2013 SENATE HUMAN SERVICES

SB 2342

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2342
2/11/13
Recording Job Number: 18678

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to wholesale drug distribution.

Minutes: Attached testimony

Chairman Lee opens hearing on SB 2342.

Senator Anderson, from District 8 and Executive Director of the North Dakota Board of Pharmacy, introduces the bill to the committee. See attached testimony #1.

(0:10:00) Senator Anderson proposes the following amendments as wells as offers further explanation as to why. Legislative Council is in the process of drafting them and should have them for the committee soon. These amendments include:

- Remove all of section 6
- Remove the "medical equipment" references in the three definitions: authentication, authorized distributor of record, and pedigree

(0:12:50) Senator Dever asks if there is sales tax on this equipment and whether or not this equipment is taxed under the ND Affordable Care Act.

Senator Anderson explains that you are exempt from sales tax if you have a prescription, regardless of what the prescription is for. He is not up to speed on the Affordable Care Act taxes so he is unable to answer that part of the question.

Chairman Lee states that there is additional tax on durable medical equipment and also mentions the fiscal note to the committee.

(0:14:39) Mark Hardy, PharmD and Assistant Executive Director of the North Dakota State Board of Pharmacy, testifies in support. See attached testimony #2.

(0:23:34) Chairman Lee notes a typo on page 2 of his testimony - it should be page 23, not page 12. She also inquires about the fees being charged to providers relating to the Prescription Drug Monitoring Program and asks if these are in addition to the increases in fees here in order to make that program self-sustaining.

Mr. Hardy explains that there is a bill in House Human Services that has to do with the Control Substance Registration and this was their initial plan to fund the Prescription Drug Monitoring Program moving forward. They are less than optimistic that this is going to get passed so this is their backup plan.

(0:25:30) Senator Axness reads from a constituent's email who is involved with respiratory equipment and asks if we are duplicating or adding another layer of accountability.

Mr. Hardy states that they are not looking to regulate the individual practitioners. This is about the businesses that are conducting it and to have some sort of license structure for them to be able to continue to provide those services and set the standards for what they are expecting.

Chairman Lee asks where IPAT (Interagency Program for Assistive Technology) fits in.

Dr. Hardy is unable to answer and suggests that Senator Anderson might be able to offer some insight.

Senator Anderson states that he is not really familiar with how they work but if they are licensed individuals then they are fine.

(0:27:44) Chairman Lee proceeds to explain what IPAT is to the committee and expresses that she would like to have this question answered. She asks Dr. Hardy to contact Judy Lee, the Director of IPAT, to see if there is any conflict with what they do.

Senator Dever offers the local contact name for IPAT (Peggy) to Mr. Hardy.

(0:30:25) Senator Larsen references the Drug Distribution Model and asks about equipment that is bought off of the internet.

Mr. Hardy explains that this will only encompass if you need a prescription for the equipment and purchasing it from a provider that is specifically billing Medicare.

Senator Dever asks if Medicare deals with used equipment.

Mr. Hardy thinks that they do a little bit and that there may be some provisions.

No further questions from the committee and no further testimony in favor.

(0:32:58) Sharon D'Agostino with Johnson & Johnson testifies in opposition. She spoke to Senator Anderson before this hearing and would be in support of his proposed amendments. They are working with the FDA on developing what is called the UDI (Unique Device Indicator) Database which would be a global database so they hope that at some point they will be able to honor his intent on ensuring integrity in devices. She also suggests taking a look at the "medical equipment" reference in sections 7, 8, and 9. Ms. D'Agostino is confident that the discussion with Senator Anderson will continue to where they can get the bill in a condition that they would be in support of.

(0:34:44) Chairman Lee asks Senator Anderson or Dr. Hardy to explain why "medical equipment" was only removed from certain definitions and not from sections 7, 8 and 9.

Senator Anderson explains that once you take the pedigree requirement out this applies to those people who are going to be licensed. If you are going to license them then this language needs to be left in to control what they do with the license.

Senator Dever questions who supplies oxygen/medical gas.

Senator Anderson states that many of the welding companies are in the medical gas business and explains the problem with licensing them to go directly to the consumer.

Ms. D'Agostino asks to discuss this further with Senator Anderson offline once the amendment comes through.

(0:38:53) Joel Gilbertson from Pharma stands in opposition but states that he has also worked with Senator Anderson and agrees with Ms. D'Agostino that they would be okay with the amendments as Senator Anderson described them.

No further testimony.

The hearing on SB 2342 is closed.

(Recording was stopped after the hearing was closed but Chairman Lee decided to offer some thoughts before moving on. The recording misses a few seconds but jumps back in at 0:39:44.)

Additional testimony submitted - see attachments #3-5.

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2342
2/11/13
Recording Job Number: 18683

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to wholesale drug distribution.

Minutes:

Vice Chairman Larsen opens committee discussion on SB 2342:

Senator Anderson goes over the amendments with the committee. They are still waiting on the hard copy draft from Legislative Council.
The amendments they review are:
Page 1, lines 12 & 16 - remove "medical equipment"
Page 4, line 26 - remove "medical equipment"
Pages 17 - 19 - remove section 6

Further discussion and clarification takes place on the removal of the "medical equipment" reference.

Senator Anderson moved to adopt the amendments as long as the committee is comfortable not seeing them yet.

Senator Dever seconded.

Roll Call Vote: 5-0, motion passes. (Chairman Lee was not present during the vote so it was left open for her. She voted "YES" off the record and it was noted on the roll call sheet.)

Senator Anderson moved Do Pass as Amended and Rerefer to Appropriations.

Senator Dever seconded.

Discussion: Senator Axness reads his constituent's email again and wants to clarify that these changes will take care of his concerns. Senator Anderson proceeds to explain how this bill will ensure his constituents involvement.

Roll Call Vote: 5-0, motion passes. (Chairman Lee was not present during the vote so it was left open for her. She voted "YES" off the record and it was noted on the roll call sheet.)

Senator Anderson is the carrier.

FISCAL NOTE
Requested by Legislative Council
01/29/2013

Bill/Resolution No.: SB 2342

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.*

	2011-2013 Biennium		2013-2015 Biennium		2015-2017 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$343,200	$0	$343,200
Expenditures	$0	$15,000	$0	$0	$0	$0
Appropriations	$0	$0	$0	$0	$0	$0

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

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
Counties	$0	$0	$0
Cities	$0	$0	$0
School Districts	$0	$0	$0
Townships	$0	$0	$0

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).*

Bill to amend and clarify wholesale drug pedigree to encompass those businesses involved in the manufacturing/distributing of prescription drugs, medical gases and medical equipment. The increased fiscal revenue will be mostly associated with a increase in the annual license fee.

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.*

Currently the annual fee is $200 for all the businesses needing to obtain a wholesale license. The fees in the current legislation are broken down as to the type of business being licensed. The fees for wholesalers/distributors and manufacturers are increased by $200. The increase in fees based on our number of current licensees is how we determined the biannual impact. This also adds a license fees for those durable medical equipment distributors and retailers of which there is no current clear license structure available which may have a minimal fiscal impact.

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.*

Current amount of licensed business affected are 858. Annual revenue increase $171,600 and biannually is $343,200

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.*

We envision expenditures to be associated with the database programming necessary to implement the changes set forward in the legislation. No changes in FTE are envisioned with the legislation.

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 is also included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy
Agency: ND Board of Pharmacy
Telephone: 701-328-9535
Date Prepared: 02/04/2013

13.0807.02003
Title.03000

Adopted by the Human Services Committee

February 11, 2013

2-11-13

PROPOSED AMENDMENTS TO SENATE BILL NO. 2342

Page 1, line 3, remove "43-15.3-06,"

Page 1, line 12, remove ", medical gas, or medical equipment"

Page 1, line 16 remove ", medical gas, or medical equipment"

Page 4, line 26, remove ", medical gas, or medical equipment"

Page 9, line 30, after "for" insert "a"

Page 9, line 30, replace "wholesalers" with "wholesaler applicant,"

Page 9, line 31, after "individual" insert "identified as the prescription drug wholesaler applicant's designated representative for the facility"

Page 10, line 1, after "individual" insert "identified by a prescription drug wholesaler applicant as a designated representative for a facility and therefore"

Page 17, remove lines 3 through 31

Page 18, remove lines 1 through 30

Page 19, remove lines 1 through 5

Page 22, line 25, remove ", medical gas, or"

Page 22, line 26, remove "medical equipment"

Page 22, line 28, remove ", medical gas, or medical equipment"

Page 22, line 28, remove the third underscored comma

Page 22, line 29, remove "medical gas, or medical equipment"

Page 22, line 30, remove ", medical gas, or medical equipment"

Page 23, line 2, remove ", medical gases, or medical equipment"

Page 23, line 19, remove ", medical gas, or medical equipment"

Page 23, line 20, remove "medical gas, or medical equipment,"

Page 23, line 22, remove ", medical"

Page 23, line 23, remove "gas, or medical equipment"

Renumber accordingly

Date: 2/11/13
Roll Call Vote #: 1

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2342

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 13.0807.02001

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☑ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Sen. Anderson Seconded By Sen. Dever

Senators	Yes	No	Senator	Yes	No
Chariman Judy Lee	✓		Senator Tyler Axness	✓	
Vice Chairman Oley Larsen	✓				
Senator Dick Dever	✓				
Senator Howard Anderson, Jr.	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment

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

Date: 2/11/13
Roll Call Vote #: 2

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2342

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 13.0807.02001

Action Taken: ☑ Do Pass ☐ Do Not Pass ☑ Amended ☐ Adopt Amendment
☑ Rerefer to Appropriations ☐ Reconsider

Motion Made By Sen. Anderson Seconded By Sen. Dever

Senators	Yes	No	Senator	Yes	No
Chariman Judy Lee	✓		Senator Tyler Axness	✓	
Vice Chairman Oley Larsen	✓				
Senator Dick Dever	✓				
Senator Howard Anderson, Jr.	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment Sen. Anderson

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

REPORT OF STANDING COMMITTEE

SB 2342: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** and **BE REREFERRED** to the **Appropriations Committee** (5 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2342 was placed on the Sixth order on the calendar.

