise, or of the clinical application of the test," he says.

To address these issues, Gibson and Afrow offer the following five strategies:

1. *Designate a qualified staff person to oversee orientation and training and competency assessment.* "Appoint someone who is not only qualified but also detail oriented," says Gibson. "Orientation and competency assessment programs work best when they're well structured and well documented, and a good process is in place for ongoing compliance and competency assessment."

p6

2 *Choose two methods of determining competency.* "Although The Joint Commission doesn't designate which methods an organization chooses, I personally recommend that one method be a written exam," Gibson says. "With a written exam, the questions can be changed based on weaknesses. For example, if a problem is apparent with quality control and test performance, you can add questions about technique. Written exams can help identify areas of concern that can direct education. Some organizations also hold an annual competency fair for return demonstrations. The bottom line is that no matter which methods you choose, you must choose two. You don't even have to use the same two methods for every person you assess."

3 *Include providers in orientation, training, and competency assessment.* "Many organizations do a good job of training nurses and medical assistants, but not providers [physicians, nurse practitioners, physician assistants]," says Afrow. "If the test doesn't require an instrument, then the organization can assess provider competency as part of credentialing and privileging. If it does require an instrument, the provider needs to go through the same orientation and training process as the staff members, and competency should be reassessed annually. It's also important to note that provider-performed microscopy is not considered a waived test and does not fall under this standard. That requires a separate CLIA certificate."

4 *Develop a competency assessment schedule.* "One way to make sure competency is assessed annually is to put everyone on the same schedule," Gibson says. "Larger organizations may want to do half of their assessment in January and half in June. Smaller organizations might do them all at once. New employees may need to have their first reassessment done early to get them into the cycle."

5 *Document all orientation, training, and competency assessment efforts.* "A lot of times, organizations are doing what's required, but end up being cited because they forget to document what they've done," says Afrow. "Make sure you give yourself credit for what you're already doing." S

Standard WT.03.01.01

Staff and licensed independent practitioners performing waived tests are competent.

Elements of Performance for WT.03.01.01

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, provides orientation and training to, and assesses the competency of, staff and licensed independent practitioners who perform waived testing.
2. Staff and licensed independent practitioners who perform waived testing have received orientation in accordance with the organization's specific services. The orientation for waived testing is documented.
3. Staff and licensed independent practitioners who perform waived testing have been trained for each test that they are authorized to perform. The training for each waived test is documented.
4. Staff and licensed independent practitioners who perform waived testing that requires the use of an instrument have been trained on its use and maintenance. The training on the use and maintenance of an instrument for waived testing is documented.
5. Competency for waived testing is assessed using at least two of the following methods per person per test:
   - Performance of a test on a blind specimen
   - Periodic observation of routine work by the supervisor or qualified designee
   - Monitoring of each user's quality control performance
   - Use of a written test specific to the test assessed
6. Competence for waived testing is assessed according to hospital policy at defined intervals, but at least at the time of orientation and annually thereafter. This competency is documented.

   Note 1: *When a licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within his or her specialty, the organization may use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to the scope of practice that he or she is authorized to perform. At the discretion of the person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or according to organization policy, more stringent competency requirements may be implemented.*

   Note 2: *Provider-performed microscopy (PPM) procedures are not waived tests.*

p7

Mar 14, 2017

3

Testimony: Senate Bill No. 2202

Introduction and Credentials:

Chair and members of the Committee, I am Mark A. Koponen, M.D. I am the physician member of the North Dakota Board of Clinical Laboratory Practice. I am an Associate Professor in the Department of Pathology at the University of North Dakota School of Medicine and Health Sciences and am board certified in Anatomic, Clinical and Forensic Pathology by the American Board of Pathology.

I am here today in opposition to the proposed amendment to engrossed Senate Bill 2202.

Position on SB 2202:

Strongly opposed to the bill as it left the Senate with the following Addendum:

Page 2, lines 18-20

"Personnel performing waived tests as categorized by the food and drug administration based on criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a_seq.I.]"

This addendum would allow for the performance and reporting of waived tests in a health care setting without training or supervision of the individuals performing the testing or any institutional system of quality control.

Reason for Opposition:

Laboratory testing plays a critical role in the health care system. Laboratory test results are essential in the screening, diagnosis, monitoring and management of disease. Laboratory testing affects approximately 70% of all medical decisions. Point-of-care testing is becoming increasingly utilized to provide rapid and cost effective information for medical decision making. Technological advances have made certain laboratory tests simpler and allowed for the performance of more testing to occur in non-traditional settings such as nursing homes, school clinics and health fairs. The number of waived tests under the Clinical Laboratory Improvement Act of 1988 have increased dramatically and this number of tests is expected to grow.

The Clinical Laboratory Improvement Act was enacted to ensure the accuracy, reliability and timeliness of test results regardless of where the test was performed. This effort was to reduce medical errors and improve health care delivery. The reduction of medical errors and increased patient safety has been a prominent national health care strategy.

CLIA waved tests should have a very insignificant risk for erroneous results that could be incorrectly alter medical decision making. However, these tests are not completely error-proof. These tests are not always performed by trained and competent individuals in settings that are designed to provide for maximal patient safety. The Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report of November 11, 2005 addressed this specific topic. The report is entitled "Good Laboratory Practices for Waived Testing Sites; Survey Finding from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing". This study found that while Certificate of Waiver sites performing waived testing "generally" take measures to perform tests correctly, there were "quality concerns about practices that could lead to errors in testing and poor patient outcomes."

p 1

The recommendations highlighted in this report include but are not limited to management responsibility for waived testing, personnel considerations (staffing, training, competency assessment, development of procedure manuals), cost considerations, specimen collection, safety, test ordering, patient identification, results reporting and documentation, quality control and confirmatory testing. The conclusion of this report is that "monitoring of waived testing, with a focus on personnel education and training is needed to improve practices and enhance patient safety as waived testing continues to increase".

Compromise:

Page 2, line 10; after "performing" insert "whole blood glucose".

Rationale: This compromise would allow long term care facilities the ability to designate a group of individuals to train in the competent performance of whole blood glucose testing and not broadly include the multitude of other waived tests.

Thank you.

Mark A. Koponen, M.D.

Member: North Dakota Board of Clinical Laboratory Practice

Associate Professor: University of North Dakota School of Medicine and Health Sciences

March 14, 2017

4

Testimony: Senate Bill No. 2202

Introduction and credentials

Chair, and members of the Committee, I am Dr. Ruth Paur, a member of the North Dakota Board of Laboratory Practice and Chair of the Medical Laboratory Science Department in the North Dakota School of Medicine and Health Sciences.

I am here in opposition to the proposed amendment to engrossed Senate Bill 2202.

Position on SB 2202

- Strongly opposed to the bill as it left the Senate with the following addendum:
  - Page 2, Lines 18-20
    - "Personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a_seq.I.]"
    - This addendum would allow any individual, including your barber, to complete and report waived tests without supervision by a medical center laboratory, licensed nurse, or health care provider.

