17.0365.01000

# FISCAL NOTE
**Requested by Legislative Council**
**01/11/2017**

Bill/Resolution No.: SB 2184

1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

| | 2015-2017 Biennium | | 2017-2019 Biennium | | 2019-2021 Biennium | |
|---|---|---|---|---|---|---|
| | General Fund | Other Funds | General Fund | Other Funds | General Fund | Other Funds |
| **Revenues** | | | | $50,000 | | $50,000 |
| **Expenditures** | | | $142,218 | $50,000 | $84,969 | $50,000 |
| **Appropriations** | | | $142,218 | $50,000 | $84,969 | $50,000 |

1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

| | 2015-2017 Biennium | 2017-2019 Biennium | 2019-2021 Biennium |
|---|---|---|---|
| **Counties** | | | |
| **Cities** | | | |
| **School Districts** | | | |
| **Townships** | | | |

2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

Creates a new chapter to regulate/register phlebotomists & requires basic care and nursing facilities, hospitals, and home health agencies to file a public notification plan for potential exposures to infectious organisms. Requires DoH to investigate reports & ensure implementation of corrections.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

Section 1 requires the Department of Health (DoH) to establish and administer a phlebotomist registry. The DoH is also required to charge a registration and registration renewal fee to be deposited in the department's operating fund.

Sections 2, 3 and 4 require the Department to review and approve notification plans submitted from Basic Care Facilities, Nursing Facilities, Hospitals, and Home Health Agencies, receive reports of potential exposures to infectious organisms, to complete investigations, and to monitor to ensure plans and corrective actions are implemented.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

2017-2019:
It is estimated that there are approximately 1,000 phlebotomists in the state that would need to register and renew their registration each year. At an estimated cost of $25 for initial registration and renewal the revenue generated would be $50,000 during the biennium.

2019-2021:
With uncertainty as to the number of retirements and new entrants into the field we estimated the same amount of revenue to be collected as in 2017 - 2019.

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

2017-2019:
To implement this bill an FTE will be needed for 21 months of the biennium as the effective date is January 1, 2018 at a cost of $104,437, along with one-time IT and office equipment less than $5,000 of $5,225. Ongoing general operating costs, travel and system storage / maintenance costs are estimated to be $13,264 for the 21 months. Additionally, there would be a capital cost for a registry system developed by the Information Technology Department quoted at $69,292. Total biennial costs - $192,218.

2019-2021:
Salary costs for a full biennium are $119,356 and the ongoing general operating costs for a full biennium, inflated by 3% amount to $15,613. Total biennial costs - $134,969.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

The expenditures have not been included in the Executive Budget and would require an appropriation.

**Name:** Brenda M. Weisz

**Agency:** Department of Health

**Telephone:** 328-4542

**Date Prepared:** 01/20/2017

**2017 SENATE HUMAN SERVICES**

**SB 2184**

# 2017 SENATE STANDING COMMITTEE MINUTES

**Human Services Committee**
Red River Room, State Capitol

SB 2184
1/23/2017
Job Number 27195

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature Marie Johnson

**Explanation or reason for introduction of bill/resolution:**

A bill relating to phlebotomists and notification protocol in the case of exposure to an infectious organism, and to provide an effective date.

**Minutes:** 5 attachments

**Chair J. Lee:** Brought the meeting to order. Sen Clemens was absent.

**Senator Randy Burckhard (1:18-3:30) provided testimony in favor please see attachment #1.**

**V-Chair Larsen:** Nominal fee is it going to be $5.00, $10 or $ 20 or have they just determined what that fee the cost would be?

**Sen. Burckhard**: I will really don't know that answer, but I have a plethora of experts behind me who might have that knowledge.

**Chair J. Lee:** Gave FN is for $142,218 in General Fund expenditures and $50,000 in other funds. What it says it is an estimated there are approximately 1,000 phlebotomists that would meet the register and renew at an estimated cost at $25 for initial registration and renewal, revenue generated would be $50,000 during the biennium. But uncertainty as to the number of retirements and new entrance into the field, we estimate the same amount of revenue to be collected in the biennium.

**Sen Burckhard:** I heard in discussion this morning that there might be a full time employee that goes with this, so I don't know what I don't know.

**Senator Anderson:** Have you identified any instances when a phlebotomist is not employed by a hospital, a clinic, a laboratory, or in the case where your given blood by Blood Services or somebody else so that there is somebody who is responsible for the employment and training of those individuals. Are there any phlebotomists who are not underneath somebody else's direction?

**Sen. Burckhard:** Not that I am aware of. They probably all are employed by a facility that has done some training obviously, I would expect that.