Page 1, line 3, remove "43-15.3-06,"

Page 1, line 12, remove ", medical gas, or medical equipment"

Page 1, line 16 remove ", medical gas, or medical equipment"

Page 4, line 26, remove ", medical gas, or medical equipment"

Page 9, line 30, after "for" insert "a"

Page 9, line 30, replace "wholesalers" with "wholesaler applicant,"

Page 9, line 31, after "individual" insert "identified as the prescription drug wholesaler applicant's designated representative for the facility"

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Page 22, line 26, remove "medical equipment"

Page 22, line 28, remove ", medical gas, or medical equipment"

Page 22, line 28, remove the third underscored comma

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Page 23, line 2, remove ", medical gases, or medical equipment"

Page 23, line 19, remove ", medical gas, or medical equipment"

Page 23, line 20, remove "medical gas, or medical equipment,"

Page 23, line 22, remove ", medical"

Page 23, line 23, remove "gas, or medical equipment"

Renumber accordingly

2013 SENATE APPROPRIATIONS

SB 2342

2013 SENATE STANDING COMMITTEE MINUTES

Senate Appropriations Committee
Harvest Room, State Capitol

SB 2342
02-18-2013
Job # 19121

☐ Conference Committee

Committee Clerk Signature Alice Dubord

Explanation or reason for introduction of bill/resolution:

Relating to wholesale drug distribution

Minutes: See attached testimony

Chairman Holmberg called the committee to order on Monday, February 18, 2013 at 3:00 pm in regards to SB 2342. All committee members were present. Brittani Reim from Legislative Council and Tammy R. Dolan from OMB were present.

Senator Anderson, District 8 and Director of State Board of Pharmacy: He is the prime sponsor of the bill and he explained what the bill does. There are no state appropriated dollars in here. These are strictly license fees. (4.03)

Mark J. Hardy, ND Board of Pharmacy provided Testimony attached # 1 in support of the bill.

Senator Warner: Are the definitions of durable medical identical in this bill with federal law?

Mark J. Hardy: They are very similar. Yes.

Senator Warner moved a do pass. Senator Robinson 2nd.

Chairman Holmberg: Discussion Call the roll on a Do Pass on SB 2342.

A Roll Call vote was taken. Yea: 11 Nay: 1 Absent: 1. Senator Anderson from Human Services will carry the bill. The hearing was closed on SB 2342.

FISCAL NOTE
Requested by Legislative Council
02/12/2013

Amendment to: SB 2342

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.*

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	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$343,200	$0	$343,200
Expenditures	$0	$15,000	$0	$0	$0	$0
Appropriations	$0	$0	$0	$0	$0	$0

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

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
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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).*

Bill to amend and clarify wholesale drug pedigree to encompass those businesses involved in the manufacturing/distributing of prescription drugs, medical gases and medical equipment. The increased fiscal revenue will be mostly associated with a increase in the annual license fee.

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.*

Currently the annual fee is $200 for all the businesses needing to obtain a wholesale license. The fees in the current legislation are broken down as to the type of business being licensed. The fees for wholesalers/distributors and manufacturers are increased by $200. The increase in fees based on our number of current licensees is how we determined the biannual impact. This also adds a license fees for those durable medical equipment distributors and retailers of which there is no current clear license structure available which may have a minimal fiscal impact. The amendments would create no change to the fiscal note on this bill.

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.*

Current amount of licensed business affected are 858. Annual revenue increase $171,600 and biannually is $343,200 All revenue associated with the bill is generated by licensure fees.

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.*

We envision expenditures to be associated with the database programming necessary to implement the changes set forward in the legislation. No changes in FTE are envisioned with the legislation.

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 is also included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy
Agency: ND Board of Pharmacy
Telephone: 701-328-9535
Date Prepared: 02/04/2013

FISCAL NOTE
Requested by Legislative Council
01/29/2013

Bill/Resolution No.: SB 2342

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.*

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Appropriations	$0	$0	$0	$0	$0	$0

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

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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).*

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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.*

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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.*

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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.*

We envision expenditures to be associated with the database programming necessary to implement the changes set forward in the legislation. No changes in FTE are envisioned with the legislation.

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 is also included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy
Agency: ND Board of Pharmacy
Telephone: 701-328-9535
Date Prepared: 02/04/2013

Date: 2-18-13

Roll Call Vote # 1

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 2342

Senate Appropriations Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken DO pass

Motion Made By Seconded By

Senators	Yes	No	Senator	Yes	No
Chariman Ray Holmberg	✓		Senator Tim Mathern	✓	
Co-Vice Chairman Bill Bowman	✓		Senator David O'Connell		✓
Co-Vice Chair Tony Grindberg	✓		Senator Larry Robinson	✓	
Senator Ralph Kilzer	✓		Senator John Warner	✓	
Senator Karen Krebsbach	✓				
Senator Robert Erbele	✓				
Senator Terry Wanzek	✓				
Senator Ron Carlisle	✓				
Senator Gary Lee	✓				

Total (Yes) 11 No 1

Absent 1

Floor Assignment Anderson

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

REPORT OF STANDING COMMITTEE

SB 2342, as engrossed: Appropriations Committee (Sen. Holmberg, Chairman) recommends **DO PASS** (11 YEAS, 1 NAYS, 1 ABSENT AND NOT VOTING). Engrossed SB 2342 was placed on the Eleventh order on the calendar.

2013 HOUSE HUMAN SERVICES

SB 2342

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2342
March 20, 2013
Job #20241

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

Relating to wholesale drug distribution and to provide a penalty.

Minutes: *See Testimonies #1-7*

Chairman Weisz opened the hearing on SB 2342.

Sen. Howard Anderson: Introduced and sponsored the bill. (See Testimony #1)

7:35
Chairman Weisz: Are you aware of amendments Rep. Koppelman is going to offer?

Anderson: Yes. We don't want to say that everybody can ship things to other than licensees. That is the only section that we may change. We are aware of the amendment. I don't think it makes a large difference in the bill one way or another.

Rep. Kim Koppelman: From District 13 in West Fargo and co-sponsored the bill. Some people dealing in illicit drugs also were involved in counterfeit prescription drugs in the supply chain. ND was one of the first states to have a drug pedigree program. The people of ND can be assured when they get a prescription filled it is exactly what the prescription called for. This bill seeks to do something similar with medical devices. (Passed out an amendment. See Attachment #2) I think with these amendments and the amendments Sen. Anderson gave in the Senate will clean up this bill and the work that was begun in the Senate. (Went through amendment.) I think this is a good bill.

15:37
Mark Hardy: Executive Director of the State Board of Pharmacy testified in support of the bill. (See Testimony #3)

22:00
Chairman Weisz: You are aware of the amendments?

Hardy: Yes, we briefly looked at them this morning. We have a couple of tweaks we may ask for if that is ok. We feel we can work with the people from the industry and come together with a compromise.

Rep. Silbernagel: Are wholesale medical gas distributors a new licensure?

Hardy: It is a new licensure. There is no provision within our current wholesale statute to provide medical gases directly to patients. They are currently doing this now as a business practice, but this provides the provisions in the law to allow them to do that.

Chairman Weisz: On the amendments, they are removing Section 5 and the rationale for that?

Hardy: There are issues as far as the pedigree requirements and there are valid points to the medical equipment side of the business. Their industry works a little different from the drug industry. We can certainly work with those issues. What we would like to maintain in that section is that they are only shipping durable medical equipment to a licensed facility or licensed individual. That is number 2 within that section. I think we can work on the language to make that amendable to what we envision; so it is going to that new class of license that we have toward the end of the bill is a durable medical equipment retailer. All of those companies are licensed under the new provisions of this bill. It shouldn't really affect them.

OPPOSITION

25:15
Ashley Palmer: Director of Government Affairs with the Health Industry Distributors Association (HIDA) testified in opposition of the bill. (See Testimony #4)

28:20
Chairman Weisz: Can you reference exactly on the bill?

Palmer: Pages 4 and 5.

Chairman Weisz: You are only taking them out on 4 and 5.

Palmer: Yes sir. The normal distribution channel is on page 4.

Chairman Weisz: Number 16?

Palmer: Yes sir. And the definition of repackage is on page 5, number 20. Both of those definitions would be addressed through the proposed amendment.

29:21
Palmer: (Resumes testimony)

31:44
Chairman Weisz: If these amendments are adopted, are you comfortable with the bill?

Palmer: We would be.

Bob Sutton: Speaking on behalf of Kreisers. Kreisers is a medical, surgical distributor at the purest form. We are headquartered in Sioux Falls, SD. I have managed the branch in Fargo for the past 25 years. We cover Montana, Wisconsin, ND and all the way south to Kansas. I've been in the business for 38 years and it is safe to say with Kreisers that there isn't a hospital, nursing home, care center, assisted living, or surgery center in ND that doesn't know us and more than likely purchase from us. We ask that you amend the bill by removing the references to medical equipment from areas of the bill that really pertain to pharmacy and pharmaceutical supply chain. The law without the amendments would interrupt the efficiencies and add cost. It was discussed earlier that the two are apples and oranges and our systems don't track that very well. As a medical products distributor I am concerned the bill inadvertently expands the pharmaceutical track and trace regulations and restrictions to the medical devices and equipment prior to the amendments discussed. We are comfortable with the amendments discussed.

35:19
Rep. Muscha: My daughter has diabetes and receives shipments directly to her home because she has a pump. According to the bill it says, "Any person who receives"; she wouldn't need a license would she?

Sutton: The way it is written, she would.

Rep. Mooney: The amendments brought forth by Rep. Koppelman; you would be satisfied with?

Sutton: Yes.

36:48
Sharon D'Agostino: From Johnson and Johnson. I worked with Dr. Hardy and Senator Anderson and tried to work with them on some of the adjustments referred to this morning and thought we had taken care of it. We are in support of the amendment and would be comfortable with it.

Chairman Weisz closed the hearing.

HANDED IN TESTIMONY IN OPPOSITION

Carrie Hartgen: From Advanced Medical Technology Association. (See Testimony #5)

Medline Industries Inc.: (See Testimony #6)

Pam Scherrer: A licensed wholesale drug/device distributor: (See Testimony #7)

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2342
March 26, 2013
Job 20513

☐ Conference Committee

Lynnell Thueson

Explanation or reason for introduction of bill/resolution:

Minutes: Testimony 1

Chairman Weisz: Additional amendment by the Board of Pharmacy. Everyone has seen this and agrees with it. This bill is for licensing the revenue stream to pay on the medical suppliers to help fund their prescription drug monitoring program.

4:19 Representative Porter: I **move a Do Pass on both sets of amendments**. Seconded by Representative Looysen. Voice vote taken, motion carried.

Chairman Weisz: We have an amended bill before us.

Representative Porter: I have a concern about this being the revenue producer. Someone will pay for this. Consumers will with their health insurance premiums. I think it's a broad stretch of the authority of a pharmacy board to be licensing durable medical equipment.

Representative Mooney: Did we hear any real benefit to any of this?

Chairman Weisz: After all the amendment the benefit is funding the prescription drug monitoring program so that the board of pharmacy doesn't have to take that from their internal funds.

Representative Mooney: So then do we hear any real benefits to the client?

Chairman Weisz: You could try to make an argument as far as licensing to know who they are. Does that have a public safety benefit? You could argue there is some public safety.