Reasons for Opposition

- Protection of the health of ND citizens.
  - Approximately 30 years ago when the Clinical Laboratory Improvement Act of 1988 was created, there were about 8-10 waived tests that would allow anyone to perform and report laboratory data. Now there are thousands of tests that are listed as "waived"….which are easy to do, but do not necessarily give the result that reflects the disease or lack of the disease in the patient. We do not want this for the citizens of North Dakota.
  - I have brought along an example of a "waived test" to demonstrate this issue. This example of a "waived" test is for Influenza testing (three levels of testing: waived, moderate complexity and high complexity). Everyone is familiar with influenze….what we are all hoping not to catch today. Very serious upper respiratory viral infection that is either classified as Type A….the worst group, or Type B…the weaker of the two groups of viruses. You can get an influenze sample by getting a nasal swab and swishing the swab into the container of liquid. You then take a pipet and drop a few drops onto the filter paper and allow it to flow up the paper. The liquid flows up the filter paper and in a few minutes a line appears that shows the result. Yes, easy to do…so waived status. Now comes the dangerous part……what is the manufacturer telling us with the result? Representative Becker, you know where I am going with this. Let's say that Representative Keiser is the unfortunate ND citizen that is feeling pretty bad today. Representative Bosch got the nasal sample and is now running this "waived" test kit and it showed a positive result.

p1

Representative Keiser, now thinks that he has influenze. In actuality, if you are a laboratory scientist or physician you can wade through this package insert provided by this manufacturer that indicates that the positive test that Representative Bosch is giving may only be correct about 53% of the time in comparison to a high complexity test.....almost as bad as flipping a coin.

- This was an example of a "waived test" status. We do not want just anyone, including your barber and Representative Bosch, completing the thousands of easy to do, but not to interpret "waived" tests.

- Very, very dangerous for the people of ND to not have any regulations on the accuracy and interpretation of their laboratory testing and can be performed and reported without supervision or guidelines.

Compromise

- **Page 2, line 10 , after "performing" insert "whole blood glucose".**

  - The reason for the compromise is to allow long term care facilities, the ability to assign individuals they wish to complete the testing for whole blood glucose testing and not broadly include the other thousands of tests that are considered "waived".

Support Compromise

I would support the compromise proposal: Page 2, line 10, after "performing" insert "whole blood glucose".

Thank you.

Ruth Paur, PhD, MLS(ASCP)
Member: North Dakota Board of Clinical Laboratory Practice
Chair: Department of Medical Laboratory Science, North Dakota School of Medicine and Health Sciences
paur@polarcomm.com
701-869-2892

Mar 14, 2017

5

Testimony SB 2202
Industry, Business and Labor
March 14, 2017
North Dakota Department of Health

Good morning, Chairman Keiser and members of the Committee. My name is Bridget Weidner, and I am the Clinical Laboratory Improvement Amendments (CLIA) program manager for the North Dakota Department of Health, Division of Health Facilities. I am here today to testify in opposition of SB 2202, and provide information regarding CLIA as it relates to the bill. SB 2202 was amended in committee to add language that exempts personnel performing waived tests from licensure by the N.D. Board of Clinical Laboratory Practice. The waived tests are categorized by the Food and Drug Administration (FDA) based on the criteria established by the Clinical Laboratory Improvement Act of 1988.

CLIA is a federal program with requirements related to the practice of laboratory testing. CLIA regulates all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings. CLIA mandates that laboratories meet applicable federal requirements and have a CLIA certificate based on the complexity of testing performed.

A laboratory can apply for CLIA certification in several categories, and a CLIA Certificate of Waiver is one of those categories. A Certificate of Waiver is issued to a laboratory that performs only waived tests. A laboratory with a Certificate of Waiver is not subject to routine inspections and must follow the current manufacturer's instructions for the waived test systems they are using for patient testing. A Certificate of Waiver laboratory must appoint a director; however, there are no specific educational background, training or experience qualifications. In addition, CLIA does not have qualification requirements for personnel performing the testing. Under CLIA, anybody can apply for a Certificate of Waiver, be appointed laboratory director and perform laboratory testing without any qualifications and minimal oversight.

When CLIA was first enacted, there were eight CLIA waived tests, and today there are 127 different tests classified as FDA waived. The listing of FDA waived tests can further be listed by specific test system, assay and examination. From this perspective, it takes 232 pages to print out the approximately 26,000 different test systems, assays and examinations classified as waived by the FDA. These 232

pages were printed from the FDA website just a few weeks ago. The list is continuously growing and encompasses so many different tests that an individual could set up a fairly robust lab service just with waived testing, with the exception of microbiology cultures and blood banking.

The Division of Health Facilities performed surveys in Certificate of Waiver labs for many years. The survey of Certificate of Waiver laboratories halted nationally as of October 2016. North Dakota specific data from the past 15 years shows approximately 43 percent of the laboratories were noncompliant with regulatory requirements, 42 percent were noncompliant with laboratory best practices, and only approximately 15 percent were compliant with regulatory requirements and laboratory best practices.

In summary, I oppose SB 2202, which as passed out of the Senate allows anybody to perform any of the approximately 26,000 tests categorized by the FDA as waived, without regard for training or oversight of personnel performing the testing. The information I provided to you regarding the federal CLIA program demonstrates there is very little regulation or oversight of Certificate of Waiver laboratories. Based on the results of the Certificate of Waiver surveys conducted by the Department of Health, it would be a safer option to at least limit the waived testing to one specific test.

This concludes my testimony. I am happy to answer any questions you may have.

6

Testimony on SB 2202

House Industry, Business and Labor Committee

March 14, 2017

Good morning Chairman Keiser and members of the House Industry, Business and Labor Committee. My name is Shelly Peterson, President of the North Dakota Long Term Care Association (NDLTCA). We represent 212 assisted living, basic care and nursing facilities in North Dakota. We are here today to support SB 2202 as amended. I understand the ND Board of Clinical Laboratory Practice may be proposing a different amendment and if that amendment exempts the task of blood glucose testing under the preview of the Clinical Lab Board we would be supportive.

Assisted living, basic care and nursing facilities employ well over 12,000 individuals and care annually for over 16,000 North Dakotans. Numerous individuals cared for in long term care facilities are diabetic and require various levels of assistance throughout the day.

In assisted living, forty-two percent of tenants have impaired mental status ranging from mild confusion to forgetfulness to a mental health diagnosis. Forty-seven percent of tenants need full assistance with medication administration. These tenants on average take 10.4 over the counter and prescription medications daily. Many could probably take care of their own blood sugars, but their arthritic hands or poor eye sight cause them to seek assistance. Sometimes the mild confusion, doesn't allow them with confidence to monitor this vital component of their health so it is turned over to the facility.

In basic care, we see more cognitive and physical limitations. Eighty percent of residents have impaired mental status ranging from early stage dementia to disorientation. Ninety-five percent of all residents need full medication administration.

p1

Residents in both assisted living and basic care have stable medical conditions, but undoubtedly are dealing with chronic health issues and aging is becoming more evident.

Up until May 2014, the task of blood glucose testing though the use of various devices has been done by nurses and those under their supervision; nurse assistants, certified nurse assistants, medication assistant I and medication assistant II's. Attached is a handout detailing the scope of delegated medication administration for medication assistant I & II. Under this system the nurse is ultimately responsible to assure those under her supervision are properly trained, including demonstration of continued competency (annually).