**Senator Kreun:** Page 1 line 22, person exempt from this section, who is exempt?

**Sen Burckhard:** I don't know that.

**Senator Heckaman:** So, if you already have this in your scope of practice, you' wouldn't need to re-register, if you're a med tech or nurse or somebody like that or EMT, or whatever. But you wouldn't have to be registered under this additional section would you?

**Sen Burckhard:** I would guess they'd create that registry so that it would be a new statewide registry, so I would think they would.

**Chair J. Lee:** Former med tech, ex of function that people follow that would be covered by more than one scope of practice. We are just talking about actually are those who just phlebotomists, just stick people and not doing any of the lab results involved because that is what most facilities are doing now, with the exception of blood banks.

**Senator Heckaman:** Page 2 bottom about notification to public if there is a breach, was that done in Minot? Was the public notified right away on that or was that after the fact, quite a while after? Looking on here, should we have a timeline in there, maybe?

**Sen. Burckhard** I'm not sure how soon they were notified. I do not know that.

**Chair J. Lee:** It'd be hard to notify if you don't know you did it. So that will be part of our discussion.

**Cheryl Rising, (9:20-11:20) testified in favor, provided testimony please see attachment #2.**

**Derick Solberg** (**11:40-16:45**) testified in favor. Did not provide written test. Related personal stories.

**Chair J. Lee:** Similar expectation of anybody else, do they have to disclose. What is the responsibility of individual with infectious disease telling other people that they have it? There are some privacy rights that are pretty strong for the patient as well. So your saying that basic care needs to disclose to patient that they might be exposed. But I am not hearing you say that that the person who has an infectious disease, whatever it might be, has to disclose that they have that because that is part of why, it isn't just the facility.

**Mr. Solberg:** Some responsibility would fall to me, if it's me to let them know.

**Chair J. Lee:** I would point out one difference between phlebotomist and barber. Most barbers practice independently, no phlebotomists practice independently. They will be working under the supervision of either people in the clinical lab or in the other medical facilities or care facilities in which the work might need to be done, but there are protocols in place for those places if somebody failed the protocol that is already there, that's different

than it would be for them not to have a protocol. So, there is a difference between a barber and the phlebotomist. Barbers work independently.

**Senator Kreun:** Sen Burckhard's testimony it says it seems to be evidence that the disease may have been spread through phlebotomy. Where did this take place?

**Mr. Solberg:** Manor Care, Trinity hospital. He had phlebotomy done, do that's what I can tell you.

**Chair J. Lee:** There was no determination in the investigations of what the actual origin of the problem was, but there is some theory and thought that maybe where it comes from. There is no and we don't have a report that says this is where it came from.

**Senator Kreun:** How many instances have we had in the past 2-3 years of a situation that are like this within the state?

**Mr. Solberg:** I haven't heard of any other. It's rare in US. This is a huge outbreak, considered a very big outbreak.

**Chair J. Lee:** We will have test from Health Dept.

**Mr. Solberg:** There are court filings you may want to look at

**Senator Anderson:** You have a sense that the requirements we are putting in place with this bill, would have changed anything related to the people who were at the facility, how would it have changed anything if this was in place?

**Mr. Solberg:** It would have reduced the risk, the safety. I would have had my father moved had I known that this was going on. Yes, but with this in place, I think it would have reduced the possibility. That being said, we're not asking you to reduce this by 100%, and that will never happen again, that is impossible. We're just asking you to take steps to reduce the possibility.

**Chair J. Lee:** Do you think the notifications anytime anybody is stuck is going to impede the ability of people to have test done because they are going to be now worried about it?

**Mr. Solberg:** Will it impede?

**Chair J. Lee:** If my elderly relative had some light cognitive issues and was in a memory care unit, and they are giving this disclosure and there's still cognitive enough to be able to read a disclosure, but perhaps not to think clearly entirely or even if they are to say, I don't want any chance of that happening, what do you think might be the potential of somebody even though the odds are very slim that something like this might happen. Believe me I want everybody health and safe, but what kind of resistance do you think might give cause among people who are being stuck, whether in a lab, clinic or long term care facility.

**Mr. Solberg:** That's hard to say, I'd seek out another facility.

**Chairman J. Lee**: But you are requiring every facility, by disclosure, maybe I misread this, I thought a disclosure says you've got to tell somebody when they are being stuck that they have a risk of exposure but being stuck, are you just saying that?

**Chair J. Lee:** That's a little over the top. The paperwork is mind boggling. This bill isn't clear on that. We have to make sure we are not putting a heavy burden on the providers as well. They are already regulated by the Health Department, and the Feds and the state, all that kind of stuff.