Representative Mooney: Did they say that we've had any issues?

Chairman Weisz: Not that I'm aware of.

9:10 Representative Silbernagel: I discussed this with my brother who is involved in the medical gas distribution industry and we both agree with Representative Porters

comments, if there are issues in the marketplace it's a way to generate some additional taxes. If there were industry issues, we would have heard about them.

10:00 Representative Muscha: There aren't many producers of those types of supplies necessarily.

Representative Oversen: When looking at the testimony, are we not in compliance with something then?

Representative Porter: This is a question that needs to be answered. All of the industry that came and testified on the bill said that it needed significant work just being generous, not to kill it. They are dealing and selling nationwide.

Chairman Weisz: We need more answers to this.

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2342
March 27, 2013
Job #20549

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

Relating to wholesale drug distribution.

Minutes:

Chairman Weisz: Let's take up SB 2342. We will finish our discussion from yesterday. Mr. Hardy would you come up please. If the bill would die, there was some testimony that implied we had to do the licensing because the federal. Is that or is that not a requirement?

Mark Hardy: As far as durable medical equipment retailers for them to provide those services in each one of the states, they need some sort of license to do the competitive bidding process that works through the federal Medicare provisions.

Chairman Weisz: They don't have an issue selling to you and me in the state, but would selling equipment in North Dakota for federal.

Hardy: Yes, through Medicare.

Chairman Weisz: That answers the question Rep. Oversen had?

Rep. Oversen: Yes.

Vice-Chair Hofstad: I move a Do Pass as Amended on engrossed SB 2342.

Rep. Fehr: Second.

ROLL CALL VOTE: 11 y 2 n 0 absent

Bill Carrier: Rep. Mooney

FISCAL NOTE
Requested by Legislative Council
03/27/2013

Amendment to: SB 2342

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.*

	2011-2013 Biennium		2013-2015 Biennium		2015-2017 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$343,200	$0	$343,200
Expenditures	$0	$15,000	$0	$0	$0	$0
Appropriations	$0	$0	$0	$0	$0	$0

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

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
Counties	$0	$0	$0
Cities	$0	$0	$0
School Districts	$0	$0	$0
Townships	$0	$0	$0

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).*

Bill to amend and clarify wholesale drug pedigree to encompass those businesses involved in the manufacturing/distributing of prescription drugs, medical gases and medical equipment. The increased fiscal revenue will be mostly associated with a increase in the annual license fee.

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.*

Currently the annual fee is $200 for all the businesses needing to obtain a wholesale license. The fees in the current legislation are broken down as to the type of business being licensed. The fees for wholesalers/distributors and manufacturers are increased by $200. The increase in fees based on our number of current licensees is how we determined the biannual impact. This also adds a license fees for those durable medical equipment distributors and retailers of which there is no current clear license structure available which may have a minimal fiscal impact. The amendments would create no change to the fiscal note on this bill.

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.*

Current amount of licensed business affected are 858. Annual revenue increase $171,600 and biannually is $343,200 All revenue associated with the bill is generated by licensure fees.

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.*

We envision expenditures to be associated with the database programming necessary to implement the changes set forward in the legislation. No changes in FTE are envisioned with the legislation.

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 is also included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy
Agency: ND Board of Pharmacy
Telephone: 701-328-9535
Date Prepared: 02/04/2013

FISCAL NOTE
Requested by Legislative Council
02/12/2013

Amendment to: SB 2342

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.*

	2011-2013 Biennium		2013-2015 Biennium		2015-2017 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$343,200	$0	$343,200
Expenditures	$0	$15,000	$0	$0	$0	$0
Appropriations	$0	$0	$0	$0	$0	$0

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

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
Counties	$0	$0	$0
Cities	$0	$0	$0
School Districts	$0	$0	$0
Townships	$0	$0	$0

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).*

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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.*

Currently the annual fee is $200 for all the businesses needing to obtain a wholesale license. The fees in the current legislation are broken down as to the type of business being licensed. The fees for wholesalers/distributors and manufacturers are increased by $200. The increase in fees based on our number of current licensees is how we determined the biannual impact. This also adds a license fees for those durable medical equipment distributors and retailers of which there is no current clear license structure available which may have a minimal fiscal impact. The amendments would create no change to the fiscal note on this bill.

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We envision expenditures to be associated with the database programming necessary to implement the changes set forward in the legislation. No changes in FTE are envisioned with the legislation.

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 is also included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy
Agency: ND Board of Pharmacy
Telephone: 701-328-9535
Date Prepared: 02/04/2013

FISCAL NOTE
Requested by Legislative Council
01/29/2013

Bill/Resolution No.: SB 2342

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.*

	2011-2013 Biennium		2013-2015 Biennium		2015-2017 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$343,200	$0	$343,200
Expenditures	$0	$15,000	$0	$0	$0	$0
Appropriations	$0	$0	$0	$0	$0	$0

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

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
Counties	$0	$0	$0
Cities	$0	$0	$0
School Districts	$0	$0	$0
Townships	$0	$0	$0

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).*

Bill to amend and clarify wholesale drug pedigree to encompass those businesses involved in the manufacturing/distributing of prescription drugs, medical gases and medical equipment. The increased fiscal revenue will be mostly associated with a increase in the annual license fee.

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.*

Currently the annual fee is $200 for all the businesses needing to obtain a wholesale license. The fees in the current legislation are broken down as to the type of business being licensed. The fees for wholesalers/distributors and manufacturers are increased by $200. The increase in fees based on our number of current licensees is how we determined the biannual impact. This also adds a license fees for those durable medical equipment distributors and retailers of which there is no current clear license structure available which may have a minimal fiscal impact.

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.*

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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.*

We envision expenditures to be associated with the database programming necessary to implement the changes set forward in the legislation. No changes in FTE are envisioned with the legislation.

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 is also included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy
Agency: ND Board of Pharmacy
Telephone: 701-328-9535
Date Prepared: 02/04/2013

VR
3/27/13

13.0807.03003
Title.04000

Adopted by the Human Services Committee

March 27, 2013

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2342

Page 1, line 3, remove "43-15.3-05,"

Page 4, line 3, remove the underscored comma

Page 4, line 4, remove "medical gas, or medical equipment"

Page 4, line 5, remove "medical gas, or medical equipment,"

Page 4, line 10, remove ", gas, or equipment"

Page 4, line 12, remove ", gas, or equipment"

Page 4, line 16, remove ", gas, or equipment"

Page 4, line 20, remove ", gas, or equipment"

Page 5, line 8, overstrike the comma

Page 5, line 8, remove "medical gas, or"

Page 5, line 9, remove "medical equipment"

Page 15, remove lines 23 through 31

Page 16, remove lines 1 through 31

Page 17, remove lines 1 through 5

Page 24, line 5, after the underscored period insert "A durable medical equipment retailer may only obtain medical equipment from a manufacturer or wholesaler that is duly licensed by the state."

Renumber accordingly

Date: 3-26-13
Roll Call Vote #: 1

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2342

House Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☒ Adopt Amendment S

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Porter Seconded By Rep. Looysen

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ			REP. MOONEY		
VICE-CHAIRMAN HOFSTAD			REP. MUSCHA		
REP. ANDERSON			REP. OVERSEN		
REP. DAMSCHEN					
REP. FEHR					
REP. KIEFERT					
REP. LANING					
REP. LOOYSEN					
REP. PORTER					
REP. SILBERNAGEL					

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent: ADOPT 03003 amendment and additional amendment (see attachment 1)

Voice Vote
Motion Carried

Date: 3-27-13
Roll Call Vote #: 1

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2342

House Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☒ Do Pass ☐ Do Not Pass ☒ Amended ☐ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Hofstad Seconded By Rep. Fehr

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ	✓		REP. MOONEY	✓	
VICE-CHAIRMAN HOFSTAD	✓		REP. MUSCHA	✓	
REP. ANDERSON	✓		REP. OVERSEN	✓	
REP. DAMSCHEN	✓				
REP. FEHR	✓				
REP. KIEFERT	✓				
REP. LANING	✓				
REP. LOOYSEN	✓				
REP. PORTER		✓			
REP. SILBERNAGEL		✓			

Total (Yes) 11 No 2

Absent 0

Floor Assignment Rep. Mooney

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

REPORT OF STANDING COMMITTEE

SB 2342, as engrossed: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (11 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). Engrossed SB 2342 was placed on the Sixth order on the calendar.

Page 1, line 3, remove "43-15.3-05,"

Page 4, line 3, remove the underscored comma

Page 4, line 4, remove "medical gas, or medical equipment"

Page 4, line 5, remove "medical gas, or medical equipment,"

Page 4, line 10, remove ", gas, or equipment"

Page 4, line 12, remove ", gas, or equipment"

Page 4, line 16, remove ", gas, or equipment"

Page 4, line 20, remove ", gas, or equipment"

Page 5, line 8, overstrike the comma

Page 5, line 8, remove "medical gas, or"

Page 5, line 9, remove "medical equipment"

Page 15, remove lines 23 through 31

Page 16, remove lines 1 through 31

Page 17, remove lines 1 through 5

Page 24, line 5, after the underscored period insert "A durable medical equipment retailer may only obtain medical equipment from a manufacturer or wholesaler that is duly licensed by the state."

Renumber accordingly

2013 TESTIMONY

SB 2342

Attachment #1

Senate Bill 2342
Senate Human Services Committee
9:00AM Monday, February 11, 2013
Red River Room

Chairman Lee and Members of the Senate Human Services Committee, I am Howard Anderson, Senator from District 8 and the Executive Director of the North Dakota State Board of Pharmacy.

I have been working on this rewrite for three years, in consultation with those in North Dakota who are in the Medical Equipment, Medical Gas and Device business.

Since the Federal Government decided that they wanted to bid out the sale of much of this equipment and devices to mail order, which will come mostly from Florida and California we have gotten hundreds of calls about what license they need to supply these devices directly to North Dakota patients from their mail order locations. The Federal requirements include being appropriately licensed by the states and we had nothing to answer this need.

Therefore we got together and I wrote an interpretation, which resides on the board's web site, that they need someone licensed in North Dakota to help the patient and be responsible for their care. Our wholesale act, adopted in 2007, requires sale to only licensees. These might be pharmacies, Hospitals, Respiratory Therapists, Physicians and a whole host of people who have a license authorizing them to serve the public, however we have no way to capture that information or license the direct sale to consumers, on a prescription order, except to have a pharmacy license. Many of these companies are not pharmacies in their home state and thus are not eligible for one here.

Therefore this bill was written to revise the Wholesale licensing act to accomplish the following:

#1

Provide a licensing mechanism for the sale of medical equipment and supplies directly to the consumer, when prescribed by a practitioner and intended to be paid for by a third party payer, such as a Medicare Part D plan, Medicaid, or another insurer. It does not affect sales of these items when sold without the need for a prescription, except in the case of Legend Devices that would require a prescription under Federal Law.

