2023 SENATE HUMAN SERVICES

SB 2156

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2156
1/16/2023

Relating to the drug use review board and medical assistance prior authorization.

11: 02 AM **Madam Chair Lee** called the hearing to order.
Senators Lee, Cleary, Clemens, K. Roers, Weston, Hogan were present.

Discussion Topics:

- Generic drugs
- Drug review board
- KEPR review organizations
- Foster care with medications

11:03 AM **Senator Judy Lee** introduced SB 2156 in favor.

11:05 AM **Dr. Brendan Joyce, Clinical Services Director, Medical Services, Department of Health and Human Services,** testified in favor. #13502

11:35 AM **Donna Thronsen, Communications Director, ND Medical Association,** introduced Dr. Gabriela Balf-Soran.

11:36 AM **Dr. Gabriela Balf-Soran, Psychiatrist Bismarck ND** testified neutrally online. #13431

11:41 AM **Madam Chair Lee** closed the hearing on SB 2156.

Patricia Lahr, Committee Clerk

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2156
2/7/2023

Relating to the drug use review board and medical assistance prior authorization.

3:02 PM. **Madam Chair Lee** called the meeting to order. **Senators Lee, Clemens, K. Roers, Weston, Hogan** were present. **Senator Cleary** was absent.

Discussion Topics:

- Prefer in state member
- Four positions
- Recruit
- Telemedicine

Senator Lee calls for discussion.

3:03 PM **Dr. Brendon Joyce**, **Administrator Pharmacy Services, North Dakota Department of Health and Human Services** provided amendment. #19338

Senator K. Roers moved to adopt Amendment LC 23.0192.01001.

Senator Hogan seconded.

Roll call vote.

Senators	Vote
Senator Judy Lee	Y
Senator Sean Cleary	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Kristin Roers	Y
Senator Kent Weston	Y

Held vote open from 2/7/2023 for **Senator Cleary**; **Senator Cleary** voted Yes in the afternoon on 2/8/2023.

Motion Passes 6-0-0

Senator K. Roers moves **DO PASS** as **AMENDED**.

Senator Hogan seconded.

Roll call vote.

Senators	Vote
Senator Judy Lee	Y
Senator Sean Cleary	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Kristin Roers	Y
Senator Kent Weston	Y

Held vote open from 2/7/2023 for **Senator Cleary**; **Senator Cleary** voted Yes in the afternoon on 2/8/2023.

Motion passed 6-0-0

Senator K. Roers will carry SB 2156

3:22 PM **Madam Chair Lee** closed the meeting.

Patricia Lahr, Committee Clerk

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2156
2/8/2023

Relating to the drug use review board and medical assistance prior authorization.

3:10 PM. **Madam Chair Lee** called the meeting to order. **Senators Lee, Clemens, K. Roers, Weston, Hogan, Cleary** are present.

Discussion Topics:

- Roll Call Vote – Held open on 2-7-2023.

3:11 PM Senator Cleary voted Yes on the Amendment (LC 23.0192.01001) and Yes on SB 2156 for DO PASS as AMENDED. Both motions passed 6-0-0. (See minutes/video from 2/7/23 held at 3:02 PM)

3:11 PM **Madam Chair Lee** closed the meeting.

Patricia Lahr, Committee Clerk

23.0192.01001
Title.02000

Adopted by the Senate Human Services Committee

February 7, 2023

BR
1/1
2-7-2023

PROPOSED AMENDMENTS TO SENATE BILL NO. 2156

Page 2, line 26, after "6." insert "A board member appointed under subdivision a through d of subsection 2 is not subject to the bona fide resident of the state requirement under section 44-03-04 if the board member is providing services to residents of the state receiving medical assistance through telemedicine or telepharmacy. The affected association shall continue to recruit in-state board members for that board member position and will replace the nonresident board member once the affected association has enough appointees for all of their board member positions.

7."

Page 3, line 14, after the period insert "The department shall work with the medical assistance recipient's health care provider to assure treatment can be found for diagnoses with no compendia supported medications."

Page 3, line 20, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 7, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 21, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 24, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 29, overstrike "pediatric" and insert immediately thereafter "child and adolescent"

Renumber accordingly

REPORT OF STANDING COMMITTEE

SB 2156: 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). SB 2156 was placed on the Sixth order on the calendar. This bill does not affect workforce development.