**Jerry Jurena:** (26:50-32:05) provided testimony for a do not pass, see attachment #3

**Senator Anderson:** Hospitals already required to report, walk us through a scenario and how that works that now with the notification, who's notified, and so forth?

**Jerry Jurena:** Each hospital has to have a plan that is compatible with the conditions of participation and if they are a large hospital the joint commission of accreditation. Each hospital may have their own plan, I could step you through what we did in Rugby, when I was there for 15 years. Ex cited.

**Senator Anderson:** That notification never got to the hospitals patients directly? That is really what this bill is asking, if the patients be notified, correct?

**Jerry Jurena:** Yes, in the notification process, we notified everybody involved. When we report to state, all that information has to be sent to the state as to what and who was contacted.

**Chair J. Lee:** Did that include notifying other patients who may have been in the hospital at the time?

**Jerry Jurena** If they were involved in this incident, same area, same blood draw our fish boating would go back through and clarify as to who needed to contacted.

**V-Chair Larsen:** Turnover rate, in Minot idea, how did they find those people not registered if they worked there a little while, and then quit. Did they run them down, how did they get ahold of those folks?

**Jerry Jurena:** I can't answer how they would do that in Minot, in Rugby, we'd had were individuals who were lab technicians, MLT's that they would do the blood drawing and they were the ones that were going out there. When we got up into long term care, if you were doing blood sticks for glucose tests, all those people had to be trained. We had to log the training that they had to do, and then we kept notes in the patients record as to who was the one that did the glucose sticking up there. So we would have a record of who did what, to that patient.

**V-Chair Larsen:** They were doing blood sticks, then quit, how did they find them, is there a follow up? That's what the registry would be and say these guys were working here with his name and address and call him, this would streamline getting ahold of these folks even if they worked or not worked anymore in the field.

**Jerry Jurena:** We had never had an incident, we never had to find anyone, I would assume, these were the employees at the time, notifying them these were the employees, that were employed at the time who had direct contact with the patient and then we would determine either through our own process, or the Department of Health how are we going to track these people down.

**Chair J. Lee:** What about the people who leave, go on Facebook? My point is a turnover. Repetitious. Talk to me about liability if they weren't careful about this because I know you have infectious control offices and procedures in place right now. What is the liability for the hospital if you weren't careful about this?

**Jerry Jurena:** The liability runs deep in to each facility if I employ lab tech or an MLT or a CAN, who's doing lab procedures or patient sticks, if I am employing somebody at a long-term care facility who is doing glucose monitoring, all of that would be under our umbrella, and we would be liable 100%, for our plan and for any issues that would come about.

**Chair J. Lee:** So you have an incentive to keep everything on the right tract.

**Jerry Jurena**: We have a huge incentive because our processes are deeper than anybody else's.

**Senator Anderson:** The individual that draws my blood fixes name to draw. I am not sure that they ever record who actually is the one who sticks you and takes your blood. Maybe that's an issue here, can you answer that, are those individual available to track down?

**Jerry Jurena:** In the hospital setting, the lab tech draw blood, their name is logged that they are drawing that. When the CAN's up in long term care are doing the glucose sticks their name is in the lab. Larger facility, I don't know if log happens, I'm barcoded, I would assume that individual has a name attached to that.

**Senator Heckaman:** Is there any place in Century code where phlebotomist defined and tells much about what they can do, or where they can do it.? I know it's a new section, but is that term anyplace else?

**Jerry Jurena:** I'd have to read through the conditions that participation to see exactly what it says, I am not sure at this time.

**Chair J. Lee:** We can ask Ian to do that?

**Kirby Krueger, Medical Services Section Chief, ND Dept. of Health: (42:25-46:05) Provided neutral testimony. Please see attachment #4.** 23-07.5-02 Already addresses blood borne pathogens, **please see attachment #5.**

**Senator Anderson:** Explain nosocomial infection is because for those of us who don't know.

**Kirby Krueger:** A nosocomial infection is an infection that occurs as a result of receiving health care.

**Senator Anderson:** You were involved in trying to track down the cause of these things. Can you explain to us whether the system we have now of recording individuals that actually perform the services was adequate in this case for you to track down those individuals and ask your questions?

**Kirby Krueger:** During our investigation we were able to pull lab records for every patient that we were interested in and those laboratory records gave us the name of the person who drew the blood, the time that it was drawn, the date it was drawn.

**Chair J. Lee:** Are there other infections besides those that might be because of a uni-puncture, and I know that we don't have these numbers of big infectious outbreaks but could you review briefly for us how many more and we must understand whether that is something that might be related to this particular cause?

