

2019 SENATE HUMAN SERVICES COMMITTEE

SB 2327

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2327
1/29/2019
JOB #31635

☐ Subcommittee
☐ Conference Committee

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| Committee Clerk Signature: Justin Velez/Florence Mayer |
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Explanation or reason for introduction of bill/resolution:

Relating to license exception for outsourcing facility regarding certain sales.

Minutes:

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| Attachment # 1 - 2 |
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Chair Lee: Opened the hearing on SB 2327.

Senator Howard Anderson, District 8: Introduced SB 2327 and gave a brief description.

Senator Larsen: Is that hydrochloride, is that just battery acid? Are we talking about the eye wash station with saline solution or a system that has gallons of it?

Senator Anderson: It could be compared to having 100 red ants biting you in the eye if you were exposed. I'll let the refinery people tell you how they use that product.

(09:56-12:15) Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy: Testified in favor of SB 2327. Please see Attachment #1 for testimony.

(12:23) Ron Day, Government and Public Affairs Manager for Marathon Petroleum Corporation, Mandan: Testified in favor of SB 2327. Please see Attachment #2 for testimony. Calcium Gluconate is the antidote for an HF acid exposure. We have saline bags on site, so that if someone does get it in their eyes we can wash it out while the ambulance is on the way.

Senator K. Roers: How often have you had to use it?

Ron Day: Never. This is chemical we use as a catalyst, we know the hazards, we handle it with the utmost care. It would be an extreme accident.

Senator Anderson: How do you use the hydrochloric acid?

Ron Day: We take butane out of the Bakken crude. We convert it by mixing it with hydrochloric acid solution. We combine the 2 liquids and it turns into gasoline. There is no HF acid waste stream, it gets consumed by our process.

(16:27) Brady Pelton, Government Affairs Manager, ND Petroleum Council: Safety is key to our industry and this bill supports that. We ask for a do pass on SB 2327.

Chair Lee: Asked for further testimony for, against, neutral.

Senator Anderson: I don't much about petroleum compounds. Professor Schwartz at NDSU many years ago developed the "cracking" system that oil refineries use. When you pump oil out of the ground it is like tar. The carbon chains are long. The cracking breaks those chains into smaller pieces so they become the thing you can burn as gasoline. They are joining 2 of those carbon chains together to make something that will burn as gasoline, rather than butane.

Discussion was had by committee about personal experiences with chemistry classes.

Mark Hardy: You might want to put an emergency measure on this.

Senator Anderson: Moved to add an emergency clause.

Senator Roers: Seconded.

A Roll Call Vote Was Taken: 6 yeas, 0 nays, 0 absent.

Senator Clemens walked in and Chair Lee gave him a brief overview of the bill.

Senator Roers: Moved a Do Pass as Amended.

Senator Larsen: Seconded.

A Roll Call Vote was Taken: 6 yeas, 0 nays, 0 absent.

Senator Anderson will carry the bill.

January 18, 2019

SK
130

PROPOSED AMENDMENTS TO SENATE BILL NO. 2327

Page 1, line 3, after "sales" insert "; and to declare an emergency"

Page 1, after line 10, insert:

"SECTION 2. EMERGENCY. This Act is declared to be an emergency
measure."

Renumber accordingly

Date: 1/24/19
Roll Call Vote #:)

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2327

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.1126.01001

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

Motion Made By Sen. Anderson Seconded By Sen. K. Roers

| Senators | Yes | No | Senators | Yes | No |
|-------------------|-----|----|---------------|-----|----|
| Chair Lee | X | | Senator Hogan | X | |
| Vice Chair Larsen | X | | | | |
| Senator Anderson | X | | | | |
| Senator Clemens | X | | | | |
| Senator Roers | X | | | | |
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Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

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

Date: 11/29/19
Roll Call Vote #: 2

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2327

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.1126.01661

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

Motion Made By Sen. Roers Seconded By Sen. O. Larsen

| Senators | Yes | No | Senators | Yes | No |
|-------------------|----------|----|---------------|----------|----|
| Chair Lee | <u>X</u> | | Senator Hogan | <u>X</u> | |
| Vice Chair Larsen | <u>X</u> | | | | |
| Senator Anderson | <u>X</u> | | | | |
| Senator Clemens | <u>X</u> | | | | |
| Senator Roers | <u>X</u> | | | | |
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Total (Yes) 6 No 0

Absent 0

Floor Assignment Sen. Anderson

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

REPORT OF STANDING COMMITTEE

SB 2327: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2327 was placed on the Sixth order on the calendar.