Provides a mechanism to capture the name and license number of the North Dakota licensed professional that will be responsible to see that the patient knows how to use the device properly. If you get a gastric suction pump in the mail, someone needs to help you use it properly and that person should not be on the phone from Florida. If there is a patient complaint, we need a way to address that with the licensee through their own North Dakota Licensing Board.

Provides an increase in license fees for some of our licensees, to help the Board of Pharmacy finance the Prescription Drug Monitoring Program, help with drug take back programs and make upgrades to the Prescription Drug Repository Program. We have been spending down our reserves to finance these programs since 2009 and the companies who manufacture and sell the products are needed to help pay for those programs.

We have an excellent web site where licenses can be applied for and renewed, without repeating required information each year, and we will use some of the money to make enhancements and maintain this licensee friendly system. It also allows a very easy to use "Verify a License" program that saves licensees the $25 fee when they need that verification for the Federal Requirements or for licensure in another state.

You have heard from some of the manufacturers of this equipment and devices that the pedigree requirements we have in place for prescription drugs are not yet applicable to this industry. Therefore we

#1

have taken the suggestion of Joel Gilbertson and suggested an amendment to remove the changes to Section SIX and leave the pedigree requirements to drugs until the industry gets their Universal Product Identifier projects completed. The Pedigree requirements are intended to protect consumers from counterfeit products and thus can help the legitimate manufacturers as well, when they are ready.

My Assistant Executive Director, Mark Hardy, Pharm D. has some additional information for you and will explain the fiscal note and Pharmacy Board Budget in as much detail as you would like.

Thank you.

Attachment #2

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536

BOARD OF PHARMACY
State of North Dakota

E-mail= ndboph@btinet.net www.nodakpharmacy.com

Jack Dalrymple, Governor

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

Senate Bill 2342 – Wholesale Drug Distribution
Senate Human Services Committee – Red River Room
9:00 AM - Monday – February 11, 2013

Chairperson Lee, members of the Senate Human Services Committee, for the record I am Mark J. Hardy, PharmD, Assistant Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today about Senate Bill 2342.

This Bill provides revisions and enacts sections to North Dakota Century Code 43-15.3 which the Board of Pharmacy has been looking to incorporate. We currently have two sections of wholesale statutes in our law. This legislation is intended to combine these and also clear up any differences throughout the bill. I would like to walk through the changes in the Bill so that you may have a good understanding of what this legislation does.

You will notice the inclusion of *medical gas, or medical equipment* throughout much of the legislation. This makes it clear that the movement of medical gases and/or legend medical equipment requires licensure.

We have added the definitions of: Broker – Device – Durable medical equipment – Medical device – Medical equipment – Medical gas – Pharmacy distributor and Trace and Track, along with Virtual distributor and Virtual manufacturer. Again this clarifies much of the ambiguities that are in the current wholesale statute and makes it very clear what business activities require licensing in North Dakota.

I would like to talk just a bit about the businesses of a Virtual distributor and Virtual manufacturer. These are relatively new and increasing models that, in the case of a virtual manufacturer, are a company that does not take actual control of a drug or device, but contracts the manufacturing to a separate facility and the delivery to a logistics provider, but does handle the billing and the FDA Registration, along with having the name of their "company" on the product. This type of business can be a source of questionable activity, so we feel it is necessary to make it clear that licensure is required of these business practices. We currently ask these virtual distributors and virtual manufacturers to license under our current law, but this bill will make it clear a license is required. Once again, this will ensure supply chain integrity and should any issues arise with North Dakota citizens we are able to hold the right business accountable for those concerns.

#2

On page 9 of this bill, lines 6 through 10 is language that will maintain the Board of Pharmacy's position of ensuring a wholesale distributor of prescription drugs must obtain accreditation from the National Association of Boards of Pharmacy [NABP] Verified Accredited Wholesale Distributor [VAWD] program. This accreditation has been a proven tool for Boards of Pharmacy to ensure out-of-state wholesale distributors are in compliance with laws and rules, to again safeguard supply and product integrity. This accreditation is becoming a national standard for legitimate wholesale distributors and it is commendable that North Dakota was a leader in this requirement to bring an enhanced level of safety to our citizens.

On page 15, beginning on line 4 – allows the Board of Pharmacy to inspect facilities which are licensed with the Board. It also allows a designee of the Board to conduct inspections; this may be pertinent if we were to feel any suspicious activity is being conducted, especially in an out-of-state license.

On page 17 under 43-15.3-06 Electronic Pedigree – you will notice that the dates are moved back from the previous legislation. To give you some background on this track and trace pedigree technology, this has been something that has been widely discussed as a method to better control the movement of prescription drugs, medical gases and medical equipment. The technology is progressing, however not as quickly as many had first envisioned. California is attempting to lead the way on the electronic track and trace requirement. The Board certainly sees good reason for implementing this technology across the pharmaceutical supply chain.
Essentially this would address issues with the gray market of pharmaceuticals, which is certainly a large issue in the nation. I am sure you have heard one of the many news reports of counterfeit substances being found or even reaching the patient level.

As we get to page 12 beginning on line 26, a new section is being created for retail medical gas retailers. This provides clarification that medical gas retailers need to be licensed with the Board of Pharmacy to provide medical gases directly to a North Dakota citizen. They currently license under the provisions of the current law.

On page 25 beginning on line 3 is also a new section that creates a new class of license for retail durable medical equipment retailers. This has been a recent issue for the Board, as we do not currently have a license class to license **d**urable **m**edical **e**quipment, retailers or DME products, especially out-of-state companies.

This has been brought to our immediate attention due to the Medicare competitive bidding process put forward in the new healthcare proposals. Currently a DME retailer has two options to conduct this type of business when sending their products directly to patients in North Dakota. They may be licensed as a pharmacy, but many of these businesses do not even employ pharmacists and are not licensed as pharmacies in the state they are actually located, hence do not qualify for a North Dakota Pharmacy Permit. Or, their other option is to contract with a North Dakota licensed individual who is authorized to dispense the DME product pursuant to their practice act.

#2

This new section still maintains that a DME retailers must employ or contract with a North Dakota healthcare professional authorized by their practice act to do business directly with our citizens. The Board feels that this is very important for any problems that may arise with a product or we receive a complaint from a North Dakota citizen. Ultimately this is for the patient's safety and well-being.

A simple example is receiving a cane in the mail. If that cane has not been fitted to the patient, or a healthcare professional is not made available for questions about how to properly fit that cane, it could put that patient at a higher risk for falling and adverse events from happening. It certainly is in the best interest of our patients to have a North Dakota licensed individual to oversee these types of activities.

For those businesses that are currently in North Dakota and operate as medical equipment retailers, such as Sanford or Altru or our local Great Plains Rehabilitation, they employ or have licensed professionals on staff to answer these types of questions. The Board feels this is ideal to ensure that the patient is properly educated on the devices and equipment that they receive.

On page 26 beginning on line 27 – the fees are listed according to each license category. Currently the wholesale fee is $200 for all licenses. The new categories that are not identified in the current law are the durable medical equipment distributors and retailer licenses. The fees are increased by $200 for manufacturers, distributors and brokers.

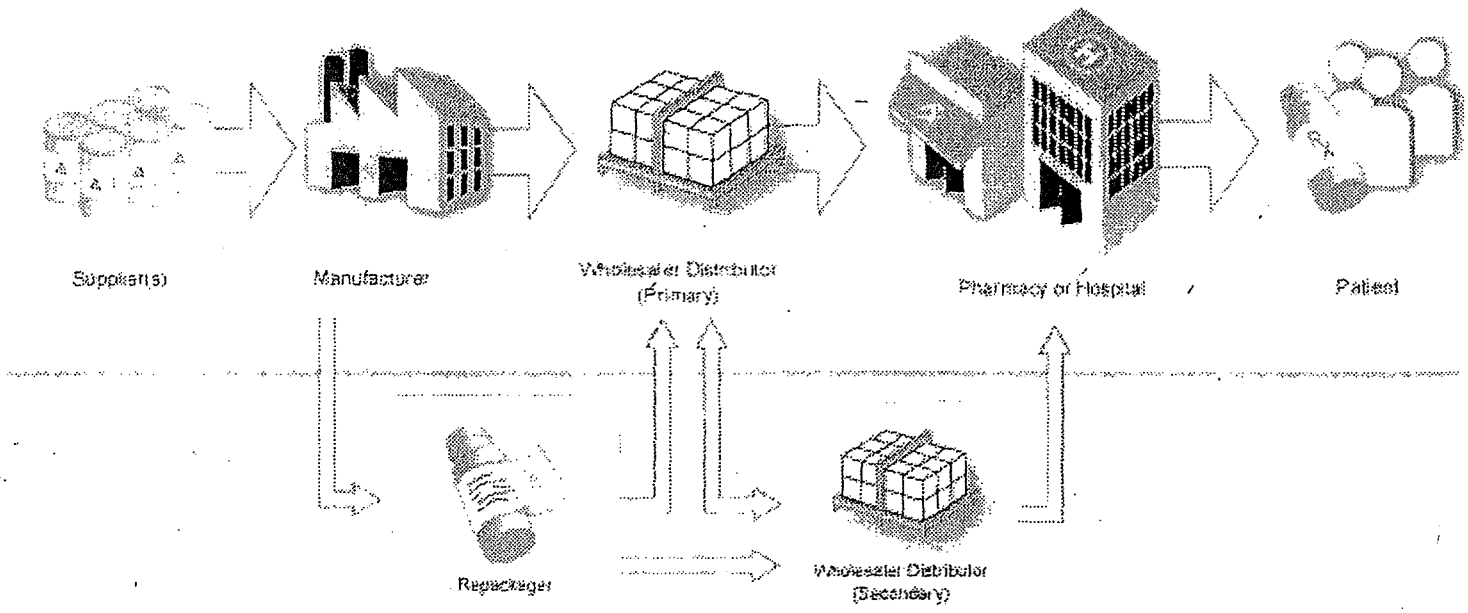
The fiscal note on this bill accounts for this increase in annual licensure fees. The additional money is to help provide take-back programs for prescription drugs, fund the Repository Program help provide the funds for the inspections of these licensees. Additional revenue will help fund the Prescription Drug Monitoring Program, which is currently being funded by the Board of Pharmacy's reserves. The expenses related to the fiscal note are the estimated cost of implementing the data base revisions to account for these changes. We feel these fees are in line with what other states are charging for such annual licenses. The Board feels that we have reached out to many of the interested parties to ensure all issues are addressed in this legislation, including the DME retailers and distributors.

Thank you for your time in hearing my explanation of Senate Bill 2342 and the Board of Pharmacy would appreciate your support.