**Kirby Krueger:** We investigate 3-4 a year they range from antibiotic resistance organisms, to influenza, gastrointestinal outbreaks, and we help those facilities. The division of disease control is not a regulatory division, so our job is to go and provide technical assistance, guidance, encouragement, whatever we can do to try to put one of these into place.

**Chair J. Lee:** There is also a Quality Health Facility. What does it do for the benefit for the committee members who are not familiar with that?

**Jerry Jurena:** We have worked for many years with Quality Health Associates. Before they were the North Dakota Health Care Review. They track quality issues for the hospitals and submit that information to CMS. They are currently tracking 10 different criteria with the HIN program for the hospitals. They also do a lot of tracking for physicians, and other components; all of it is quality based.

**Senator Heckaman:** Other than blood born contaminations, were other sources also investigated, other sources of contamination in this outbreak in Minot?

**Kirby Krueger:** The outbreak was Hep C, and it was a blood born pathogen, strictly a blood born pathogen, so we were able to focus on those procedures that might result in transmission of infected blood from one person to another.

**Senator Kreun:** From information gathered that you did, I am assuming you were heavily involved in Minot, what was the outcome and the solution to this problem that may or may not have existed in one of those facilities. What conclusion did we come too?

**Kirby Krueger:** Our investigation revealed that out of the 52 cases, 48 cases were current or former residents of one facility. Our focus was really on that facility and we weren't able to see actual breaches in infection control, reviewing some procedures could be improved. The solution in order to prevent the outcomes that the Department of Health contracted with infection control expert that spent a week up in the facility, helping them to review procedures, implement policy, make suggestions for changes and that's how we proceeded with that.

**Senator Kreun:** That took care of the problem up to this point?

**Kirby Krueger:** We have conducted testing from 2013-2016 up in Minot about 1600 tests on 1300 people, some were tested serially over time, and our last testing didn't find any evidence of further transmission. The one facility that had the majority of the cases in it, that facility was required to perform monthly testing on all of the residents, all the new admits, and on discharge patients everybody was tested and we did not find any evidence of ongoing transmission.

**Senator Kreun:** What we did was a thorough investigation, as safely as we possibly can be, am I understanding that correctly?

**Kirby Krueger:** We feel comfortable that we got to the root of this, yes.

**Senator Anderson:** Clinical lab board I would like their take on this.

**Bruce Pritchett, Designate for the Health Department on the Clinical Lab Board:** I'm at a conflict of interest with this situation. I can tell you what the Board does, but I can't make decisions for them.

**Chair J. Lee:** Mention to board president, to come and visit with us.

**Bruce Pritchett:** They have been notified, and they know that the Health Department was going to testify to move it to the Board, and I thought maybe one would show up here this morning but they didn't. I am the only member in Bismarck, the others are in Grand Forks, Dickinson and Fargo.

**Chair J. Lee:** They can email us.

**Senator Anderson:** Maybe some info, some might be required to register, how might be exempt, or whatever, to make some estimates on that.

**Bruce Pritchett:** It is a fairly large guess, it varies, some places professionals, some places don't, it is a very large guess, perhaps 800-1000. There are also a number of entities across the state that intervene constantly. The Blood Services was mentioned and also the Plasma Centers across the state do the same thing. So there is a lot of phlebotomy going on that is not the clinical lab diagnosis.

**Chair J. Lee:** (57:00) related a story about x-ray techs.

**Senator Piepkorn:** So what actually happened did anybody ever figure that out?

**Bruce Pritchett:** Hep C is an infection affects liver, new treatments available, not well studied in age group, many might not have impacted life.

**Chair J. Lee:** There are new drugs that can cure Hep C, but they are expensive. Cheaper than liver transplant though.

**Senator Heckaman:** You mentioned podiatrists, should we be talking about them? Was that a significant enough finding that some issues should be direct addressed?

**Kirby Krueger:** There were some issues in the space that they were working, the Board of Podiatry regulates themselves. Obviously we rely on them to do this and we provided our recommendation.

**Chair J. Lee: Closed hearing on 2184.**

# 2017 SENATE STANDING COMMITTEE MINUTES

**Human Services Committee**
Red River Room, State Capitol

SB 2184
1/30/2017
Job Number 27602

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature BAnderson

**Explanation or reason for introduction of bill/resolution:**

A bill relating to phlebotomists and notification protocol in the case of exposure to an infectious organism, and to provide an effective date.

**Minutes:**

**Chair J. Lee** opened committee work on SB 2184.

**Senator Anderson** gave his opinion on this bill. His sense from the beginning of the testimony was that it is a reaction to the Hepatitis C outbreak in Minot. He didn't feel like this bill would have changed anything in that outbreak. These reactionary things put additional hardship on the agencies that are trying to employ these people. His personal opinion is that there are enough requirements in place. He wasn't sure the Clinical Laboratory Board always agrees with that in the case of the phlebotomists.

