2021 HOUSE HUMAN SERVICES

HB 1033

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1033
1/6/2021

Relating to prescribing of biosimilar drugs

Chairman Weisz opened the hearing at 10:45 a.m.

Representatives	Roll Call
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Interchangeable biosimilars
- Electronic medical records system
- Electronic prescribing technology

Jennifer Clark, Legislative Council (10:49) testified neutral.

Mark Hardy, Executive Director ND State Board of Pharmacy (10:53) testified in favor and submitted testimony #614.

Additional written testimony: #14, #93

Chairman Weisz adjourned at 11:00 am

Tamara Krause, Committee Clerk

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
Email= Mhardy@ndboard.pharmacy
www.ndboard.pharmacy

Mark J. Hardy, PharmD
Executive Director

House Bill No 1033 – Prescribing of Biosimilar Drugs

Human Services Committee – Pioneer Room
10:45 AM - Wednesday – January 6th 2021

Chairman Weisz, Members of the House Human Services Committee for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy and I thank you for providing me the opportunity to offer testimony on HB 1033 relative to the prescribing of biosimilar drugs.

The Board of Pharmacy considers this legislation a positive step to better allow for and remove barriers in the dispensing of biological products and their interchangeable biosimilars. The topic of biological products, their corresponding biosimilars, and the concept of interchangeability have been very widely discussed topics over the past decade.

The explosion of biological products now available to patients has exponentially expanded just as many thought when the legislature last discussed this topic in passing this portion of the law back in 2013. Biological products are highly complex and specialized medications used to treat medical conditions and disease states. Most of these medications are extremely expensive, many are well over $1,000 per month of treatment. The concept of biosimilars and the reference biologic drug is not simply a "*Brand*" verses "*Generic*" model. In reality, biological products are extremely complex molecules, the certainty of being able to create "*copies*" of biosimilar products exhibiting the same intended patient outcome is a difficult parameter to meet. Thus, the FDA came up with the term "*interchangeability*" to have a rigorous process to ensure that two biological products would be able to be interchanged, to ensure that the same patient outcome is achieved by either product. This process involves complex studies as well as reviews to ensure consistency. It is important to note that to our knowledge there has not been an interchangeable product approved by the FDA to date. However, many biosimilars have come to market.

Of course, the intention of having interchangeable biosimilars is to provide competition in products resulting in cost savings to the patient and the health care system.

Regarding the changes set forth in the legislative bill by the Health Care Committee, the Board of Pharmacy supports these to allow for a more seamless process in transitioning patients from the biological to an interchangeable biosimilar product.

For those who may not have been involved or aware of the legislative history, SB2190 in 2013 enacted the original legislation. Much of the controversy revolved around the notification that the pharmacist may need to provide to the prescribing practitioner. Many indicated that this notification would prove so burdensome that it would prevent biosimilars from being dispensed, as well as creating regulatory patchwork of laws between states that could limit interchangeable biosimilars from being approved.

The way we interpret the new language in Section 2 (d) as written includes more provider notification options, including a simple notification by the pharmacist placing a record of dispensing in their software system, which seemingly applies to both hospital and retail pharmacy locations. The Board of Pharmacy is unsure of how the Pharmacy record, once entered, would translate back to be viewable by the prescribing practitioner. Regarding Section 4, we are currently making available an internet link to the US FDA approved biosimilar / biological interchangeable products, which is now termed to be the "Purple Book".

The Board of Pharmacy does support the changes made in this bill and would appreciate any opportunity to be involved in any dialogue that would bring clarity to the notification requirements. It has been our view since 2013 that if a biosimilar meets the high standard of being interchangeable a notification is not necessary.

I would be happy to answer any questions you may have on this complex topic and hope to be a resource to you in any way you deem appropriate.

#14

January 4, 2021

The Honorable Chairman Robin Weisz
The Honorable Vice-chair Karen M. Rohr
North Dakota House Human Services Committee
North Dakota State Capitol
Bismarck, ND

Dear Chairman Weisz, Vice-chair Rohr, and members of the committee,

The Biotechnology Innovation Organization supports HB 1033.

BIO is the world's largest trade association representing over 1,000 biotechnology companies, academic institutions, state biotechnology centers, such as Bioscience Association of North Dakota, and related organizations across the United States and in more than 30 other nations.