In most states, blood glucose testing is a nursing task and delegated as such. As you know, checking blood sugars is a vital piece of information to assure those who are diabetic are within acceptable ranges and if not, interventions are made.

In May 2014 we became aware through a posting on the Board of Nursing website that nurses, according to NDCC Clinical Laboratory Personnel 43-48-03 Exemptions, may perform certain laboratory tests but nurses could not delegate laboratory tests to UAP or other unlicensed persons.

That posting disrupted the care and services to individuals living in basic care, assisted living, and nursing facilities causing statewide confusion and panic, especially in settings where a nurse is not required to be present 24/7, in our basic case and assisted living setting.

We reached out to the Board of Clinical Laboratory Practice and they indicated this was a lab test under their authority and as such nurses could perform this test, but others under their delegated authority could not. They indicated a licensed lab professional must supervise the testing and competence of an individual performing this test. We reached out to various hospital and clinic labs and almost universally they refused to fulfill this testing/supervision role. Their concern was

they were not comfortable, nor did they feel competent and the entity they worked for had concerns on liability. "How can I supervise people not in my lab, I see once a year and have no idea if they are following the correct protocol." Thus, we found ourselves in a very difficult situation.

We understood the reluctance of lab professionals.

NDCC 43-48 & NDAD 96-02-10-10 supervision for them meant:

1. The supervisor shall identify the individuals being supervised on a form provided by the board and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.
b. Not allow an individual supervised to start to continue performing tests until the individual has been properly trained and demonstrated competency.
c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon requests.
4. The supervisor shall regularly monitor and be available to consult with the individual being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

On July 14, 2014 the Board of Nursing reconsidered and rescinded their position, opening the door again for nurses and those under their delegation to complete this vital function. They did this out of concern for safety, as a gap was occurring when labs could not fulfill this statewide need. CNA's, nurse aides, medication assistants I & II's are still doing this function today, under the delegation of a nurse. Based upon a recent statewide survey, lab professionals are still not training, testing and supervising this function, nurses are. It is working and working well.

Legally the Clinical Lab Board indicated to use this test is under their jurisdiction, thus they continued to feel uncomfortable with nurses being allowed to delegate this task.

We did propose a solution to the Clinical Practice Board on July 8, 2014. We requested that they remove whole blood glucose testing by blood glucose monitoring system, as a test that must be completed, supervised or delegated by a lab professional. I believe that is the amendment the Clinical Lab Board is proposing today.

We believe the best option that is safe, proven and cost effective, assuring all residents in our care get the monitoring and intervention they depend on is having this specific test exempt from the oversight of the Clinical Practice Board and under the preview of a nurse. This is also the practice of most states.

Thank you for your consideration of SB 2202. I would be happy to answer any questions you may have.

Shelly Peterson, President
North Dakota Long Term Care Association
1900 North 11th Street
Bismarck, ND 58501
(701) 222-0660

p4

North Dakota Department of Health

Medication Assistant I

Scope of Delegated Medication Administration Statement

Registry Requirements:

- Must hold a current registration on the ND Department of Health Nurse Aide Registry as a Nurse Aide or Certified Nurse Aide prior to entry into the Medication Assistant I Training Program ,
- Must have completed a medication assistant I training and competency program (study and clinical practice in the administration of routine, regularly scheduled medications which meets the department's requirements), and
- Must hold a current registration on the department's registry as a Medication Assistant I.

Required Licensed Nurse Supervision and Delegation:

- May perform medication administration that has been delegated and supervised by a licensed nurse, consistent with completion of a department approved training program, scope of practice defined by regulation, and facility policies and procedures.
- May not perform medication administration if not under the supervision and delegation of a nurse.

Settings where a Medication Assistant I <u>can be employed</u> to provide delegated medication administration:

- Settings where the licensed nurse is <u>not</u> regularly scheduled including Assisted Living Facilities and Basic Care Facilities, however, none of the settings listed in the next section.
- If considering employment in a setting other than Basic Care or Assisted Living, contact the Department of Health to determine if it is an allowable setting for a Medication Assistant I to work in.

Settings where a Medication Assistant I <u>cannot be employed to provide medication administration</u>:

- Skilled Nursing Facilities,
- Acute Care setting,
- Clinics,
- Home Health Agency setting, and
- Private Home setting.

Medication administration that may be delegated to a Medication Assistant I who is supervised by a nurse include:

- Routine, regularly scheduled medication for individuals or groups of individuals with stable conditions which are administered on a routine basis and do not require determination of need, drug calculation, or dosage conversion.
- A stable patient is a patient the registered nurse has determined to have a predictable, non-fluctuating, and consistent clinical and behavioral status, and may have fluctuations that are expected with planned interventions.

Routine, regularly scheduled medications may be delegated by a licensed nurse to a Medication Assistant I for administration to individuals or groups of individuals with stable, predictable conditions via the following routes according to facility policies and procedures:

- Oral, sublingual, and buccal medications;
- Eye medications;
- Ear medications;
- Nasal medications;
- Rectal medications and enemas;
- Vaginal medications;
- Skin ointments, topical medications, including patches and transdermal medications;
- Metered hand-held inhalants; and
- Unit dose nebulizers.

<u>When specifically delegated by a licensed nurse to a Medication Assistant I for a specific</u> patient with a stable predictable condition, regularly scheduled medications via the additional following routes:

- Gastrostomy;
- Jejunostomy;
- Subcutaneous; and
- Premeasured injectable medication for allergic reactions.

A Medication Assistant I <u>may not administer medications via the following routes</u>:

- Central lines;
- Colostomy;
- Intramuscular injection;

A Medication Assistant I may not administer medications via the following routes (Cont.):

- Intravenous;
- Intravenous lock;
- Intrathecal;
- Nasogastric tube;
- Nonmetered inhaler;
- Intradermal;
- Non-unit dose aerosol or nebulizer; or
- Uretheral catheter.

A Medication Assistant I may not administer the following kinds of medications:

- Barium and other diagnostic contrast media;
- Chemotherapeutic agents except oral maintenance chemotherapy; or
- Through any medication pumps, or assume responsibility for medication pumps, including patient-controlled analgesia.

A Medication Assistant I cannot be delegated the decision to administer a pro re nata (PRN) medication in situations where an onsite assessment of the patient is needed prior to administration.

- For example, if a chemical restraint (medication) is needed for a documented emergency or to prevent injury to the resident or others, the chemical restraint must be authorized and documented by a physician for a limited period of time and the chemical restrain must be administered by a licensed nurse or physician.
- Some situations allow administration of PRN medications without directly involving the licensed nurse prior to each administration based on the following:
  - The decision regarding whether an onsite assessment is required is at the discretion of the licensed nurse.
  - Written parameters specific to an individual patient's care must be written by the licensed nurse for use by the Medication Assistant I when an onsite assessment is not required prior to administration of a medication. The written parameters: 1) Supplement the physician's PRN order; and 2) Provide the medication assistant with guidelines that are specific regarding the PRN medication.