**Senator Anderson** moved a **Do Not Pass.**

**Senator Kreun** seconded the motion.

**Discussion: Chair J. Lee** said the Clinical Lab Board doesn't want them. They can't handle the registry. **Senator Heckaman** remembered somebody had testified that maybe it had something to do with the foot care facility.

Roll call vote 7-0-0. **Motion carried**.

**Carrier is Senator Clemens.**

Date: 1/30 2017

Roll Call Vote #: 1

**2017 SENATE STANDING COMMITTEE**
**ROLL CALL VOTES**

**BILL/RESOLUTION NO.** 2184

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

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

Other Actions: ☐ Reconsider ☐ _____

Motion Made By 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. Clemens

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

## REPORT OF STANDING COMMITTEE

**SB 2184: Human Services Committee (Sen. J. Lee, Chairman)** recommends **DO NOT PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2184 was placed on the Eleventh order on the calendar.

**2017 TESTIMONY**

**SB 2184**

SB2184 Attach #1 1/23

SB2184

(introduction by State Senator Randy Burckhard, District 5, Minot)

*Relating to notification protocol in the case of exposure to an infectious organism and to provide an effective date.*

*This bill relates to Chapter 23 of the NDCC pertaining to Health & Safety, Basic Care Facilities and Home Health Agency Licensure.*

There was an unfortunate outbreak of Hepatitis C that occurred in Minot in 2014. Experts have not pinpointed an exact cause of this outbreak. There seems to be evidence that the disease may have been spread through phlebotomy.

Phlebotomists, as we all know, often are the first employee a patient will see after they are admitted to a facility. It was a surprise to me that there is no registry for phlebotomists in our state.

*We do not know how many phlebotomists are working in North Dakota, nor who they are. Through this bill we will know who they are and what the common denominator is.* ***There is no cost to the state****, but there will be a nominal cost/fee for each phlebotomist.*

To make sure there is ongoing compliance for the standards of licensure, SB2184 contains clear recommendations on surveying of healthcare facilities, including the adoption of maintenance of personnel folders on each agency employee. Also included in this bill is the mandate, as a condition of licensure and licensure renewal, that each facility file with the Dept. of Health, a department approved notification plan.

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Prevention, education and readiness are essential and SB2184 provides these layers of patient safety in a necessary way for the citizens of North Dakota.

I would stand for any questions??

SB 2184
Attach #2
1/23

NDNPA
NORTH DAKOTA
Nurse Practitioner Association

TESTIMONY TO:

SENATE HUMAN SERVICES COMMITTEE

65TH NORTH DAKOTA LEGISLATIVE ASSEMBLY

Senate Bill 2184 1/23/2017

Madam Chairman Senator Lee and Committee Members:

I am Cheryl Rising, Family Nurse Practitioner (FNP) and Legislative Liaison for the North Dakota Nurse Practitioner Association (NDNPA). I am here to testify in support of Senate Bill 2184 A BILL for an Act to create and enact a new section to chapter 23-01 and a new section to chapter 23-16 of the North Dakota Century Code, relating to phlebotomists and notification protocol in the case of exposure to an infectious organism; to amend and reenact sections 23-09.3-04 and 23-17.3-05 of the North Dakota Century Code, relating to notification protocol in the case of exposure to an infectious organism; and to provide an effective date.

NDNPA does support safety, education and competence in regards to venipuncture and phlebotomy.

NDNPA does question who this phlebotomist registry applies to. This bill refers to basic care facilities on Page 2, hospitals and home health agencies on page 3. It does state on page 1 line 22 that it will define persons exempt.

For example would this bill affect an organization that has an APRN that educates, observes and documents the correct protocol for venipuncture? I personally am a Family Nurse Practitioner at a local Ophthalmology Clinic. I am responsible for

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educating, demonstrating and observing 3 or more successful venipuncture on technicians that are training to assist with certain testing. Records are kept of individuals educated, date, time and site of venipunctures. Our request would be clinics or other facilities that participate in this kind of education are exempt.

NDNPA does support this bill If agencies that have protocols already in place are exempt from sending individuals to additional training, registering and paying a fee every year.

Cheryl Rising, FNP crisingnp@gmail.com 701-527-2583

SB 2184
Attach #3
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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 2184
## Senate Human Services Committee
## Senator Judy Lee, Chairman
## January 23, 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 (NDHA). I am here to testify regarding 2017 Senate Bill 2184 and ask that you give this bill a **Do Not Pass** recommendation.