In 2013, North Dakota was one of the first states to pass legislation to allow pharmacists to substitute an interchangeable biologic product for the innovator product, with the physician's approval. As passed, the responsibilities of communicating substitution information to the physician could be a time-consuming effort by the pharmacist. In working with pharmacists, physicians, and patient groups across the state, we asked the interim health care committee to amend this requirement resulting in the language that is before the committee today.

HB 1033 presumes that communication between the pharmacist and the prescriber has taken place when the pharmacist enters the substitution information into an electronic records system as outlined in Section 1, paragraph 2d (1). No other steps need to be taken unless an electronic system is not available. Only then would the pharmacist need to contact the prescriber through facsimile or telephone. HB 1033 also extends the time for this meaningful communication to two business days following the dispensing of an interchangeable biologic. We believe this will provide patients, prescribers, and pharmacists a complete medical record of the patient's biologic therapy while not increasing pharmacists' workload.

Thank you for your consideration,

/s/

Greg Hoke
Director, State Government Affairs
Biotechnology Innovation Organization (BIO)

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

House Human Services Committee
HB 1033 – Relating to the Prescribing of Biosimilar Drugs
January 6, 2021 – 10:45 am
PCMA Testimony in Support of HB 1033

CHAIRMAN WEISZ AND COMMITTEE MEMBERS:

My name is Michelle Mack and I represent the Pharmaceutical Care Management Association, commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PCMA supports HB 1033, and is encouraged by the revisions to the biosimilar drug dispensing statute. These revisions meet the goal of removing barriers to the use of biosimilar medications. The language pertaining to notification in the bill is what has been adopted in the vast majority of the country and modifies the current notification requirement so it can be done via various means, including electronic transmissions.

Thank you for your time and consideration. I would be happy to answer any questions.

Sincerely,

Michelle Mack
Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1033
2/10/2021

Relating to prescribing of biosimilar drugs

Chairman Weisz opened the hearing at 10:39 a.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Notification system
- Interchangeable biosimilar substitution

Rep. Gretchen Dobervich (10:40) motion for **Do Pass**

Rep. Mary Schneider (10:40) second

Rep. Gretchen Dobervich (10:48) rescinded her motion

Rep. Mary Schneider (10:48) second

Rep. Gretchen Dobervich (10:48) motion to adopt amendment changing physician to prescribing practitioner.

Rep. Mary Schneider (10:48) second

Voice Vote – Motion Carried

Rep. Gretchen Dobervich (10:53) motion for **Do Pass As Amended**

Rep. Mary Schneider (10:53) second

Representatives	Vote
Representative Robin Weisz	N
Representative Karen M. Rohr	Y
Representative Mike Beltz	Y
Representative Chuck Damschen	Y
Representative Bill Devlin	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Dwight Kiefert	Y
Representative Todd Porter	Y
Representative Matthew Ruby	Y
Representative Mary Schneider	Y
Representative Kathy Skroch	Y
Representative Bill Tveit	Y
Representative Greg Westlind	Y

Motion Carried Do Pass As Amended 13-1-0

Bill Carrier: Rep. Gretchen Dobervich

Chairman Weisz adjourned at 10:55 a.m.

Tamara Krause, Committee Clerk

21.0011.03001
Title.04000

Adopted by the Human Services Committee

February 10, 2021

2/10/21

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1033

Page 2, line 17, replace "physician" with "practitioner"

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1033: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (13 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). HB 1033 was placed on the Sixth order on the calendar.

Page 2, line 17, replace "physician" with "practitioner"

Renumber accordingly

2021 SENATE HUMAN SERVICES

HB 1033

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1033
3/10/2021

A BILL for an Act to amend and reenact section 19-02.1-14.3 of the North Dakota Century Code, relating to prescribing of biosimilar drugs.

Madam Chair Lee opened the hearing on HB 1033 at 2:39 p.m. Members present: Lee, Hogan, Anderson, Clemens, O. Larsen. Members absent: K. Roers.

Discussion Topics:

- Electronic system accessibility
- Practitioner notification

[2:40] Jennifer Clark, Senior Counsel, Legislative Council. Introduced HB 1033.

[2:45] Mark Hardy, PharmD, Executive Director, ND State Board of Pharmacy. Provided testimony #8522 in favor.

Additional written testimony: (2)

Michelle Mack, Director, State Affairs, Pharmaceutical Care Management Association. Written testimony #8469 in favor.

Paula Moch, BSN, MSN, FNP-BC, Legislative Liaison, ND Nurse Practitioner Association. Written testimony #7694 in favor.

Madam Chair Lee closed the hearing on HB 1033 at 2:52 p.m.