A Medication Assistant I, or other individual on the department's registry, may not perform the following acts even if delegated by a licensed nurse:

- Conversion or calculation of medication dosage;
- Assessment of patient need for or response to medications; and
- Nursing judgment regarding the administration of pro re nata medications.

Specific Delegation of Medication Administration from a licensed nurse to a Medication Assistant I must comply with department regulation and facility policies and procedures. (Please note the four additional routes of medication administration that can be delegated through specific delegation by the licensed nurse.) The delegation must be for the delivery of a specific drug to a specific patient, and include the following steps:

1. The Medication Assistant I must receive a copy of the facility policies and procedures to follow regarding specific delegation.
2. The Medication Assistant is taught by the licensed nurse for each specific patient's medication administration with both verbal and written instructions (beyond the physicians order). The specific instructions include: a)The medication trade name and generic name; b) The purpose of the medication; c) Signs and symptoms of common side effects, warnings, and precautions; d) Route and frequency of administration; and e) Instructions under which circumstances to contact the licensed nurse or licensed health care provider.
3. The Medication Assistant I must be observed by a licensed nurse administering the medication to the specific patient until competency is demonstrated.
4. Areas the Medication Assistant I must be verified to be competent include: a) Knows the six rights for each medication for the specific patient, including the right patient, right medication, right dosage, right route, right time, and right documentation; b) Knows the name of the medication and common dosage; c) Knows the signs and symptoms of side effects for each medication; d) Knows when to contact the licensed nurse; e) Can administer the medication properly to the patient; and f) Documents medication administration according to organization policy.
5. Documentation that the Medication Assistant I has received the training related to specific delegation of medication administration for each patient must be maintained and updated when further instruction is received as necessary to implement a change.

Regulatory sources:

- NDCC Chapters 23-44 and 50-10.2
- NDAC ARTICLE 33-43
- Link to Applicable Rules: http://www.ndhealth.gov/HF/PDF_files/Nurse%20Aide%20Registry/Medication_Rules_10-22-2012.pdf

Effective Date: July 1, 2011

North Dakota Department of Health

Medication Assistant II

Scope of Delegated Medication Administration Statement

Registry Requirements:

- Must hold a current registration on the ND Department of Health Nurse Aide Registry as a Certified Nurse Aide prior to entry into the Medication Assistant II training and competency program,
- Must have completed a medication assistant II training and competency program (study and clinical practice in the administration of routine, regularly scheduled medications which meets the department's requirements), and
- Must hold a current registration on the department's registry as a Medication Assistant II.

Required Licensed Nurse Supervision and Delegation:

- May perform medication administration that has been delegated and supervised by a licensed nurse, consistent with completion of a department approved training program, scope of practice defined by regulation, and facility policies and procedures.
- May not perform medication administration if not under the supervision and delegation of a nurse.

Settings where a Medication Assistant II <u>can be employed</u> to provide <u>delegated</u> medication administration:

- Settings where the licensed nurse is either scheduled regularly or not regularly including Skilled Nursing Facilities, Assisted Living Facilities and Basic Care Facilities, however, none of the settings listed in the next section.
- If considering employment in a setting other than Nursing Facility, Basic Care Facility, or Assisted Living, contact the Department of Health to determine if it is an allowable setting for a Medication Assistant II to work in.

Settings where a Medication Assistant II <u>cannot be employed to provide medication administration</u>:

- Acute Care setting,
- Clinics,
- Home Health Agency setting, and
- Private Home setting.

Medication administration that may be delegated to a Medication Assistant II who is supervised by a nurse include:

- Routine, regularly scheduled medication for individuals or groups of individuals with stable conditions which are administered on a routine basis and do not require determination of need, drug calculation, or dosage conversion.
- A stable patient is a patient the registered nurse has determined to have a predictable, non-fluctuating, and consistent clinical and behavioral status, and may have fluctuations that are expected with planned interventions.

Routine, regularly scheduled medications may be delegated by a licensed nurse to a Medication Assistant II for administration to individuals or groups of individuals with stable, predictable conditions via the following routes according to facility policy and procedures:

- Oral, sublingual, and buccal medications;
- Eye medications;
- Ear medications;
- Nasal medications;
- Rectal medications and enemas;
- Vaginal medications;
- Skin ointments, topical medications, including patches and transdermal medications;
- Metered hand-held inhalants; and
- Unit dose nebulizers.

<u>When specifically delegated by a licensed nurse to a Medication Assistant II for a specific</u> patient with a stable predictable condition, regularly scheduled medications via the additional following routes:

- Gastrostomy;
- Jejunostomy;
- Subcutaneous; and
- Premeasured injectable medication for allergic reactions.

A Medication Assistant II <u>may not administer medications via the following routes</u>:

- Central lines;
- Colostomy;
- Intramuscular injection;
- Intravenous;
- Intravenous lock;

A Medication Assistant II <u>may not administer medications via the following routes (Cont.)</u>:

- Intrathecal;
- Nasogastric tube;
- Nonmetered inhaler;
- Intradermal;
- Non-unit dose aerosol or nebulizer; or
- Uretheral catheter.

A Medication Assistant II <u>may not administer</u> the following kinds of medications:

- Barium and other diagnostic contrast media;
- Chemotherapeutic agents except oral maintenance chemotherapy; or
- Through any medication pumps, or assume responsibility for medication pumps, including patient-controlled analgesia.

A Medication Assistant II <u>cannot be delegated the decision to administer a pro re nata (PRN) medication</u> in situations where an onsite assessment of the patient is needed prior to administration.

- For example, if a chemical restraint (medication) is needed for a documented emergency or to prevent injury to the resident or others, the chemical restraint must be authorized and documented by a physician for a limited period of time and the chemical restraint must be administered by a licensed nurse or physician.
- Some situations allow administration of PRN medications without directly involving the licensed nurse prior to each administration based on the following:
  - The decision regarding whether an onsite assessment is required is at the discretion of the licensed nurse.
  - Written parameters specific to an individual patient's care must be written by the licensed nurse for use by the Medication Assistant II when an onsite assessment is not required prior to administration of a medication. The written parameters: 1) Supplement the physician's PRN order; and 2) Provide the medication assistant with guidelines that are specific regarding the PRN medication.

A Medication Assistant II, or other individual on the department's registry, <u>may not perform the following acts even if delegated</u> by a licensed nurse:

- Conversion or calculation of medication dosage;
- Assessment of patient need for or response to medications; and
- Nursing judgment regarding the administration of PRN medications.