This bill would place additional burdens on healthcare facilities that are unnecessary. While we appreciate the intent, we do not believe it will add any protections for patients and merely duplicates many of the obligations that are already contained in licensing, accreditation, and conditions of participation requirements. And it would be difficult, if not impossible, for facilities to comply with the other requirements of this bill.

Our members oppose this bill for the following reasons:

- This bill would set up a new system of regulation of anyone who draws blood from a human being. It would require these individuals to register with the State department of health and pay a fee not to exceed $25 to be determined by the State health council in rule. This new fee adds additional expense for healthcare facilities. There is high turnover with phlebotomists – it is not uncommon for such a worker to remain in the position for only a few months. This will require facilities to pay the registration fee each time a phlebotomist quits and a new one is hired.

- This bill would require anyone who draws blood to establish proof of completion of "health safety education requirements". These requirements are not defined in the bill

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

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and will instead be established by the State health council by rule. It is unclear how much, or what kind of, training individuals will need to have.

- Individuals will also have to satisfy any other "registration criteria" established by rule. It is unclear what these other requirements may be.

- The bill provides no exemption for other healthcare practitioners such as physicians, registered lab techs, or nurses who have extensive training in how to draw blood. It would, instead, require the State health council to adopt rules to address persons exempt from the requirements of the bill.

- It would require healthcare facilities including hospitals to file with the department of health an "approved public notification plan". The public notification plan must provide the facility's protocol for notifying individuals of potential exposure to infectious organisms due to an unsafe practice or infection control breach. The plan must include notification of potential exposure of a patient, an employee, a contractor, or a member of the public.

  Facilities already have infection control requirements. For example, Medicare conditions of participation require hospitals to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases and have an active program for the prevention, control, and investigation of infections and communicable diseases. Hospitals must also designate an infection control officer to develop and implement policies governing control of infections and communicable diseases. The infection control officer must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel and must maintain a log of incidents related to infections and communicable diseases. The chief executive officer, the medical staff, and the director of nursing services must ensure that the hospital-wide quality assessment and performance improvement program and training programs address problems identified by the infection control officer and they are responsible for the implementation of successful corrective action plans in affected problem areas.

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- The bill also requires the facility to report the event to the Department of Health which triggers the department to investigate the event and ensure the plan is implemented and notifications have occurred. Again, hospitals are already required to report such events.

In summary, this bill will impose numerous obligations on facilities which are yet to be defined. It will impose new costs to register every employee that draws blood. It will require facilities to prepare a public notification plan that must be approved by the State which will impose onerous requirements to notify patients, employees, contractors, and members of the public of "unsafe practice or infection control breach" without description of what such practices may be or who determines when they occur. Most importantly, patient safety in this area is already regulated by state hospital licensing requirements, CMS conditions of participation, and The Joint Commission accreditation standards. This bill would add nothing to patient safety while imposing new, as yet to be defined, regulatory burdens on hospitals.

For these reasons, we oppose this bill and ask that 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

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Attach #4
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# Testimony
# Senate Bill 2184
# Senate Human Services Committee
# Monday, January 23, 2017
# North Dakota Department of Health

Good morning, Chairman Lee and members of the committee. My name is Kirby Kruger, and I am the Medical Services Section Chief for the North Dakota Department of Health. I am here today to provide information and suggest some changes to Senate Bill 2184.

Senate Bill 2184 requires the Department of Health to establish and administer a phlebotomist registry and that the health council adopt rules to implement this section. There are estimated to be 800-1100 phlebotomists in North Dakota who are hired to draw blood from a vein for diagnostic and donation purposes. Currently, these individuals are not regulated and are not listed on a registry. While there is a benefit to having these individuals regulated and registered, we do not believe that the North Dakota Department of Health is the appropriate agency for this function. The regulation and registry of laboratory personnel is currently performed by the North Dakota Board of Clinical Laboratory Services. The individuals on this board have the knowledge to provide the oversight for the regulation and registration of phlebotomists as this relates to laboratory testing and services. Most phlebotomists work within laboratory services of health care entities.

Senate Bill 2184 also requires health care entities to notify residents, employees or members of the public of potential exposure to infectious organisms due to an unsafe practice or infection control breach and requires health care entities to provide the department with a plan for public notification of all potential exposures to infectious organisms. Finally it requires health care entities to notify the department of potential exposures and the department to investigate these events and ensure the plan is implemented and notification to the public has occurred. The department currently has requirements for the reporting of certain infectious diseases as well as nosocomial infections. This differs from reporting of all potential exposures to infectious organisms discussed in this bill.