I will be happy to answer any questions you may have.

#2

– FDA Drug Distribution Model



#2

ND Board of Pharmacy

Income Statement - Actual vs. Budget
PDMP
For the Twelve Months Ending June 30, 2010

	YTD Actual	Budget
Revenue:		
Miscellaneous Income	$275	
Total Revenue	*275*	
Operating Expenses:		
Employee-Related Expenses:		
Payroll Expenses	6,842	
Salaries Expense	53,194	
Total Employee-Related Expens	*60,036*	
Other Operating Expenses:		
Expense	3,293	
Consultants/ Contracts Expense	6,277	
Insurance Expense	3,551	
Travel/Meeting Expense	2,403	
Total Other Operating Expenses	*15,524*	
Total Operating Expenses	*75,560*	
Income(Loss)	*($75,285)*	

Income Statement - Actual vs. Budget
Enhancement
For the Twelve Months Ending June 30, 2010

	YTD Actual	Budget
Revenue:		
Income	$82,529	
Total Revenue	*82,529*	
Operating Expenses:		
Employee-Related Expenses:		
Other Operating Expenses:		
Expense	222	
Consultants/ Contracts Expense	65,210	
Travel/Meeting Expense	16,958	
Total Other Operating Expenses	*82,390*	
Total Operating Expenses	*82,390*	
Income(Loss)	*$139*	

#2

ND Board of Pharmacy

Income Statement - Actual vs. Budget
PDMP
For the Twelve Months Ending June 30, 2011

	YTD Actual	Budget
Revenue:		
Operating Expenses:		
Employee-Related Expenses:		
Payroll Expenses	$7,002	
Salaries Expense	52,573	
Total Employee-Related Expens	*59,575*	
Other Operating Expenses:		
Expense	3,297	
Consultants/ Contracts Expense	75,512	
Insurance Expense	10,393	
Travel/Meeting Expense	3,546	
Total Other Operating Expenses	*92,748*	
Total Operating Expenses	*152,323*	
Income(Loss)	*($152,323)*	

#2

ND Board of Pharmacy

Income Statement - Actual vs. Budget
PDMP
For the Twelve Months Ending June 30, 2012

	YTD	
	Actual	*Budget*
Revenue:		
Miscellaneous Income	$1,859	
Total Revenue	*1,859*	
Operating Expenses:		
Employee-Related Expenses:		
Payroll Expenses	5,758	7,795
Salaries Expense	36,604	35,050
Total Employee-Related Expens	*42,362*	*42,845*
Other Operating Expenses:		
Expense	5,267	5,000
Consultants/ Contracts Expense	77,314	93,104
Insurance Expense	11,098	12,782
Travel/Meeting Expense	7,827	6,000
Total Other Operating Expenses	*101,506*	*116,886*
Total Operating Expenses	*143,868*	*159,731*
Income(Loss)	*($142,009)*	*($159,731)*

#2

NORTH DAKOTA STATE BOARD OF PHARMACY

STATEMENTS OF CHANGES IN NET ASSETS
FOR THE YEARS ENDED JUNE 30, 2011 AND 2010

	Unrestricted			
	Undesignated	Designated	Capital Assets	Total
June 30, 2009	$ 616,568	$ 380,312	$ 20,887	$ 1,017,767
Excess of revenues over expenses	(70,345)	-	-	(70,345)
Equipment acquisitions	(23,076)	-	23,076	-
Depreciation	11,521	-	(11,521)	-
Increase designated net assets	(212,518)	212,518	-	-
June 30, 2010	322,150	592,830	32,442	947,422
Excess of expenses over revenues	(132,964)	-	-	(132,964)
Equipment acquisitions	-	-	-	-
Depreciation	14,309	-	(14,309)	-
Increase designated net assets	(129,947)	129,947	-	-
June 30, 2011	$ 73,548	$ 722,777	$ 18,133	$ 814,458

See Notes to Financial Statements.

701 Pennsylvania Avenue, Ste. 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

Attachment #3

AdvaMed
Advanced Medical Technology Association

February 10, 2013

The Honorable Judy Lee, Chair
Senate Human Services Committee
State House
Bismarck, ND 58505

Dear Senator Lee:

I am writing on behalf of the members of the Advanced Medical Technology Association, AdvaMed, to share some information relating to Senate Bill 2342, relating to pedigree.

AdvaMed represents more than 1,300 of the world's leading medical technology innovators and manufacturers who provide advanced technologies improving health outcomes across the continuum of care, from diagnostic tests to wound care and orthopedics, cardiovascular therapies and beyond. Over 70% of our member companies are relatively small, with less than 100 employees and sales of less than $30 million.

No state that has adopted a pharmaceutical pedigree law has included medical devices, or medical products of any kind, in their law. Pedigree laws are designed specifically to address concerns with counterfeit and adulterated drugs in the supply chain. Medical devices are very different from drugs in the way that they are developed and get to patients. It is inappropriate to try to force fit them into laws designed for drugs. AdvaMed has been a leader in the development of a unique device identifier (UDI) system that will enable health officials to track medical devices.

If the sponsor's intent is to license suppliers of home medical equipment, which at least twenty-six other states have done, we would urge the sponsor and Committee to look at the statutes in those states, Kentucky perhaps being the most recent state to adopt licensure requirements with the 2012 passage of HB 282. Laws like these can provide effective oversight and deter fraud and abuse.

We hope that this information is helpful. We would be glad to discuss the issue further.

Sincerely,

Thomas E. Tremble

Thomas E. Tremble
Vice President, State Government Relations

cc: Senator Howard Anderson

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

February 8, 2013

The Honorable Howard Anderson Jr.
2107 Seventh Street NW
Turtle Lake, ND 58575-9667

Re: *SB 2342*

Dear Senator Anderson:

On behalf of the Health Industry Distributors Association (HIDA), which represents the interests of over 600 medical-surgical products distributors that are committed to promoting safety and cost savings within the healthcare supply chain, I write to express our concerns with respect to SB 2342. As currently drafted, the legislation would expand track and trace, pedigree requirements to medical equipment. We respectfully request that this bill not move forward until certain technical changes are made.

HIDA's members deliver lifesaving healthcare products to more than 294,000 points of care including over 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the nation.[1]

Pharmaceutical pedigrees are not well-suited for medical equipment

As medical-products distributors, we are concerned that many of the devices that fall under the definition of "medical equipment" in the bill may also be distributed to hospitals, physician offices, and long-term care facilities. When a distributor purchases products from a manufacturer, there is no way to know at the outset which products will be distributed to which patient care setting. Moreover, the average medical products distributor affords healthcare providers access to more than 200,000 medical products from as many as 2,200 manufacturers. A single distribution center supplies an average of 440 healthcare sites with medical products.

Additionally, there is no infrastructure for pedigree with medical products, which would add significant cost and complexity to the North Dakota medical products supply chain. Likewise, the creation of a tracking system for a subset of products would interrupt the efficiency of the supply chain and the delivery of everyday medical products.

[1] "The Economic Impact of the Healthcare Distribution Industry," HIDA, retrieved on October 17, 2012.

SB 2342 conflicts with federal efforts to implement UDI

As currently written, SB 2342 does not harmonize with federal efforts to establish a unique device identification (UDI) system for medical equipment and devices. The U.S. Food and Drug Administration (FDA) is required by the 2007 Food and Drug Administration Amendments Act (FDAAA) to develop regulations establishing a UDI system for medical devices. Federal policymakers envision a national product identification system that can improve both medical device tracking and safety surveillance. In July 2012, the FDA published a proposed rule to establish the parameters and timeline to implement UDI for medical devices. The final rule is expected to be released in the spring of 2013.

Thank you for your time and consideration. We welcome the opportunity to speak with you in more detail about our concerns and to partner with you to find a workable solution to address the safety and security of the healthcare supply chain. If you have any questions or are interested in learning more about medical products distributors, please contact Ashley Palmer at palmer@hida.org or (703) 838-6113.

Kind regards,

Linda Rouse O'Neill
Vice President, Government Affairs

CC:
The Honorable Judith Lee
The Honorable Kim Koppelman
Assistant Executive Director, Board of Pharmacy Mark Hardy

310 Montgomery Street • Alexandria, VA 22314-1516
Phone: (703) 549-4432 • Fax: (703) 549-6495 • www.HIDA.org

Attachment #4

Attachment #5

Lee, Judy E.

From: Matt Jensen <mattj@delasco.com>
Sent: Friday, February 08, 2013 3:39 PM
To: handerson@nd.com; Lee, Judy E.
Subject: S. 2342 - Pedigree requirements for medical equipment

Dear Senator Anderson and Ms. Lee,

Dermatologic Lab & Supply, Inc. (d.b.a. Delasco) is a medical-products distributor. As such, we are concerned that S. 2342 would expand pharmaceutical track and trace regulations to medical equipment and I encourage the bill sponsors to remove the bill from consideration for the following reasons:

1. Pedigrees for medical equipment are unprecedented and would add significant cost and complexity to the North Dakota medical products supply chain.

- There is no infrastructure for pedigree with medical products.
- To create a pedigree tracking system for a subset of products would interrupt the efficiency of the supply chain.
- Many of the devices that fall under the definition of "medical equipment" may also be distributed to hospitals, physician offices, and long-term care facilities.
- A pharmaceutical law is not applicable to medical products.
- The average medical products distributor provides healthcare providers access to more than 200,000 medical products from as many as 2,200 manufacturers.
- A single distribution center supplies an average of 440 healthcare sites with medical products.
- When a distributor purchases product from a manufacturer, there is no way to know at the outset which products will be distributed to which patient care setting.

2. This legislation does not harmonize with federal efforts to establish a unique device identification (UDI) system for medical equipment and devices.

- The U.S. Food and Drug Administration (FDA) is required by the 2007 Food and Drug Administration Amendments Act (FDAAA) to develop regulations establishing a UDI system for medical devices. Federal policymakers envision a national product identification system that can improve both medical device tracking and safety surveillance.
- In July 2012, the FDA published a proposed rule to establish the parameters and timeline to implement UDI for medical devices. The final rule is expected to be released in the spring of 2013.

Sincerely,

--
Matt Jensen
Director of Regulatory Affairs
Delasco
Phone: 712-323-3269
Fax: 712-323-1156
mattj@delasco.com
tp://www.delasco.com

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536

BOARD OF PHARMACY
State of North Dakota

E-mail= ndboph@btinet.net www.nodakpharmacy.com

Jack Dalrymple, Governor

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

278-13

Senate Bill 2342 – Wholesaler Drug Distribution
Senate Appropriations Committee – Harvest Room
3:00 PM – Monday – February 18, 2013

Chairperson Holmberg, members of the Senate Appropriations Committee, for the record I am Mark J. Hardy, PharmD, Assistant Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you briefly about Senate Bill 2342 Wholesale Drug Distribution.