Page 1, line 3, after "sales" insert "; and to declare an emergency"

Page 1, after line 10, insert:

"SECTION 2. EMERGENCY. This Act is declared to be an emergency measure."

Renumber accordingly

2019 HOUSE HUMAN SERVICES

SB 2327

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee Fort Union Room, State Capitol

SB 2327
2/27/2019
32950

- ☐ Subcommittee
☐ Conference Committee

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| Committee Clerk: Nicole Klamann by Marjorie Conley |
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Explanation or reason for introduction of bill/resolution:

Relating to license exception for outsourcing facility regarding certain sales; and to declare an emergency.

Minutes:

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|--------------------|
| Attachment 1, 2, 3 |
|--------------------|

Chairman Weisz: Opened hearing on SB 2327.

Senator Anderson: (See attachment 1) (00:19-05:17)

Rep. Porter: Do we need to put the emergency clause on this?

Senator Anderson: I believe it is on there already. I have an engrossed bill here.

Rep. Rohr: Who does that and who is responsible for the education training regarding this compound?

Senator Anderson: The refinery has their own people who are trained. This is one of the things that they would be fully trained on in case someone would get exposed to the hydrofluoric acid product that they use.

Rep. Rohr: Are there specific contra requirements for this antigen?

Senator Anderson: The antidote is what (inaudible) and itself is not dangerous. It is the chemical that they use at the plant, which they have very strict system for that and once it is utilized at the plant, it becomes nontoxic. It is not that it's a toxic by product when it comes out of the plant. It is the chemical itself that's used as a catalyst which is if somebody got it in their eyes would be very irritating.

Chairman Weisz: Further questions for the Senator? Further testimony in support?

Mark Hardy, Executive Director of the ND State Board of Pharmacy: See (Attachment 2). Supporting SB 2327.

Chairman Weisz: Any questions for Mr. Hardy? Any further support?

Ron Day, Government and Public Affairs Manager for Marathon Petroleum Corporation: Supports SB 2327 (08:40-10:40). (**Attachment 3**)

Chairman Weisz: Further support?

Brady Pelton, ND Petroleum Council: We represent over 500 members of the oil and gas industry. We support this bill. We urge a Do Pass on SB 2327.

Chairman Weisz: Any further questions? Further support? Opposition? Seeing none we will close the hearing on SB 2327.

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

SB 2327
3/5/2019
33221

☐ Subcommittee
☐ Conference Committee

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|---|
| Committee Clerk: Nicole Klamon by Marjorie Conley |
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Explanation or reason for introduction of bill/resolution:

Relating to license exception for outsourcing facility regarding certain sales; and to declare an emergency

Minutes:

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Chairman Weisz: Reopen SB 2327.

Rep. Porter: I would move a **Do Pass** to the engrossed version of SB 2327.

Rep. Rohr: Second.

Chairman Weisz: Any further discussion?

Roll Call Vote: Yes 13 No 0 Absent 1

Rep. Westlind is the **Carrier**.

Chairman Weisz: Hearing closed.