We believe it would be difficult for facilities to publically report any potential exposure to an infectious organism that may occur for a resident, an employee, or member of the public. For example, as the bill is written, any time a physician would have contact with a patient without washing his or her hands, a public report may need to be made as there is no way of knowing if a potential infectious organism is present, if transmission of that agent actually occurred, or if there is ability to identify an infection control breech or unsafe practice. It is hard to know what to publically report if no infectious organism has been identified.

The Division of Disease Control, as well as the Division of Health Facilities both participate in investigating infections that have been reported in these health care entities. We work to ensure plans of correction have been implemented to prevent further infections from occurring. We do not believe that it is reasonable to expect that an investigation take place until such time as there is a known infectious disease present.

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The department has provided a fiscal note of $192,218 with $142,218 from the general fund and 1 FTE for the 2017-19 biennium and $134,969 with $84,969 from the general fund and 1 FTE for the 2019-21 biennium. The estimated revenue from registration fees is $50,000 using a registration fee of $25 per year.

I would be happy to answer any questions that you may have at this time.

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# CHAPTER 23-07.5
# BLOODBORNE PATHOGEN TESTING

**23-07.5-01. Definitions.**

In this chapter, unless the context otherwise requires:

1. "Bloodborne pathogen" means a micro-organism that is present in human blood or in other bodily fluid or tissue which can cause a disease in humans, including the hepatitis B virus, the hepatitis C virus, and the human immunodeficiency virus, and for which testing is recommended by the United States public health service.
2. "Exposed individual" means an individual, including a patient, health care provider, firefighter, peace officer, correctional officer, court officer, law enforcement officer, emergency medical technician, laboratory personnel, or an individual trained and authorized by law or rule to render emergency medical assistance or treatment, including an individual rendering aid under chapter 32-03.1, who is exposed to a bloodborne pathogen.
3. "Exposure" means a percutaneous injury, including a needle stick or cut with a sharp object; contact with blood, bodily fluid, or tissue of a mucous membrane or nonintact skin, including exposed skin that is chapped, abraded, or afflicted with dermatitis; or contact with other bodily fluids that are potentially infectious as determined under guidelines of the United States public health service.
4. "Health care" means any services included in the furnishing to an individual of hospitalization, or medical or dental care, or any services incident to the furnishing of that care or hospitalization, as well as the furnishing to an individual of any other services for the purpose of preventing, alleviating, curing, or healing human illness or injury.
5. "Health care provider" means an individual licensed, certified, or otherwise authorized by the law of this state to provide health care and includes personnel at the state crime laboratory or any commercial or research laboratory that handles blood, bodily fluid, or tissues.
6. "Informed consent for testing" means that the individual to be tested for bloodborne pathogens has been informed of the nature of the testing; the reason for the testing; the relevant risks, benefits, and potential alternatives for testing; and the individual has granted permission to be tested.
7. "Personal representative" means any person who has authority under law to act on behalf of an individual or deceased individual in making decisions related to health care or health information.
8. "Test subject" means the individual who is the source of the blood, other bodily fluids, or tissue that caused the exposure.

**23-07.5-02. Informed consent for testing - Exception.**

1. Except when testing is otherwise permitted by law, a health care provider, blood bank, blood center, or plasma center may not subject an individual who is the source of an exposure to a test for bloodborne pathogens unless the subject of the test or the subject's personal representative if the subject is a minor or is incapacitated first provides informed consent for testing.
2. If an individual who is the source of an exposure has had blood drawn that is available for testing and the individual has refused to grant consent to have that individual's blood tested for bloodborne pathogens, that individual's blood may be subjected to a test for the presence of bloodborne pathogens, without that individual's consent, if a physician or other qualified health care provider based on available information determines and certifies in writing that the individual had an exposure and before testing the test subject is informed that the test subject's blood may be tested for the presence of bloodborne pathogens; that the test results may not be disclosed without the test subject's authorization, except to the exposed individual, the individual's health care provider, and any other person as authorized by law; that if the exposed individual knows the identity of the test subject, the exposed individual may not disclose the

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identity of the test subject except for the purpose of having the test performed; and that a record of the test results may be kept in the exposed individual's medical record only if the record does not reveal the test subject's identity. Each exposed individual who had an exposure and to whom test results are disclosed must first be given a document indicating the exposed individual's understanding that the exposed individual may not disclose the test subject's identity and that disclosing this information constitutes a class C felony.