Justin Velez, Committee Clerk

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

Email= Mhardy@ndboard.pharmacy
www.ndboard.pharmacy

State of North Dakota
Doug Burgum, Governor

Mark J. Hardy, PharmD
Executive Director

House Bill No 1033 – Prescribing of Biosimilar Drugs

Senate Human Services Committee – Sakakawea Room
2:30 PM - Wednesday – March 10th 2021

Madam Chair Lee, Members of the Senate Human Services Committee for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy and I thank you for providing me the opportunity to offer testimony on HB 1033 relative to the prescribing of biosimilar drugs.

The Board of Pharmacy considers this legislation a positive step to better allow for and remove barriers in the dispensing of biological products and their interchangeable biosimilars. The topic of biological products, their corresponding biosimilars, and the concept of interchangeability have been very widely discussed topics over the past decade.

The growth of biological products now available to patients has exponentially expanded just as many thought when the legislature last discussed this topic in passing this portion of the law back in 2013. Biological products are highly complex and specialized medications used to treat medical conditions and disease states. Most of these medications are extremely expensive, many are well over $1,000 per month of treatment. The concept of biosimilars and the reference biologic drug is not simply a "*Brand*" verses "*Generic*" model. In reality, biological products are extremely complex molecules, the certainty of being able to create "*copies*" of biosimilar products exhibiting the same intended patient outcome is a difficult parameter to meet. Thus, the FDA came up with the term "*interchangeability*" to have a rigorous process to ensure that two biological products would be able to be interchanged, to ensure that the same patient outcome is achieved by either product. This process involves complex studies as well as reviews to ensure consistency. It is important to note that to our knowledge there has not been an interchangeable product approved by the FDA to date. However, many biosimilars have come to market.

Of course, the intention of having interchangeable biosimilars is to provide competition in products resulting in cost savings to the patient and the health care system.

Regarding the changes set forth in the legislative bill by the Interim Health Care Committee, the Board of Pharmacy supports these to allow for a more seamless process in transitioning patients from the biological to an interchangeable biosimilar product.

For those who may not have been involved or aware of the legislative history, SB2190 in 2013 enacted the original legislation. Much of the controversy revolved around the notification that the pharmacist may need to provide to the prescribing practitioner. Many indicated that this notification would prove so burdensome that it would prevent biosimilars from being dispensed, as well as creating regulatory patchwork of laws between states that could limit interchangeable biosimilars from being approved.

The way we interpret the new language in Section 2 (d) as written includes more provider notification options, including a simple notification by the pharmacist placing a record of dispensing in their software system, which seemingly applies to both hospital and retail pharmacy locations. The Board of Pharmacy is unsure of how the Pharmacy record, once entered, would translate back to be viewable by the prescribing practitioner. Regarding Section 4, we are currently making available an internet link to the US FDA approved biosimilar / biological interchangeable products, which is now termed to be the "Purple Book".

The Board of Pharmacy does support the changes made in this bill and would appreciate any opportunity to be involved in any dialogue that would bring clarity to the notification requirements. It has been our view since 2013 that if a biosimilar meets the high standard of being interchangeable a notification is not necessary.

I would be happy to answer any questions you may have on this complex topic and hope to be a resource to you in any way you deem appropriate.

#8469

March 9, 2021

The Honorable Judy Lee, Chair Senate Human Services Committee
The Honorable Kristin Roers, Vice Chair Senate Human Services Committee
North Dakota Senate Human Services Committee Members
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: **HB 1033 – Relating to the Prescribing of Biosimilar Drugs**
PCMA Testimony in Support of HB 1033

Dear Chair Lee, Vice Chair Roers and Committee Members:

My name is Michelle Mack and I represent the Pharmaceutical Care Management Association, commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PCMA supports HB 1033, and is encouraged by the revisions to the biosimilar drug dispensing statute. These revisions meet the goal of removing barriers to the use of biosimilar medications. The language pertaining to notification in the bill is what has been adopted in the vast majority of the country and modifies the current notification requirement so it can be done via various means, including electronic transmissions.

Thank you for your time and consideration. I would be happy to answer any questions.

Sincerely,

Michelle Mack
Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

NDNPA
NORTH DAKOTA
Nurse Practitioner Association

Written testimony to:

67th Legislative Assembly
House Human Service Committee

HB 1033

Chairman Senator Judy Lee and Committee Members

I am Paula Moch, a North Dakota resident and the Legislative Liaison for the North Dakota Nurse Practitioner Association (NDNPA). I am submitting this written testimony on behalf of the NDNPA. The NDNPA is supporting HB 1033 as written.