This legislation provides revisions to our current Wholesale statute and incorporates changes that will provide clarity to what business activities will require licensure in North Dakota. Part of this legislation also includes an increase of annual licensure fees for manufacturers, distributors and brokers. These fees are an annual increase of $200. The fiscal note on this bill accounts for this increase in fees. The additional money is to help provide take-back programs for prescription drugs, fund the Repository Program and help provide the funds for the inspections of these licensees. Additional revenue will help fund the Prescription Drug Monitoring Program, which is currently being funded by the Board of Pharmacy's reserves. The expenses related to the fiscal note are the estimated cost of implementing the data base revisions to account for these changes. We feel these fees are in line with what other states are charging for such annual licenses. The Board feels that we have reached out to many of the interested parties to ensure all issues are addressed in this legislation, including the DME retailers and distributors.

I am including the annual expenses for the Prescription Drug Monitoring Program [PDMP] for 2009, 2010 and 2011 fiscal years and a printout from our auditor's report showing the spend-down of the Board of Pharmacy's reserves during those years. Our 2012 auditor's report for 2012 will show a similar spend-down.

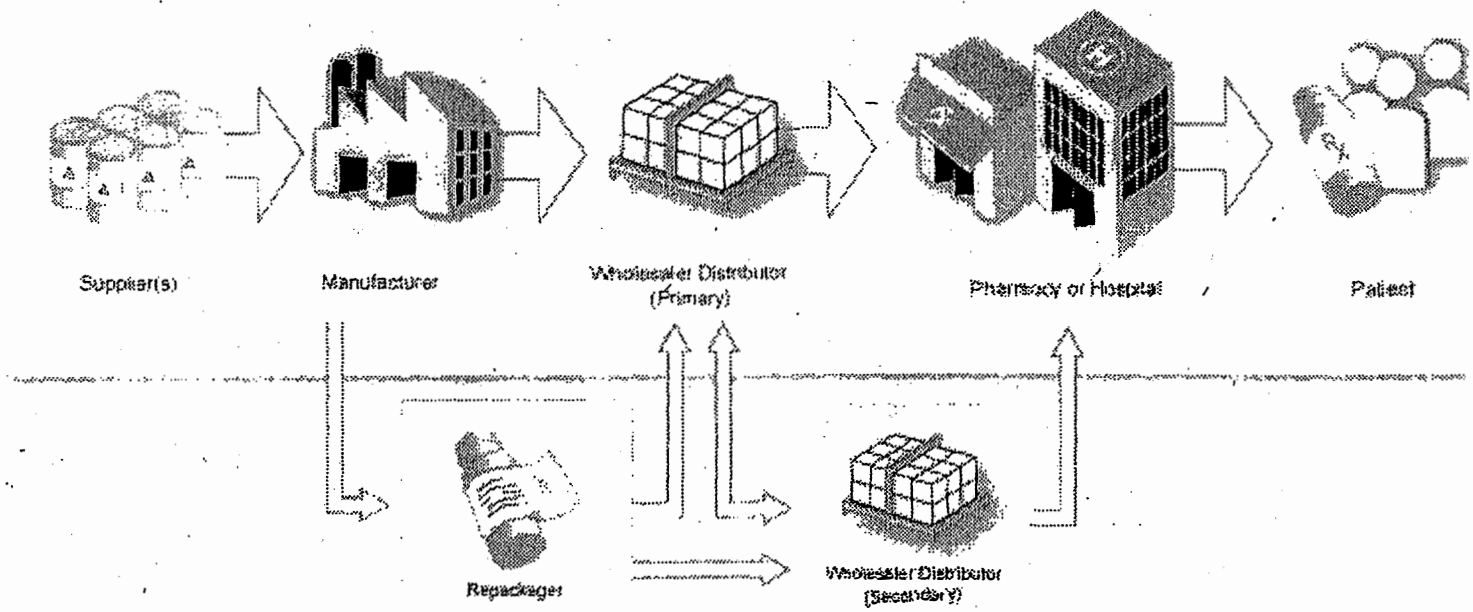
There were no oppositions during the testimony within the Senate Human Service Committee to the fee increases on the applicable parties.

Thank you for your time in hearing my explanation of Senate Bill 2342 and the Board of Pharmacy would appreciate your support.

I will be happy to answer any questions you may have.

1

– FDA Drug Distribution Model



ND Board of Pharmacy

Income Statement - Actual vs. Budget
PDMP
For the Twelve Months Ending June 30, 2010

	YTD Actual	YTD Budget
Revenue:		
Miscellaneous Income	$275	
Total Revenue	*275*	
Operating Expenses:		
Employee-Related Expenses:		
Payroll Expenses	6,842	
Salaries Expense	53,194	
Total Employee-Related Expens	*60,036*	
Other Operating Expenses:		
Expense	3,295	
Consultants/ Contracts Expense	6,277	
Insurance Expense	3,551	
Travel/Meeting Expense	2,403	
Total Other Operating Expenses	*15,524*	
Total Operating Expenses	*75,560*	
Income(Loss)	*($75,285)*	

Income Statement - Actual vs. Budget
Enhancement
For the Twelve Months Ending June 30, 2010

	YTD Actual	YTD Budget
Revenue:		
Income	$82,529	
Total Revenue	*82,529*	
Operating Expenses:		
Employee-Related Expenses:		
Other Operating Expenses:		
Expense	222	
Consultants/ Contracts Expense	65,210	
Travel/Meeting Expense	16,958	
Total Other Operating Expenses	*82,390*	
Total Operating Expenses	*82,390*	
Income(Loss)	*$139*	

ND Board of Pharmacy

Income Statement - Actual vs. Budget

PDMP

For the Twelve Months Ending June 30, 2011

	YTD Actual	Budget
Revenue:		
Operating Expenses:		
Employee-Related Expenses:		
Payroll Expenses	$7,002	
Salaries Expense	52,573	
Total Employee-Related Expens	*59,575*	
Other Operating Expenses:		
Expense	3,297	
Consultants/ Contracts Expense	75,512	
Insurance Expense	10,393	
Travel/Meeting Expense	3,546	
Total Other Operating Expenses	*92,748*	
Total Operating Expenses	*152,323*	
Income(Loss)	*($152,323)*	

ND Board of Pharmacy
Income Statement - Actual vs. Budget
PDMP
For the Twelve Months Ending June 30, 2012

	YTD	
	Actual	Budget
Revenue:		
Miscellaneous Income	$1,859	
Total Revenue	**1,859**	
Operating Expenses:		
Employee-Related Expenses:		
Payroll Expenses	5,758	7,795
Salaries Expense	36,604	35,050
Total Employee-Related Expens	**42,362**	**42,845**
Other Operating Expenses:		
Expense	5,267	5,000
Consultants/ Contracts Expense	77,314	93,104
Insurance Expense	11,098	12,782
Travel/Meeting Expense	7,827	6,000
Total Other Operating Expenses	**101,506**	**116,886**
Total Operating Expenses	**143,868**	**159,731**
Income(Loss)	**($142,009)**	**($159,731)**

NORTH DAKOTA STATE BOARD OF PHARMACY

STATEMENTS OF CHANGES IN NET ASSETS
FOR THE YEARS ENDED JUNE 30, 2011 AND 2010

	Unrestricted			
	Undesignated	Designated	Capital Assets	Total
June 30, 2009	$ 616,568	$ 380,312	$ 20,887	$ 1,017,767
Excess of revenues over expenses	(70,345)	-	-	(70,345)
Equipment acquisitions	(23,076)	-	23,076	-
Depreciation	11,521	-	(11,521)	-
Increase designated net assets	(212,518)	212,518	-	-
June 30, 2010	322,150	592,830	32,442	947,422
Excess of expenses over revenues	(132,964)	-	-	(132,964)
Equipment acquisitions	-	-	-	-
Depreciation	14,309	-	(14,309)	-
Increase designated net assets	(129,947)	129,947	-	-
June 30, 2011	$ 73,548	$ 722,777	$ 18,133	$ 814,458

See Notes to Financial Statements

#1

Senate Bill 2342
House Human Services Committee
9:00AM Wednesday, March 20, 2013
Fort Union Room

Chairman Weisz and Members of the House Human Services Committee, I am Howard Anderson, Senator from District 8 and the Executive Director of the North Dakota State Board of Pharmacy.

I have been working on this rewrite for three years, in consultation with those in North Dakota who are in the Medical Equipment, Medical Gas and Device business.

Since the Federal Government decided that they wanted to bid out the sale of much of this equipment and devices to mail order, which will come mostly from Florida and California we have gotten hundreds of calls about what license they need to supply these devices directly to North Dakota patients from their mail order locations. The Federal requirements include being appropriately licensed by the states and we had nothing to answer this need.

Therefore we got together and I wrote an interpretation, which resides on the board's web site, that they need someone licensed in North Dakota to help the patient and be responsible for their care. Our wholesale act, adopted in 2007, requires sale to only licensees. These might be pharmacies, Hospitals, Respiratory Therapists, Physicians and a whole host of people who have a license authorizing them to serve the public, however we have no way to capture that information or license the direct sale to consumers, on a prescription order, except to have a pharmacy license. Many of these companies are not pharmacies in their home state and thus are not eligible for one here.

Therefore this bill was written to revise the Wholesale licensing act to accomplish the following:

Provide a licensing mechanism for the sale of medical equipment and supplies directly to the consumer, when prescribed by a practitioner and intended to be paid for by a third party payer, such as a Medicare Part D plan, Medicaid, or another insurer. It does not affect sales of these items when sold without the need for a prescription, except in the case of Legend Devices that would require a prescription under Federal Law in any case.

Provides a mechanism to capture the name and license number of the North Dakota licensed professional that will be responsible to see that the patient knows how to use the device properly. If you get a gastric suction pump in the mail, someone needs to help you use it properly and that person should not be on the phone from Florida. If there is a patient complaint, we need a way to address that with the licensee through their own North Dakota Licensing Board.

Provides an increase in license fees for some of our licensees, to help the Board of Pharmacy finance the Prescription Drug Monitoring Program, help with drug take back programs and make upgrades to the Prescription Drug Repository Program. We have been spending down our reserves to finance these programs since 2009 and the companies who manufacture and sell the products are needed to help pay for those programs.

We have an excellent web site where licenses can be applied for and renewed, without repeating required information each year, and we will use some of the money to make enhancements and maintain this licensee friendly system. It also allows a very easy to use "Verify a License" program that saves licensees the $25 fee when they need that verification for the Federal Requirements or for licensure in another state.