3. If an individual who is the subject of an exposure is incapable of giving informed consent for testing under this section, that consent may be obtained from the individual's personal representative. If an individual who is the subject of an exposure dies without an opportunity to consent to testing, collection of appropriate specimens and testing for the presence of bloodborne pathogens must be conducted as soon as reasonably possible. Results of these tests must be provided to the physician providing care for the individual who experienced the exposure. If a facility that received the individual who died fails to test for the presence of bloodborne pathogens as required under this subsection because the facility was not aware of the exposure or it was not reasonably possible to conduct testing, the facility shall provide the physician providing care for the exposed individual or health care provider testing results of any bloodborne pathogen present in any medical records of the deceased individual which are in the facility's control as soon as reasonably possible. If there are no testing results for bloodborne pathogens within that facility and there is reason to believe that results are available from another facility, the facility that received the deceased individual shall attempt to obtain testing results of bloodborne pathogens of the deceased individual as soon as reasonably possible from the facility where it is believed results exist. The test results must be provided to the physician providing care for the individual who experienced the exposure.
4. A test for bloodborne pathogens must be conducted according to recommendations of the United States public health service. Any testing done pursuant to subsection 2 or 3 must be conducted in a reasonably expedient manner. The district court in the county where the alleged exposure occurred or in which the individual to be tested resides shall issue an order directing the individual who was the source of an exposure to have blood drawn to be tested for bloodborne pathogens. An affidavit from a physician or other qualified health care provider showing that an exposure has occurred is prima facie evidence of those facts. The affidavit may not be excluded as hearsay if the affidavit is based on evidence generally relied on by a health care provider, including statements from the provider's patient. The record of any court hearing conducted under this subsection is confidential. The court shall issue an order requiring testing under this subsection if:
   a. The court finds probable cause to believe that the individual petitioning for the testing had an exposure with the test subject;
   b. The petition substitutes a pseudonym for the true name of the test subject;
   c. The court provides the test subject with notice and reasonable opportunity to participate in the proceeding if the person is not already a party to the proceeding;
   d. The proceedings are conducted in camera; and
   e. The court imposes appropriate safeguards against unauthorized disclosure which must specify the individuals who have access to the information, the purposes for which the information may be used, and appropriate prohibition on future disclosure.
5. If the court issues an order for testing, the court may order the confinement of the test subject until blood is drawn for testing or issue an order establishing reasonable security for the individual's attendance at the test site. This order may be modified or extended.
6. A health care provider who subjects an individual to an exposure must notify the individual of the exposure. A health care provider witnessing an exposure may report the exposure pursuant to any appropriate facility or employer guidelines to which the

provider may be subject. The knowing failure to inform an individual of an exposure or refusal to submit to testing as required under this chapter may be considered by a health care provider's licensing board to constitute conduct that may subject the licensee to disciplinary action.

7. The exposed individual shall pay the expense of testing. However, if the exposure occurs at an employee's workplace, the worker's employer shall pay the expense of testing unless otherwise provided by subdivision b of subsection 10 of section 65-01-02. If the individual to be tested is convicted of a crime relating to the exposure or the exposure occurred during an arrest or other contact with the exposed individual in the course of that individual's official duties, a court may order the individual to be tested to pay for the testing.

**23-07.5-03. Written consent to disclosure.**

Repealed by S.L. 2003, ch. 211, § 27.

**23-07.5-04. Record maintenance.**

A health care provider who collects a specimen of body fluids or tissues for the purpose of testing for the presence of bloodborne pathogens caused by an exposure shall obtain from the test subject or the test subject's personal representative if the subject is a minor or is incapacitated, informed consent for testing unless testing is otherwise authorized by law. In addition, the health care provider shall maintain a record of the test results obtained.

**23-07.5-05. Confidentiality of test results.**

Repealed by S.L. 2003, ch. 211, § 27.

**23-07.5-06. Expanded disclosure of test results prohibited.**

1. The results of a test for bloodborne pathogens may be disclosed only to the individual who was tested; to an exposed individual for whom a test was conducted; and to the exposed individual's health care provider as provided by this chapter, and as permitted under title 45, Code of Federal Regulations, part 164, section 512.
2. An exposed individual to whom the results of a test for bloodborne pathogens have been disclosed under this chapter may not disclose the test results except as permitted under subsection 3, or as otherwise authorized by law.
3. If the test results are disclosed under this chapter to a law enforcement officer who was exposed to a bloodborne pathogen, the officer may disclose the test results to any other law enforcement officer who has direct physical contact with the test subject, if in the professional judgment of the officer the disclosure is necessary for the health and safety of the other officer and the disclosure is limited to the minimum amount of information needed to protect the health and safety of that officer.

**23-07.5-07. Civil liability.**

An individual who knowingly violates section 23-07.5-06 is liable to the subject of the test for actual damages and costs plus exemplary damages. A conviction for violation of this chapter is not a condition precedent to bringing an action under this section.

**23-07.5-08. Penalty.**

A person who knowingly discloses the results of a blood test in violation of this chapter is guilty of a class C felony, if the offense is committed with intent to disclose the identity of the individual who was tested.