The NDNPA supports HB 1033 as written due to the requirement's for notifying both the individual receiving the biosimilar biologic medication and the prescriber. Also the inclusion that the individual receiving this biosimilar biologic medication, will be informed that they have a right to refuse the substitution.

This concludes my written testimony on support of HB 1033 on behalf of the NDNPA. I am happy to answer any questions in writing or via telephone.

Thank you for your time.

Paula M Moch BSN, MSN, FNP-BC
NDNPA Legislative Liaison 2021
ndnpalegislative@gmail.com
701-321-3193

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1033
3/15/2021

A BILL for an Act to amend and reenact section 19-02.1-14.3 of the North Dakota Century Code, relating to prescribing of biosimilar drugs.

Vice Chair K. Roers opened the discussion on HB 1033 at 3:09 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Proposed amendment

[3:10] Senator Howard Anderson, District 8. Provided the committee with a proposed amendment 21.0011.04001 (testimony #11225).

Senator Anderson moves to **ADOPT AMENDMENT** 21.0011.04001
Senator Hogan seconded.

Voice Vote – Motion passed

Senator Anderson moves **DO PASS, AS AMENDED.**
Senator Clemens seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kristin Roers	Y
Senator Howard C. Anderson, Jr.	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Oley Larsen	Y

The motion passed 6-0-0
Senator Anderson will carry HB 1033.

Vote held open for Senator Lee.

[3:14] Recess

[3:38] Madam Chair Lee re-opened the discussion on HB 1033 and **voted YEA** for a vote total of 6-0-0.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on HB 1033 at 3:39 p.m.

Justin Velez, Committee Clerk

21.0011.04001
Title.05000

Prepared by the Legislative Council staff for
Senator Anderson
March 10, 2021

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1033

Page 2, line 9, remove "electronic records"

Page 2, replace lines 10 through 16 with "interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by"

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1033, as engrossed: Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1033 was placed on the Sixth order on the calendar.

Page 2, line 9, remove "electronic records"

Page 2, replace lines 10 through 16 with "interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by"

Renumber accordingly

21.0011.04001

Sixty-seventh
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

#11225

ENGROSSED HOUSE BILL NO. 1033

Introduced by

Legislative Management

(Health Care Committee)

moved Anderson and Hogan passed easier

A BILL for an Act to amend and reenact section 19-02.1-14.3 of the North Dakota Century Code, relating to prescribing of biosimilar drugs.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 19-02.1-14.3 of the North Dakota Century Code is amended and reenacted as follows:

19-02.1-14.3. Biosimilar biological products.

1. In this section:
   a. "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" mean the same as these terms mean under section 351 of the federal Public Health Service Act [42 U.S.C. 262].
   b. "Prescription" means a product that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].
2. A pharmacy may not substitute a prescription biosimilar product for a prescribed product ~~only if~~unless each of the following requirements is met:
   a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product~~;~~.
   b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting "brand medically necessary" on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription~~;~~.
   c. The pharmacist or the pharmacist's designee informs the individual receiving the biological product that the biological product may be substituted with a biosimilar

product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse;.

d. ~~The pharmacist notifies the prescribing practitioner orally, in writing, or by electronic transmission within twenty-four hours of the substitution; and~~Within two business days following the dispensing of the biosimilar product, the pharmacist or the pharmacist's designee notifies the prescribing practitioner of the substitution. Notification under this subdivision must include the name of the substitution product and the name of the manufacturer, and may be made using facsimile, telephone, electronic transmission, an entry into an ~~electronic records system, or other prevailing means.~~

~~(1) An entry into an electronic records system may be made through:~~

~~(a) An interoperable electronic medical records system;~~

~~(b) An electronic prescribing technology;~~

~~(c) A pharmacy benefit management system; or~~

~~(d) A pharmacy record.~~

~~(2) An entry into an electronic records system is presumed to provide notice to~~ interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by the prescribing practitioner.

e. The pharmacy and the prescribing practitioner retain a record of the interchangeable biosimilar substitution for a period of no less than five years.

3. Subsection 2 does not apply to a biologic product refill prescription that is not changed from the interchangeable biosimilar substitution dispensed on the previous filling of the prescription.

4. The board of pharmacy shall maintain on ~~its~~the board's public website a current list, or an internet link to a United States food and drug administration-approved list, of biosimilar biological products determined to be interchangeable under subdivision a of subsection 2.