Date: 3-5-2019
Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2327

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

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

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep Porter Seconded By Rep Rohr

| Representatives | Yes | No | Representatives | Yes | No |
|-------------------------------|-----|----|--------------------|-----|----|
| Robin Weisz - Chairman | X | | Gretchen Dobervich | X | |
| Karen M. Rohr - Vice Chairman | X | | Mary Schneider | X | |
| Dick Anderson | X | | | | |
| Chuck Damschen | X | | | | |
| Bill Devlin | X | | | | |
| Clayton Fegley | X | | | | |
| Dwight Kiefert | X | | | | |
| Todd Porter | X | | | | |
| Matthew Ruby | X | | | | |
| Bill Tveit | A | | | | |
| Greg Westlind | X | | | | |
| Kathy Skroch | X | | | | |
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Total (Yes) 13 No 0

Absent 1

Floor Assignment Rep Westlind

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

REPORT OF STANDING COMMITTEE

SB 2327, as engrossed: Human Services Committee (Rep. Weisz, Chairman)
recommends **DO PASS** (13 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING).
Engrossed SB 2327 was placed on the Fourteenth order on the calendar.

2019 TESTIMONY

SB 2327



State of North Dakota
Doug Burgum, Governor

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

Mhardy@ndboard.pharmacy
www.nodakpharmacy.com

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

Senate Bill No 2327 – Outsourcing Facility Exemption
Senate Human Services Committee – Red River Room
9:45 AM - Tuesday – January 29, 2019

Madam Chair Lee, members of the Senate Human Services Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy.

Thank you for taking my testimony on Senate Bill 2327 creating a narrow exception for accessing a specific medication to be used to treat exposure to Hydrofluoric Acid for individuals at the refinery in Mandan.

Compounding of pharmaceuticals has been a very hot topic on a national scale in the pharmacy industry. Compounding and marketing of non patient specific products came to be highlighted with the meningitis outbreak tied to the New England Compounding Center in Massachusetts. The FDA has decided that they should regulate these types of facilities as Outsourcing facilities at which they are able to compound medications that are non-patient specific and ship them accordingly. This category of licensure is one of the areas of most risk to the public with many of their models of business being involved in sterile injections created in bulk and sent to health facilities. We have no outsourcing facilities operating in North Dakota.

The FDA will inspect these facilities on a risk based inspection which tends to average around every 2 years. Individual states generally license outsourcing facilities however their ability to conduct inspections is difficult due to limited knowledge on compliance with the Good Manufacturing Practices (cGMP) that the FDA requires compliance. This creates a bit of a void in ensuring safety for a state like ours. This is why we have relied on our National Association of Boards of Pharmacy through their Verified Accredited Wholesaler Distributors (VAWD) accreditation program to provide inspections to assure safety and quality of an outsourcing facility to the greatest extent.

The issue specific to the refinery is their need for a specialized Calcium Gluconate product, not in an FDA approved form, which I understand from their representative to be only available from one Outsourcing Facility in the United States. The company did not feel it was able to justify going through the licensure steps and thus are requesting an exemption. The Board certainly understands this narrow need and have worked with the bill sponsors on the language to ensure it only affects this situation. The Board is happy to support this exemption.

I appreciate your time and I would be happy to answer any questions.

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#1 pg. 1

Senate Human Services Committee – SB 2327

Senator Judy Lee, Chair

January 29, 2019

Madam Chairman Lee, Members of the Committee:

My name is Ron Day and I am the Government and Public Affairs Manager for Marathon Petroleum Corporation. I am here today on behalf of Marathon Petroleum Corporation and its more than 500 employees operating refineries, gas processing plants and oil & gas pipeline systems across western North Dakota and stand in support of SB 2327.

SB 2327 is very short in length; however, the passage of this bill would have a life safety impact in the unlikely event of an accidental exposure to Hydrofluoric Acid (HF) at our Mandan Refinery and our ability to have Calcium Gluconate available for emergency treatment.

Why is the change in the North Dakota Century Code needed at this time? The Federal Government has passed legislation that has changed pharmacies practices and protocols for drug compounding. The new requirements imposed on pharmacies by the FDA has reduced the number of pharmacies willing to complete these rigorous protocols for drug compounding and establishing a shelf-life for compounded drugs beyond immediate use. With the FDA's changes, our ability to source compounded Calcium Gluconate eyewash and nebulizer drug through a North Dakota licensed compounding pharmacy was eliminated. Since this change, we have worked diligently to find a compounding pharmacy licensed in North Dakota that has completed the testing protocols. To-date, we have been unsuccessful in finding a North Dakota licensed compounding pharmacy.