<u>Specific Delegation of Medication Administration from a licensed nurse to a Medication Assistant II</u> must comply with department regulation and facility policies and procedures. (Please note the four additional routes of medication administration that can be delegated through specific delegation by the licensed nurse.) The delegation must be for the delivery of a specific drug to a specific patient, and include the following steps:

1. The Medication Assistant II must receive a copy of the facility policies and procedures to follow regarding specific delegation.
2. The Medication Assistant II is taught by the licensed nurse for each specific patient's medication administration with both verbal and written instructions (beyond the physicians order). The specific instructions include: a)The medication trade name and generic name; b) The purpose of the medication; c) Signs and symptoms of common side effects, warnings, and precautions; d) Route and frequency of administration; and e) Instructions under which circumstances to contact the licensed nurse or licensed health care provider.
3. The Medication Assistant II must be observed by a licensed nurse administering the medication to the specific patient until competency is demonstrated.
4. Areas the Medication Assistant II must be verified to be competent include: a) Knows the six rights for each medication for the specific patient, including the right patient, right medication, right dosage, right route, right time, and right documentation; b) Knows the name of the medication and common dosage; c) Knows the signs and symptoms of side effects for each medication; d) Knows when to contact the licensed nurse; e) Can administer the medication properly to the patient; and f) Documents medication administration according to organization policy.
5. Documentation that the Medication Assistant II has received the training related to specific delegation of medication administration for each patient must be maintained and updated when further instruction is received as necessary to implement a change.

Regulatory sources:

- NDCC Chapters 23-44 and 50-10.2
- NDAC ARTICLE 33-43
- Link to Applicable Rules: http://ndhealth.gov/HF/PDF_files/Nurse%20Aide%20Registry/Medication_Rules_10-22-2012.pdf

Effective Date: July 1, 2011

North Dakota
Board of Nursing

Articles / General

Blood Glucose Testing

5/19/2014

This memo is intended to remind nurses that according to NDCC Clinical Laboratory Personnel 43-48-03 Exemptions. (2) Nurses duly and currently licensed to practice nursing and practicing within the scope of nursing license means that nurses may perform certain laboratory tests but nurses **cannot** delegate laboratory tests to UAPs or other unlicensed persons.

p9

AGENDA	ACTION
5.2-3 Dakota Nursing Program – Programmatic Changes	*Discussion:* Julie Traynor, Chair of the Dakota Nursing Program was present via phone. The program had worked with a consultant to review and revise their mission, philosophy, program outcomes and student learning outcomes. Traynor reviewed each with the board.
	Motion: J. Christianson, seconded by C. Christianson to: **ACCEPT THE DAKOTA NURSING PROGRAM NOTIFICATION OF MAJOR PROGRAMMATIC CHANGES AS THE PROGRAM HAS FULL APROVAL FROM THE ND BOARD OF NURSING AND THE PROGRAMMATIC CHANGES ARE IN COMPLIANCE WITH NDAC 54-03.2-06-02.**
	Roll call vote: C Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
5.3-1 Status of Policy: Continuing Education Providers request to be displayed on website & Continuing Education online (NEC)	*Discussion:* The NEC reviewed a current policy for entities such as CE provider to have their website link posted on the board website. With the website revision, the site no longer has a "links" section and the committee discussed whether it should be added. Currently staff have been referring these requests to the ND Center for Nursing. The committee agreed providers should not be posted on the board of nursing website and should be referred to the ND Center for Nursing and suggested the board post the information on where this information can be found on the Center for Nursing website.
	Motion from the Nursing Education Committee: **RECOMMENDS THE BOARD ARCHIVE THE POLICY REGARDING CE PROVIDER REQUESTS FOR DISPLAY ON THE NDBON WEBSITE AND REFER REQUESTS TO THE ND CENTER FOR NURSING.**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
	Discussion: A second policy titled "Continuing Education Online" also applies to the same situation and staff request this policy by archived as well.
	Motion: J. Christianson, seconded by Price to: **ARCHIVE THE DOCUMENT TITLED "CONTINUING EDUCATION ONLINE".**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
5.4-1 New Policy for Programmatic Changes (NEC)	*Discussion:* Staff developed new guidelines for Major Programmatic Changes that define what changes require prior approval by the board and require a motion for approval, which changes need to be submitted to the board for notification, and changes that do not require board notification. The NEC made recommendations for clarification at what point an increase in enrollment becomes a programmatic change, and that a degree change within a program would be a programmatic change. Staff added additional clarification since the committee met and requests a motion for approval of the current document.
	Motion: J. Christianson, seconded by C. Christianson that: **THE BOARD ADOPT THE NEW PROPOSED GUIDELINES TITLED "MAJOR PROGRAMMATIC CHANGES" WITH REVISIONS TO CLARIFY #5 UNDER SECTION 1 AND CLARIFY #2 IN SECTION III.**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
5.4-4 Nursing Education Loan Awards FY 2014-2015	*Discussion:* The NEC reviewed 53 applicants for nursing education loans under blind review. The full amount of award to each applicant was above the available funding. The committee reviewed an option to award all applicants 80% of the maximum amount or to award applicants a set amount by degree with graduate loans receiving a greater percentage of the funding. The committee recommended to the board to accept the 80% of maximum option.
	Motion from the Nursing Education Committee: **RECOMMENDS THAT ACCORDING TO NDAC 54-04.1 NURSING EDUCATION LOANS THE BOARD APPROVE THE ATTACHED INDIVIDUALS FOR THE NURSING EDUCATION LOAN FOR A TOTAL AWARDED OF $92,510.**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
6.1 Update on whole blood glucose testing – delegation to unlicensed persons	*Discussion:* Char Christianson reviewed a history of the issue that ND Board of Clinical Laboratory Practice (NDBCLP) had directed that nurses could not delegate Blood Glucose testing to a UAP or other unlicensed personnel and that the training for those procedures would need to be done by someone licensed under the NDBCLP. After discussing the issue at the March & May board meetings, the board posted the directive on the board of nursing website, and it has since generated many questions. It has been discovered that most laboratory personnel will not train UAP/CNAs for blood glucose monitoring, and this has a huge impact on schools and DD facilities where nurses are not regularly scheduled. At the request of NDBCLP, representatives of the Long Term Care Association, the NDBON, and the Department of Health have been meeting to resolve the issue. It was noted that the Board of Nursing has not been made aware of any safety issues or concerns. NDBCLP has discussed the rule revisions and will work with the board to find a solution.
	Motion: C. Christianson, seconded by Hanson to: **RECONSIDER THE DIRECTIVE FROM THE MAY 2014 & MARCH 2014 BOARD MEETING RELATED TO THE EXEMPTION IN NDCC 43-48-03 (2) THAT ALLOWS NURSES DULY AND CURRENTLY LICENSED TO PRACTICE NURSING AND PRACTICING WITHIN THE SCOPE OF THE NURSING LICENSE (TO COMPLETE WAIVED LABORATORY TESTS).**
	Roll call vote: C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.