On the Senate side we heard from some of the manufacturers of this equipment and devices that the pedigree requirements we have in place for prescription drugs are not yet applicable to this industry. Therefore we have taken the suggestion of Joel Gilbertson and removed those changes to Section SIX and leave the pedigree requirements to drugs until the medical device industry gets their Universal Product Identifier projects completed. The Pedigree requirements are intended to protect consumers from counterfeit products and thus can help the legitimate manufacturers as well, when they are ready.

My Assistant Executive Director, Mark Hardy, Pharm D. has some additional information for you and will explain the fiscal note and Pharmacy Board Budget in as much detail as you would like.

Thank you.

#2

13.0807.03001
Title.

Prepared by the Legislative Council staff for
Representative K. Koppelman
March 13, 2013

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2342

Page 1, line 3, remove "43-15.3-05,"

Page 4, line 3, remove the underscored comma

Page 4, line 4, remove "medical gas, or medical equipment"

Page 4, line 5, remove "medical gas, or medical equipment,"

Page 4, line 10, remove ", gas, or equipment"

Page 4, line 12, remove ", gas, or equipment"

Page 4, line 16, remove ", gas, or equipment"

Page 4, line 20, remove ", gas, or equipment"

Page 5, line 8, overstrike the comma

Page 5, line 8, remove "medical gas, or"

Page 5, line 9, remove "medical equipment"

Page 15, remove lines 23 through 31

Page 16, remove lines 1 through 31

Page 17, remove lines 1 through 5

Renumber accordingly

#3

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BOARD OF PHARMACY
State of North Dakota

E-mail= ndboph@btinet.net www.nodakpharmacy.com

Jack Dalrymple, Governor

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

Senate Bill 2342 – Wholesaler Drug Distribution
House Human Services Committee – Fort Union Room
9:00 AM – Wednesday – March 20, 2013

Chairman Weisz, members of the House Human Services Committee, for the record I am Mark J. Hardy, PharmD, Assistant Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you briefly about Senate Bill 2342 Wholesale Drug Distribution.

This Bill provides revisions and enacts sections to North Dakota Century Code 43-15.3 which the Board of Pharmacy has been looking to incorporate. We currently have two sections of wholesale statutes in our law. This legislation is intended to combine these and also clear up any differences throughout the bill. I would like to walk through the changes in the Bill so that you may have a good understanding of what this legislation does.

You will notice the inclusion of *medical gas, or medical equipment* throughout much of the legislation. This makes it clear that the movement of medical gases and/or legend medical equipment requires licensure.

We have added the definitions of: Broker – Device – Durable medical equipment – Medical device – Medical equipment – Medical gas – Pharmacy distributor and Trace and Track, along with Virtual distributor and Virtual manufacturer. Again this clarifies much of the ambiguities that are in the current wholesale statute and makes it very clear what business activities require licensing in North Dakota.

I would like to talk just a bit about the businesses of a Virtual distributor and Virtual manufacturer. These are relatively new and increasing models that, in the case of a virtual manufacturer, are a company that does not take actual control of a drug or device, but contracts the manufacturing to a separate facility and the delivery to a logistics provider, but *does* handle the billing and the FDA Registration, along with having the name of their "company" on the product. This type of business can be a source of questionable activity. In fact, a couple months ago I participated in a task force on these business types, so we feel it is necessary to make it clear that licensure is required of these business practices. We currently ask these virtual distributors and virtual manufacturers to license under our current law, but this bill will make it clear a license is required. Once again, this will ensure supply chain integrity and should any issues arise with North Dakota citizens we are able to hold the right business accountable for those concerns.

On page 9 of this bill, lines 6 through 10 is language that will maintain the Board of Pharmacy's position of ensuring a wholesale distributor of prescription drugs must obtain accreditation from the National Association of Boards of Pharmacy [NABP] Verified Accredited Wholesale Distributor [VAWD] program. This accreditation has been a proven tool for Boards of Pharmacy to ensure out-of-state wholesale distributors are in compliance with laws and rules, to again safeguard supply and product integrity. This accreditation is becoming a national standard for legitimate wholesale distributors and it is commendable that North Dakota was a leader in this requirement to bring an enhanced level of safety to our citizens.

On page 15, beginning on line 4 – allows the Board of Pharmacy to inspect facilities which are licensed with the Board. It also allows a designee of the Board to conduct inspections; this may be pertinent if we were to feel any suspicious activity is being conducted, especially in an out-of-state license.

On page 17 under 43-15.3-06 Electronic Pedigree – you will notice that the dates are moved back from the previous legislation. To give you some background on this track and trace pedigree technology, this has been something that has been widely discussed as a method to better control the movement of prescription drugs. The technology is progressing, however not as quickly as many had first envisioned. California is attempting to lead the way on the electronic track and trace requirement. The Board certainly sees good reason for implementing this technology across the pharmaceutical supply chain.

Essentially this would help to address issues with the gray market of pharmaceuticals, which is certainly a large issue in the nation. I am sure you have heard one of the many news reports of counterfeit substances being found or even reaching the patient level.

As we get to page 23 beginning on line 26, a new section is being created for retail medical gas retailers. This provides clarification that medical gas retailers need to be licensed with the Board of Pharmacy to provide medical gases *directly to a North Dakota citizen*. They currently license under the provisions of the current law.

On page 25 beginning on line 3 is also a new section that creates a new class of license for retail durable medical equipment retailers. This has been a recent issue for the Board, as we do not currently have a license class to license **d**urable **m**edical **e**quipment, retailers or DME products, especially out-of-state companies.

This has been brought to our immediate attention due to the Medicare competitive bidding process put forward in the new healthcare proposals. Currently a DME retailer has two options to conduct this type of business when sending their products directly to patients in North Dakota. They may be licensed as a pharmacy or contract with a North Dakota licensed individual who is authorized to dispense the DME product pursuant to their practice act.

This new section still maintains that a DME retailers must employ or contract with a North Dakota healthcare professional authorized by their practice act to do business directly with our citizens. The Board feels that this is very important for any problems that may arise with a product or we receive a complaint from a North Dakota citizen. Ultimately this is for the patient's safety and well-being.

A simple example is receiving a cane in the mail. If that cane has not been fitted to the patient, or a healthcare professional is not made available for questions about how to properly fit that cane, it could put that patient at a higher risk for falling and adverse events from happening. It certainly is in the best interest of our patients to have a North Dakota licensed individual to oversee these types of activities.

For those businesses that are currently in North Dakota and operate as medical equipment retailers, they employ or have licensed professionals on staff to answer these types of questions. The Board feels this is ideal to ensure that the patient is properly educated on the devices and equipment that they receive.

On page 26 beginning on line 27 – the fees are listed according to each license category. Currently the wholesale fee is $200 for all licenses. The new categories that are not identified in the current law are the durable medical equipment distributors and retailer licenses. The fees are *increased by $200* for manufacturers, distributors and brokers.

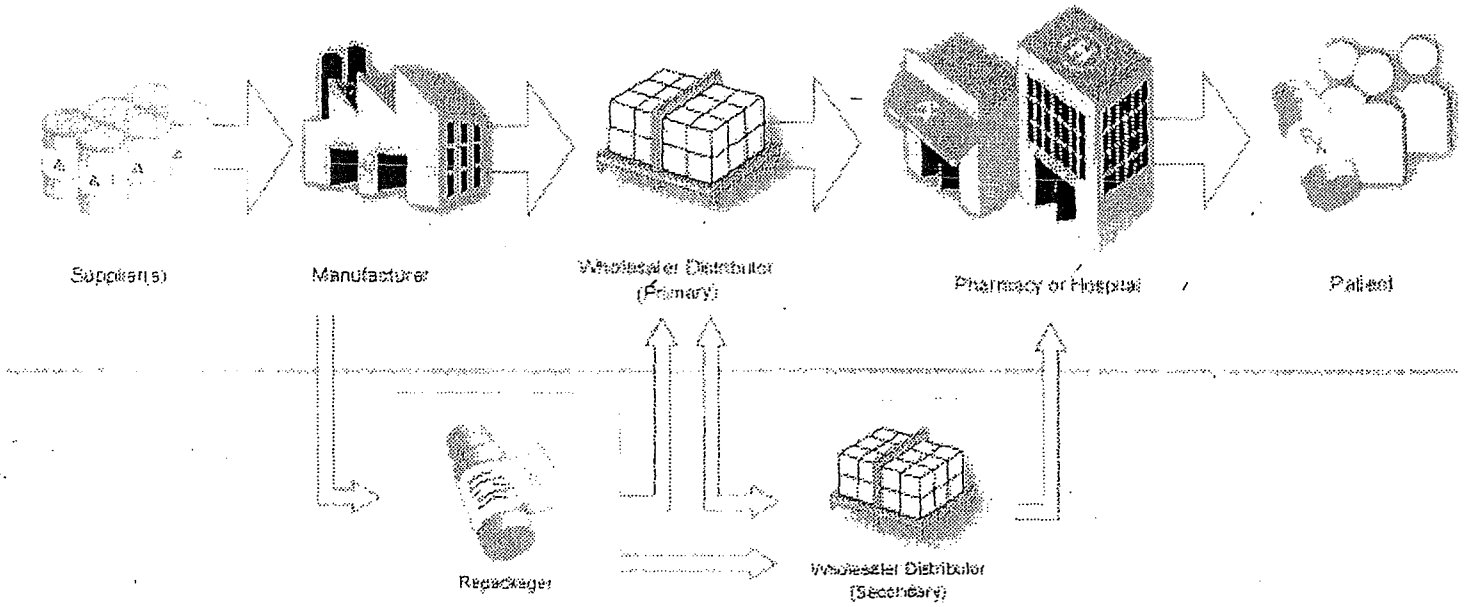
The fiscal note on this bill accounts for this increase in annual licensure fees. The additional money is to help provide take-back programs for prescription drugs, fund the Repository Program and help provide the funds for the inspections of these licensees. Additional revenue will help fund the **P**rescription **D**rug **M**onitoring **P**rogram, which is currently being funded by the Board of Pharmacy's reserves. The expenses related to the fiscal note are the estimated cost of implementing the data base revisions to account for these changes. We feel these fees are in line with what other states are charging for such annual licenses. The Board feels that we have reached out to many of the interested parties to ensure all issues are addressed in this legislation, including the DME retailers and distributors.

Also included are the expenses of the PDMP for 2009 – 2010 - 2011 annual fiscal years. Lastly a printout from our auditor's report showing the spend down of the Board of Pharmacy's reserves during the 2009 – 2010 – 2011 fiscal years. 2012 will show a similar spend down.

Thank you for your time in hearing my explanation of Senate Bill 2342 and the Board of Pharmacy would appreciate your support.

I will be happy to answer any questions you may have.