We have located a pharmacy outside of North Dakota that has completed the testing protocols and is the only known supplier to our industry for this drug; however, the pharmacy is not licensed in North Dakota. Due to our limited volume needed, the out of state pharmacy is

SB 2327

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#2 pg. 2

unwilling to become licensed in North Dakota. With an exemption from North Dakota licensing requirement as proposed in this piece of legislation, we will have the ability to source Calcium Gluconate compounded drug.

Having this drug on site at our Mandan Refinery will enable us to begin this life saving treatment immediately, where when treating a possible exposure to HF acid, minutes matter and can make a significant difference in the outcome.

Thank you for the opportunity to testify before the Senate Human Services Committee and we hope you will provide a do pass recommendation. I would be happy to stand for any question.

SB 2327

Testimony of Howard C Anderson Jr.

Senator of District 8

Chairman Weisz and members of the House Human Services Committee.

Another exception I am afraid but one that will again solve our problem connected with a federal action to create Outsourcing Facilities and United States Pharmacopeia (USP) chapter 797 which all of our compounding pharmacies must follow.

Our local refinery(s) needs an antidote for possible exposure to a very irritating substance used in the refining process and our local pharmacy can no longer make it and assign a long enough expiration date to make it feasible. Since it is a water-based compound USP and accreditation standards only allow a 24 hour expiration date. One outsourcing facility not yet licensed with North Dakota has done the follow-up testing to assign a longer date and the refinery industry is relying on them to supply the compound.

This bill creates a specific exception in the law to allow this to be sold in North Dakota without jeopardizing ND patients in general to compounds from unlicensed and potentially uninspected facilities.

Thank you.

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2/27/19
pg. 1



State of North Dakota
Doug Burgum, Governor

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

Mhardy@ndboard.pharmacy
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Mark J. Hardy, PharmD, R.Ph.
Executive Director

Senate Bill No 2327 – Outsourcing Facility Exemption

House Human Services Committee – Fort Union Room
2:15 PM - Wednesday – February 27, 2019

Chairman Weisz, members of the House Human Services Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy.

Thank you for taking my testimony on Senate Bill 2327 creating a narrow exception for accessing a specific medication to be used to treat exposure to Hydrofluoric Acid for individuals at the refinery in Mandan.

Compounding of pharmaceuticals has been a very hot topic on a national scale in the pharmacy industry. Compounding and marketing of non patient specific products came to be highlighted with the meningitis outbreak tied to the New England Compounding Center in Massachusetts. The FDA has decided that they should regulate these types of facilities as Outsourcing facilities at which they are able to compound medications that are non-patient specific and ship them accordingly. This category of licensure is one of the areas of most risk to the public with many of their models of business being involved in sterile injections created in bulk and sent to health facilities. We have no outsourcing facilities operating in North Dakota.

The FDA will inspect these facilities on a risk based inspection which tends to average around every 2 years. Individual states generally license outsourcing facilities however their ability to conduct inspections is difficult due to limited knowledge on compliance with the Good Manufacturing Practices (cGMP) that the FDA requires compliance. This creates a bit of a void in ensuring safety for a state like ours. This is why we have relied on our National Association of Boards of Pharmacy through their Verified Accredited Wholesaler Distributors (VAWD) accreditation program to provide inspections to assure safety and quality of an outsourcing facility to the greatest extent.

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I appreciate your time and I would be happy to answer any questions.

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2/27/19
Pg 1

#3
SB 2327
4/27/19
pg. 1

House Human Services Committee – SB 2327

Chairman Representative Weisz

February 27, 2019

Chairman Weisz, Members of the Committee:

My name is Ron Day and I am the Government and Public Affairs Manager for Marathon Petroleum Corporation. I am here today on behalf of Marathon Petroleum Corporation and its more than 500 employees operating refineries, gas processing plants and oil & gas pipeline systems across western North Dakota and stand in support of SB 2327.

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#3
SB 2327
2/27/19
pg 2

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Thank you for the opportunity to testify before the House Human Services Committee and we hope you will provide a do pass recommendation. I would be happy to stand for any question.