AGENDA	ACTION
6.1 Update on whole blood glucose testing – delegation to unlicensed persons (cont.)	*Motion:* C. Christianson, seconded by Holth to: **DIRECT STAFF TO WORK WITH THE NDBCLP REGARDING CHAPTER 43-48-03-02 EXEMPTIONS THAT ALLOWS NURSES TO COMPLETE WAIVED LABORATORY TESTS AS THEY HAVE IN THE PAST AND DELEGATE TO UNLICENSED ASSISTIVE PERSONS UNTIL CLARIFICATION CAN BE WORKED OUT WITH THE BOARD OF CLINICAL LABORATORY PRACTICE.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, absent; Price, yes; Rustvang, yes; Schmalz, yes. 8 yes, 1 no, 0 absent. Motion carried.
7.1-1 DARP Charting – response from ND Department of Health	In the course of a recently reviewed Potential Violation Report against a licensee, it was noted that DARP charting (Data/Action/Response/Plan) was done by the unlicensed person. An anonymous call was also received in December 2013 related to the same issue at a different facility and the appropriateness of nurse aides charting in the nurse's notes. Staff sent a letter to the ND Department of Health related to the concerns. A response from Bridget Weidner, Program Manager at the Division of Health Facilities was reviewed and indicates they found no evidence of inappropriate charting in the information provided.
7.1-2 Delegation of medication administration and nursing tasks to Direct Support Professionals (see agenda item 12.12)	Staff have been meeting with representative of the DD facilities related to Nurse Delegation, looking at case studies of individuals who are residents and reviewing what tasks can be delegated and what tasks cannot be delegated. The board reviewed the minutes of the meetings.
7.1-3 NPC Subcommittee – Aesthetic Cosmetic and Dermatological Procedures by License Nurses Practice Statement (draft)	*Discussion:* The Nurse Practice Committee convened a subcommittee to review the practice statement entitled "Aesthetic Cosmetic and Dermatological Procedures by Licensed Nurses". The subcommittee suggested some revisions to the practice statement to add clarification in regards to knowledge and education. *Motion:* Schmalz, seconded by C. Christianson to: **APPROVE THE REVISED PRACTICE STATEMENT "AESTHETIC COSMETIC AND DERMATOLOGICAL PROCEDURES BY LICENSED NURSES" AND DISTRIBUTE TO STAKEHOLDERS.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
7.2-1 APRN Compact Statue discussion – Bergeson	*Discussion:* Brian Bergeson, SAAG for the board was present via phone for this agenda item. NCSBN has been working on an interstate licensure compact for advanced practice registered nurses for the last three years. Bergeson stated that the difference between the proposed APRN compact and the RN compact is that there is an Interstate Commission for APRN Compact Administrators who would be responsible for administering the compact and review and revise rules as necessary, and all states would agree the commission rulemaking would have the status of law. The RN compact contains more local control and the APRN compact would promote uniformity throughout the states. ND Nurse Practices Act and rules currently are consistent with the proposed APRN compact model rules. It is the obligation of the nurse to know and follow the practice act and requirements of the state in which they are practicing. The NCSBN Delegate assembly will vote on the APRN compact rules and the delegates would like direction as to how the board would like them to vote. *Motion:* C. Christianson, seconded by Schmalz to: **SUPPORT APRN COMPACT STATUTE AND RULES FOR VOTING PURPOSES AT THE NATIONAL COUNCIL STATE BOARD OF NURSING DELEGATE ASSEMBLY.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
7.2-2 APRN Compact Rules	The board reviewed the proposed APRN Compact Rules.
7.2-3 Key Elements of the APRN Compact	The board reviewed key elements of the APRN Compacts.
7.2-4 APRN Compact to Delegate Assembly	The board reviewed a NCSBN memo related to proposed revisions to the APRN compact that will be voted on at Delegate Assembly.
7.2-5 2014 State of Consensus Conference – Grandfathering Guidelines	*Discussion:* The board reviewed proposed guidelines for grandfathering APRNs by Endorsement during implementation of the APRN compact. Schmalz reviewed discussions at the APRN Roundtable and rationale for the scenarios. *Motion:* J. Christianson, seconded by Price to: **ADOPT THE GUIDELINES FOR GRANDFATHERING APRNS BY ENDORSEMENT CONSISTENT WITH THE APRN CONSENSUS MODEL.** *Roll call vote:* C. Christianson, yes; J. Christianson, yes; Gravely, yes; Hanson, yes; Holth, yes; Mayer, yes; Price, yes; Rustvang, yes; Schmalz, yes. 9 yes, 0 no, 0 absent. Motion carried.
7.3-2 Model Policy for the Appropriate Use of Telemedicine	The board reviewed a report of the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup titled "Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
7.4-1 Administrative Rule Promulgation	The board reviewed numerous health care bill proposals for the upcoming legislative session.

North Dakota
Long Term Care
ASSOCIATION

Shelly E. Peterson, *President* • *email:* shelly@ndltca.org

July 8, 2014

Sandra Matthey, Chair
North Dakota Board of Clinical Laboratory Practice
PO Box 4103
Bismarck, ND 58502-4103

Dear Sandra:

My name is Shelly Peterson, President of the North Dakota Long Term Care Association (NDLTCA). We represent eighty (80) licensed nursing facilities, sixty-five (65) licensed basic care facilities and sixty-four (64) licensed assisted living facilities. Together these long term care facilities employee around 15,000 individuals and care annually for over 19,000 individuals. Thank you for the opportunity to meet and discuss with you the issue of blood glucose testing and the requirements under NDCC 43-48-03 and NDAC 96-02-10-01.

Numerous individuals cared for in long term care facilities are diabetic. Those in assisted living facilities are fairly independent and many care for their own blood sugars, while those in skilled nursing facilities require continuous nursing care and close monitoring.

Currently the task of conducting the blood glucose testing through the use of various devices has been done by nurses and those under their supervision: nurse assistants, Certified Nurse Aide's (C.N.A.'s) and Certified Medication Assistant's (C.M.A.'s). We realize through a recent posting on the Board of Nursing web site and our seeking information from your board that nurses cannot and should not have been delegating this task to those under their authority and supervision. We recently sent information to our members informing them of the need to have a licensed lab professional supervise the testing and competency of an individual performing this lab test.

As we understand from NDCC 43-48-03 and NDAC 96-02-10-01 supervision means the following:

1. The supervisor shall identify the individuals being supervised on a form provided by the board, and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
    a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.

   b. Not allow an individual supervised to start to continue performing tests until the individual has been properly trained and demonstrated competency.
   c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon request.
4. The supervisor shall regularly monitor and be available to consult with the individual being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

Recently we hosted a telephone call on this issue and were most appreciative to have three members of the North Dakota Board of Clinical Laboratory Practice, Kathy Pepple, Sherry Melby and Bruce Pritschet participating in the call. As well as Dr. Constance B. Kalanek and Patricia Hill of the North Dakota Board of Nursing. We appreciated both state boards participating in this education session.

I am here to request that you remove whole blood glucose testing by blood glucose monitoring systems, as a test that must be completed, supervised or delegated by a lab professional.

In making this recommendation we ask that you consider the following:

1. The current practice of delegation and supervision by a nurse has been a safe, secure process. We believe the public is well protected.
2. C.N.A. turnover in nursing facilities is 58% (2012 data). This rapid rate of turnover would require numerous contact by lab professionals for competency testing and supervision.
3. Currently there are a number of glucose monitoring systems, with each resident and tenant selecting their choice or Medicaid requiring a certain device. As multiple devices are used in long term care facilities the lab professional would need to competency test and "supervise" on each device. This extra layer of professional oversight is adding costs, costs that will be added to each resident/tenant bill.
4. We have heard from one major health system lab, some rural hospital/clinic labs, and one independent lab that they will not provide the competency testing and supervisor to long term care nursing personnel because of the "liability" concerns. Compliance with the clinical lab requirement is becoming difficult for many because labs are reluctant to fulfill this role.