– *FDA Drug Distribution Model*



ND Board of Pharmacy

Income Statement - Actual vs. Budget
PDMP
For the Twelve Months Ending June 30, 2010

	YTD	
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Revenue:		
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ND Board of Pharmacy
Income Statement - Actual vs. Budget
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Total Other Operating Expenses	*92,748*	
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ND Board of Pharmacy
Income Statement - Actual vs. Budget
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Salaries Expense	36,604	35,050
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Total Operating Expenses	*143,868*	*159,731*
Income(Loss)	*($142,009)*	*($159,731)*

NORTH DAKOTA STATE BOARD OF PHARMACY

STATEMENTS OF CHANGES IN NET ASSETS
FOR THE YEARS ENDED JUNE 30, 2011 AND 2010

	Unrestricted			
	Undesignated	Designated	Capital Assets	Total
June 30, 2009	$ 616,568	$ 380,312	$ 20,887	$ 1,017,767
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Equipment acquisitions	(23,076)	-	23,076	-
Depreciation	11,521	-	(11,521)	-
Increase designated net assets	(212,518)	212,518	-	-
June 30, 2010	322,150	592,830	32,442	947,422
Excess of expenses over revenues	(132,964)	-	-	(132,964)
Equipment acquisitions	-	-	-	-
Depreciation	14,309	-	(14,309)	-
Increase designated net assets	(129,947)	129,947	-	-
June 30, 2011	$ 73,548	$ 722,777	$ 18,133	$ 814,458

See Notes to Financial Statements

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

#4

Statement

of the

Health Industry Distributors Association (HIDA)

to the

North Dakota House Human Services Committee

Hearing on S.B. 2342

March 20, 2013

Chairman Weisz and Members of the Committee on Human Services:
My name is Ashley Palmer. I am Director of Government Affairs with the Health Industry Distributors Association, HIDA, the premier trade association representing medical products distributors. I appreciate this opportunity to share testimony on behalf of our members today.

Our members are committed to promoting safety and cost savings within the healthcare supply chain. HIDA represents the interests of over 600 medical products distributors who deliver medical products and supplies, manage logistics, and offer customer services to more than 294,000 points of care. Their customers include over 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the country.[1]

On behalf of the HIDA membership I want to convey our concerns with regard to SB 2342 as it is currently drafted. We respectfully request that this bill be tabled until certain technical changes are made. As currently drafted, the legislation inadvertently restricts the sales and transactions of medical devices and gases between trading partners.

We understand the objective of the legislation is to license medical gas and medical equipment suppliers. HIDA is not opposed to the licensure of these suppliers. North Dakota would not be the first state to require such licensure. However, certain provisions of the bill expand definitions and restrictions currently applicable to the pharmaceutical supply chain to the medical products supply chain that are misaligned or that are simply not feasible.

There are two key areas in the bill that concern our membership:

1. The expansion of definitions that specifically pertain to the pharmaceutical supply chain; and
2. Transaction restrictions.

[1] "The Economic Impact of the Healthcare Distribution Industry," HIDA, retrieved on October 17, 2012.

With regard to the definitions, HIDA strongly recommends removing references to medical gas and equipment from the definitions of "normal distribution channel" and "repackage" because these terms are specific to the pharmaceutical supply chain and do not translate to medical products.

The second key area of concern pertains to Sec. 5 of the bill that would expand pharmaceutical transaction restrictions to the medical equipment supply chain. Many of the supply chain restrictions in this section of the North Dakota Century Code (Section 43-15.3-05) were initially drafted for the drug supply chain for specific reasons (for example, a high-risk of diversion or to prevent entry of counterfeit product into the supply chain) that do not necessarily translate to the medical equipment supply chain.

One example of a restricted pharmaceutical transaction that would not work in the medical equipment supply chain is for *returned products*. As currently drafted in the bill, a medical equipment wholesaler would only be able to accept returns from a pharmacy or chain pharmacy warehouse. However, in addition to a home setting, many medical devices and equipment may also be distributed to hospitals, physician offices, and long-term care facilities. Therefore, restricting the wholesale distributor to only receive returns and exchanges from a pharmacy or a chain pharmacy warehouse does not work in the medical equipment supply chain.

The pharmaceutical and medical equipment supply chains are distinctly different, and the infrastructure to support the restrictions and new definitions proposed in this bill does not currently exist in the medical equipment supply chain. There are, for example, federal efforts underway by the U.S. Food and Drug Administration to implement a unique device identification (UDI) system that would enable this some of these activities on a national scale.

In summary, I want to reiterate that my organization is not opposed to the licensure of medical gas and equipment suppliers. We are, however, opposed to SB 2342 in its current form. I respectfully encourage the committee to support an amendment that makes the changes necessary to reflect the differences between the pharmaceutical and medical equipment supply chains. Thank you for your consideration and for allowing me the opportunity to provide testimony today.

#5

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AdvaMed
Advanced Medical Technology Association

The Honorable Robin Weisz
Chairman, House Human Services Committee
North Dakota House of Representatives
State Capitol
Bismarck, ND 58505

RE: SB 2342
Sent via Email

Dear Rep. Weisz:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to express concern with SB 2342 as it came to the House from the Senate. The bill needs significant work before it advances on the House side.

AdvaMed represents more than 1,300 of the world's leading medical technology innovators and manufacturers who provide advanced technologies improving health outcomes across the continuum of care, from diagnostic tests to wound care and orthopedics, cardiovascular therapies and beyond.

While we understand the bill sponsor's initial objective to license medical gas and DME suppliers, we strongly suggest a licensing bill would be a more appropriate venue for doing so. As currently written, the bill would inappropriately subject medical equipment to pedigree requirements. No other state that has adopted a pharmaceutical pedigree law has included medical devices, or medical products of any kind, in their law. As you may know, the development, manufacture, distribution, prescription and utilization of medical devices is completely different than with pharmaceuticals which have typically been the focus of pedigree legislation. Medical device (implants and the like) are already controlled from the manufacturer to the hospital.

If the intent of the legislation is to license supplier of home medical equipment, which at least twenty-six other states have done, we would then strongly urge the Committee to amend the bill in its entirety to better accomplish this objective within a licensing statute. We believe the amendments drafted by Legislative Counsel to substitute the bill would be a more prudent approach and better achieve the bill sponsor's intent of licensing medical gas and DME suppliers. If such a comprehensive rewrite of the bill is not possible, then we respectfully request that medical equipment be removed from the entire scope of the pedigree requirements contained within the bill before the bill advances.

AdvaMed
Advanced Medical Technology Association

Please don't hesitate to contact me should you need additional information.

Regards,

Carrie Hartgen

cc: Members of the House Human Services Committee
Rep. Kim Koppelman

Handed in #6

Medline Industries, Inc.
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1.800.MEDLINE

Statement of Medline Industries Inc. to the North Dakota House Human Services Committee

Hearing on S.B. 2342 - March 20, 2013

Chairman Weisz and Members of the Committee on Human Services:

The following statement for the record is submitted on behalf of Medline Industries, Inc., a manufacturer and distributor of medical products including medical devices.

We wish to express our concerns with S.B. 2342. We recognize and do not oppose the central purpose of this legislation—to license medical gas and durable medical equipment suppliers. However, as currently drafted, the legislation aims to apply pharmaceutical specific regulations to the distribution of medical equipment in a way that would impose a significant regulatory burden on industry—inevitably increasing prices of medical devices while reducing access. Furthermore, because these requirements would be exclusive to North Dakota, medical equipment manufacturers and distributors would have to create a separate supply chain with unique and complicated controls for the North Dakota market.

We do not believe that this is the intent of the North Dakota legislature. Therefore, we strongly urge you to table this legislation until certain technical changes are made.

Most concerning of these unintended consequences is the application of pedigree-related requirements for certain medical devices. The implementation of a pedigree system for the pharmaceutical supply chain has taken decades and cost tens of millions of dollars. Such a system for medical equipment would be potentially even more complicated and costly without providing benefits for patients. The FDA has recognized this fact and is working on a Unique Device Identification system that will track medical devices in a manner that takes into consideration the difference between the medical device and pharmaceutical supply chains.

The proposed legislation also unnecessarily limits several important transactions that are critical to ensuring that patients have safe and affordable access to the medical equipment they rely on.

As currently drafted, this legislation attempts to apply pharmaceutical-specific processes that are not applicable in the medical equipment supply chain. We urge the committee to support an amendment that makes the changes necessary to reflect the differences between the pharmaceutical and medical equipment supply chains. This amendment seeks to accomplish the underlying goal of the legislation in a way consistent with other states' approaches to this important issue.

Thank you for allowing us the opportunity to provide this statement for the record. Should you have any questions, please contact Rob Calia at (847)-643-4249 or via email at rcalia@medline.com.

#7

NDLA, H HMS - Crabtree, Vicky

From: Pam Scherrer <Pam.Scherrer@MMSMEDICAL.COM>
Sent: Tuesday, March 19, 2013 4:06 PM
To: NDLA, H HMS - Crabtree, Vicky
Subject: ND SB 2342 Ammendment Request

Dear Committee Members of SB2342;

As a licensed Wholesale Drug/Device Distributor shipping into the state of North Dakota I respectfully implore you to amend the SB2342 to remove any references to medical equipment and medical gases from the areas that pertain to pharmaceutical-supply chain regulations, specifically pedigree.

The honest hardworking citizens of your state will be hard pressed to get the required medical equipment and gases as trying to add these items to the Pedigree process will bring many to a halt. The Pedigree process, even for pharmaceutical drugs, is still in its infancy. It causes interruption, delays and extreme costs to the supply chain and is not beneficial to the end user or anyone involved. There is not a quick turnaround or an efficient infrastructure to implement the Pedigree process for equipment and gases. The reputable manufacturers and distributors will be the ones who err on the side of compliance and caution; thus causing interruptions and delays possibly even shutting the supply chain down completely. We do not want risk our reputation, license and business if we cannot comply to the laws and rules of North Dakota.

The suppliers who will continue to ship into your state will be the ones unfamiliar with the law or intentionally non compliant because they can make a quick profit; there products have a greater chance of not coming from a legitimate company thus defeating the goal and intention of patient safety.

Thank you for considering my request.

Sincerely,

Pam Scherrer

Pam Scherrer
Director Quality Assurance – P21 Training
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Public Member, Bismarck

March 22, 2013

SB2342 additional amendment – House Human Services

Page 24, line 5, add – **A durable medical equipment retailer shall only obtain medical equipment from a manufacturer and/or wholesalers that are duly licensed in this state.**

The board feels with the addition of this amendment to the others presented by Rep. Koppelman will clear up the ambiguities in the revisions to 43-15.3-05 (pages 15-17) and will keep the intent of ensuring the manufacturers and wholesalers will be licensed and can be held accountable for any patient complaints or concerns related to their medical equipment when a prescription is necessary