In conclusion we believe the practice of having blood glucose testing systems under the supervision and delegation of a nurse is safe practice. Clinical labs have some valid concerns and need guidance on the liability and supervision issues. To assure those thousands of individuals in long term care facilities get the care and services they need we ask that you implement an emergency rule to resolve this issue.

Thank you for listening to our concerns. We commit to working with you to assure public safety and continued care for our frail diabetic residents living in a long term care facility.

Sincerely,

Shelly Peterson

Shelly Peterson
President

SEP/pjt

SUPERVISION OF UNLICENSED PERSONNEL PERFORMING EXEMPTED TESTS FORM

North Dakota Board of Clinical Laboratory Practice
1/2006

Name of Licensee	
License Number	Work Telephone Number
Place of Employment	

As used in subsection 9 of North Dakota Century Code section 43-48-03 and section 96-02-10-01, "supervised" means the following:

1. The supervisor shall identify the individuals being supervised on a form provided by the board, and shall promptly notify the board of any changes to the information provided.
2. The supervisor shall ensure the individuals being supervised are appropriately trained in all tests and methods performed by the supervised individuals.
3. The supervisor shall:
    a. Perform annual competency assessments of the individuals supervised using generally accepted clinical laboratory standards.
    b. Not allow an individual supervised to start or continue performing tests until the individual has been properly trained and demonstrated competency.
    c. Document training and competency assessments, retain the documentation for three years, and submit the documentation to the board upon request.
4. The supervisor shall regularly monitor and be available to consult with the individuals being supervised.

Failure by the licensee to supervise is unprofessional conduct and may be subject to disciplinary action by the board.

List the following for each unlicensed personnel under your supervision:

Name	Background	Tests performed

Facility where exempted tests are being performed:

_____

Is there a plan in place for training and annual competency for the individuals listed above?

□ Yes □ No

Signature of Licensee_____ Date_____

Return completed form to: North Dakota Board of Clinical Laboratory Practice – PO Box 4103 – Bismarck, ND 58502

p15

North Dakota Hospital Association Est. 1934

Vision
The North Dakota Hospital Association will take an active leadership role in major Healthcare issues.

Mission
The North Dakota Hospital Association exists to advance the health status of persons served by the membership.

Testimony: 2017 SB 2202

House Industry, Business and Labor Committee

Representative George Keiser, Chairman

March 14, 2017

Good morning Chairman Keiser and Members of the House Industry, Business and Labor Committee. I am Jerry E. Jurena, President of the North Dakota Hospital Association. I am here to testify regarding 2017 Engrossed Senate Bill 2202 and ask that you amend this bill and give it a **Do Pass** recommendation.

This bill would add to the list of individuals exempt from the Clinical Laboratory Practice Board licensing requirements personnel who perform waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988.

We agree with the intent of the bill to provide some regulation of those who perform clinical laboratory tests, which includes blood glucose testing, without unduly mandating training and passage of a certifying exam. I understand the North Dakota Board of Clinical Laboratory Practice may propose an amendment to exempt the task of blood glucose testing from the oversight of the Board. We support such an amendment and ask that you exempt whole blood glucose testing by blood glucose monitoring systems as a test that must be completed, supervised, or delegated by a lab professional. We believe that nurse delegation and supervision of this limited testing has worked well and shows that this task may be safely and appropriately delegated by a nurse to nurse assistants, Certified Nurse Aides (CNA), and Certified Medication Assistants (CMA).

PO Box 7340 Bismarck, ND 58507-7340 Phone 701 224-9732 Fax 701 224-9529

We support this bill with the amendment described above and ask that, as so amended, you give it a **Do Pass** recommendation.

I would be happy to try to answer any questions you may have. Thank you.

Respectfully Submitted,

Jerry E. Jurena, President
North Dakota Hospital Association

8

SB 2202

Mar 14, 2017

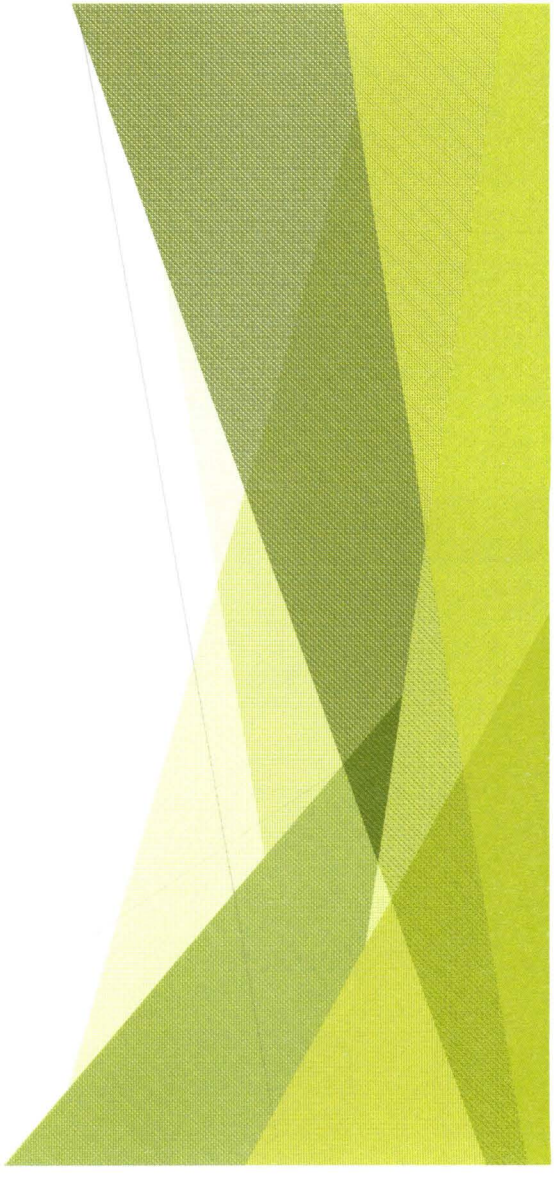
1d

Testimony Senate Bill 2202

Rebecca LaFavor MSN RN
Clinical Services Director
Edgewood Vista and Village

About me

- I have been a nurse for 19 years
- I have been the Clinical Services Director at Edgewood for 4 years
- My responsibilities include training personal care attendants (PCA) and certified nurse assistants (CNA)
- Developing quality care programs and monitoring care
- This training includes caring for the elderly with personal cares, such as activities of daily living (bathing, dressing, bathroom assistance, ect)
- It also includes training the PCA/CNA as medication assistance I



Medication Assistant I

- This training includes 4 hours self study
- 4 hours in class
- Minimum 4 hours on the floor, up to 16 hours if needed supervised by a nurse
- We follow up with the new medication aid weekly x 4, monthly x3 then quarterly. This follow up included watching all routes of medication administration and the specific delegated tasks - blood glucose testing and insulin injections are included

Medication Assistance I

- With this training they are the only ones allowed to complete blood glucose testing in my facility
- In four years I have not had safety issues related to inaccurately completing a blood glucose test
- The PCA/CNA medication aids work with several different blood glucose machines and during all the follow ups not one has put a resident at risk with this type of testing.
- With the waived CLIA definition this will allows nurses across the state to continue to delegate blood glucose testing.
- Please vote yes on Senate bill 2202

March 14, 2017

9

Testimony for Brooke Solberg: Senate Bill No. 2202

Introduction and credentials

Chair, and members of the Committee, thank you for the opportunity to speak today. My name is Dr. Brooke Solberg, and I am an Associate Professor in the Department of Medical Laboratory Science at the University of North Dakota, and a North Dakota licensed, certified and practicing Medical Laboratory Scientist (MLS) in the hematology department at Altru Hospital Lab in Grand Forks. I hold Bachelor's and Master's degrees in MLS. Currently, I am also serving as president-elect for the ND chapter of the premier professional society in our field: the American Society for Clinical Laboratory Science (ASCLS).

Position on SB 2202

I am here today in strong opposition to the proposed amendment to engrossed Senate Bill 2202 which states (page 2, lines 18-20) that "personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a_seq.I.]" would be exempt from ND licensure.

Reasons for Opposition

I am opposed to this amended bill because I feel that allowing anyone to do waived testing without training and without proper supervision would endanger the health and welfare of ND citizens for a number of reasons.

First, CLIA '88 was put in place almost 30 years ago when there were roughly 9 waived tests. The waived test list has expanded dramatically since then, from 203 in 1993, to 832 in 2000, to 1638 in 2004*. With over a 17,000% increase in waived test systems available since when it was implemented, it would seem that CLIA '88 guidelines were not established for today's waived testing environment.

Second, waived tests are considered to be simple to perform, but there seem to be some misconceptions associated with the term 'simple'. Simple does not mean that that waived tests are diagnostically irrelevant. Many waived tests provide results that providers utilize to make critical medical decisions, such as what therapy to initiate or how much of a certain drug to give. That means any mistake in performing or reporting a waived test could result in patient harm.

p1

Simple also does not mean that the consequences of improper waived testing are lessened. Infectious diseases such as Hepatitis and HIV can still be spread if proper collection techniques aren't utilized. Patients receiving a false negative result due to a testing error would still miss out on life-saving treatment, and patients receiving a false positive result might endure unnecessary emotional distress, such as in the case of a false positive HIV test.

Finally, waived tests may be simple to perform, but that does not guarantee that their 'simple' procedure will be followed, particularly by individuals who do not have a background laboratory science, and thus may not understand the consequences of their actions. For example, when performing a waived urine dipstick test, an important part is that the container must be sealed tightly after each use, so the reagent pads aren't exposed to humidity, which causes them not to work correctly and yield false results. So a person who doesn't have any training with lab tests, or isn't supervised properly, might not realize how important such a small, 'simple' step is, and may not go through the hassle of putting the cap back on every time. As a result, a Urinary Tract Infections could be missed when the dipstick gives a false negative, and patients would potentially end up with severe consequences. This is just one example of hundreds – almost all of which have some sort of consequence.

While I realize that requiring individuals performing waived tests to be supervised and/or have some training may not be the most convenient, I think it is more important that we protect patient safety. As such, I would support the compromise proposal (page 2, line 10) that limits waived testing exemptions to whole blood glucose testing only, as opposed to opening all of the waived tests up to performance by untrained, unsupervised, unlicensed individuals.

Thank you.

*data from Howerton et al.'s 2005 article in *Morbidity and Mortality Weekly Report:* Good Laboratory Practices for Waived Testing Sites

10

Testimony for Public Hearing on Senate Bill 2202
Samantha J. Peterson
March 14, 2017

Introduction and Credentials

Good morning chair and members of the committee. My name is Samantha Peterson. I am an ASCP certified and ND State licensed Medical Laboratory Scientist. I hold a Bachelor's and a Master's degree in medical laboratory science (MLS). I am currently an Assistant Professor at the University of North Dakota in the MLS department. I have practiced as a medical laboratory scientist at Altru Health System in Grand Forks, ND and worked as a graduate teaching assistant for the MLS department. I am also an active member of the American Society of Clinical Laboratory Science.

Position on SB 2202

I am here today in opposition of engrossed S.B. 2202, which states on page 2, Lines 18-20, "Personnel performing waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a_seq.I.]" and will allow all individuals in the state of ND to perform any CLIA waived laboratory test.

Reason for Position

I believe that the passing of engrossed S.B 2202 as written, will endanger the health and safety of North Dakota residents.

As defined by CLIA, waived tests are easy to perform with a low risk of inaccurate results. However, in order to obtain accurate results the performer must understand certain fundamental concepts of laboratory testing. I will highlight two of those concepts today, including quality control and interfering substances, both of which are equally important to obtaining accurate test results and are easily overlooked by those unfamiliar with laboratory testing.

Quality control is used to ensure that a test method is working correctly and that the results can be trusted. Many times, quality control is built into waived testing, but can very easily be ignored by the performer. For example, when interpreting the results of certain rapid Strep tests (a waived screening test for strep throat), you read a set of 2 lines. One line is a quality control line and the other is the result line. If the quality control line does not show up, even when the result line does, you cannot trust the test result. Something in the testing process went wrong, whether it was sample collection, sample preparation, one of the reagents, the test cartridge or simply user error. From my experience as a graduate teaching assistant training students in the laboratory, I can tell you first hand that when

an individual does not understand why they have to do something in the testing process, it often times gets skipped. When someone doesn't understand what quality control is or why it is important, it gets ignored. The mentality is that "I have a test result, so I'm good to go!", however without valid quality control, you have no idea if the result is accurate and therefore it is rendered useless.

Interfering substances are another easily ignored aspect of waived testing. Certain medications, medical conditions, foods and other substances can interfere with test results. Although all known interfering substances are listed in the manufacturer's package insert, they are not always reviewed or well understood by the test performer. An example of this occurred in 2005 by nursing staff in an ICU.* The patient was being treated with a medication that interfered with whole blood glucose testing, which was stated in the manufacturer's package insert, but was overlooked by the medical staff performing the test. When they obtained a falsely elevated blood glucose result, insulin was administered resulting in an overdose that led to severe hypoglycemia and irreversible neurological damage. This test was performed by trained healthcare professionals in a hospital setting performing a CLIA waived test, but they did not have adequate laboratory knowledge. If this can happen with trained individuals under supervision, imagine the consequences when untrained and unsupervised persons are performing waived tests.

Engrossed S.B. 2202 would not require individuals to have training prior to performing a waived test nor would it require the supervision of a medical professional. Certain waived tests are used to administer medication, such as heparin (blood thinner) and insulin (lower blood sugar). Basing medication administration on inaccurate test results could result in serious patient harm or even patient death. As a healthcare professional and a North Dakotan I feel obligated to urge you to deny a bill that would allow all individuals in the state of North Dakota to perform all CLIA waived tests. I would support the compromise proposal of: Page 2, line 10, after "performing"
insert "whole blood glucose".

Thank you for your time and consideration,

Samantha Peterson

* Case from : Alert, ISMP Medication Safety. "Be aware of false glucose results with point-of-care testing." Institute for Safe Medication Practices 10.18 (2005): 1-3.

p 2