Page 2, line 26, after "6." insert "A board member appointed under subdivision a through d of subsection 2 is not subject to the bona fide resident of the state requirement under section 44-03-04 if the board member is providing services to residents of the state receiving medical assistance through telemedicine or telepharmacy. The affected association shall continue to recruit in-state board members for that board member position and will replace the nonresident board member once the affected association has enough appointees for all of their board member positions.

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Page 3, line 14, after the period insert "The department shall work with the medical assistance recipient's health care provider to assure treatment can be found for diagnoses with no compendia supported medications."

Page 3, line 20, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 7, overstrike "twenty-one" and insert immediately thereafter "eighteen"

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Page 4, line 29, overstrike "pediatric" and insert immediately thereafter "child and adolescent"

Renumber accordingly

2023 HOUSE HUMAN SERVICES

SB 2156

2023 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2156
3/6/2023

Relating to the drug use review board and medical assistance prior authorization.

Chairman Weisz called the meeting to order at 9:30 AM.

Chairman Robin Weisz, Reps. Karen A. Anderson, Mike Beltz, Clayton Fegley, Kathy Frelich, Dawson Holle, Dwight Kiefert, Carrie McLeod, Todd Porter, Brandon Prichard, Karen M. Rohr, and Gretchen Dobervich present. Vice Chairman Matthew Ruby and Rep. Jayme Davis not present.

Discussion Topics:

- Board vacancies
- Resident requirements
- Medicaid definition of a child
- Authorization of immunosuppressants
- Dosage forms

Brendan Joyce, Clinical Services Director with the Department of Health and Human Services, supportive testimony (#22115).

Gabriela Balf, with the North Dakota Psychiatric Society and the North Dakota Medical Association, supportive testimony (#22125).

Chairman Weisz adjourned the meeting at 9:48 AM.

Phillip Jacobs, Committee Clerk

2023 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2156
3/6/2023

Relating to the drug use review board and medical assistance prior authorization.

Chairman Weisz called the meeting to order at 11:09 AM.

Chairman Robin Weisz, Reps. Karen A. Anderson, Mike Beltz, Clayton Fegley, Kathy Frelich, Dawson Holle, Dwight Kiefert, Carrie McLeod, Todd Porter, Brandon Prichard, Karen M. Rohr, and Gretchen Dobervich present. Vice Chairman Matthew Ruby and Rep. Jayme Davis not present.

Discussion Topics:

- Committee action

Chairman Weisz called for a discussion on SB 2156.

Rep. Dobervich moved a do pass on SB 2156.

Seconded by Rep. Fegley.

Roll Call Vote:

Representatives	Vote
Representative Robin Weisz	Y
Representative Matthew Ruby	AB
Representative Karen A. Anderson	Y
Representative Mike Beltz	Y
Representative Jayme Davis	AB
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Kathy Frelich	Y
Representative Dawson Holle	Y
Representative Dwight Kiefert	Y
Representative Carrie McLeod	Y
Representative Todd Porter	Y
Representative Brandon Prichard	Y
Representative Karen M. Rohr	Y

Motion carries 12-0-2.

Carried by Rep. Dobervich.

Chairman Weisz adjourned the meeting at 11:11 AM.

Phillip Jacobs, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2156, as engrossed: Human Services Committee (Rep. Weisz, Chairman) recommends **DO PASS** (12 YEAS, 0 NAYS, 2 ABSENT AND NOT VOTING). Engrossed SB 2156 was placed on the Fourteenth order on the calendar.

TESTIMONY

SB 2156

Senate Human Services Committee

Comments for Senate Bill 2156

January 16, 2023

Madam Chair Lee and Committee Members,

I am Gabriela Balf, a Bismarck psychiatrist and member of the ND Psychiatric Society, as well as a Medicaid Drug Utilization Review Board Member.

I salute the policy improvements that ND Medicaid has been working on, shown in SB 2156. They reflect an ongoing collaboration with the healthcare prescribers. In 2017, NDMA and NDPS expressed concern about the **gaps in patient care** that the prior authorization process has been proven to bring, or this bill includes the wording: " 5.b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug *without interfering with patient care activities*" (page 5, line 19) An amendment like: "*without jeopardizing the patient's clinical stability*" may bring further clarity.

I would also like to bring attention to **several situations in real medical practice** that are not yet reflected in the bill's text: "The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling […]" (page 3, lines 12,13)

In psychiatry at least, it is a well-known fact that 85% of the prescribed medications are prescribed for an "off-label" use (Hefner et al., 2022). Conversely, **more than 80% of conditions in DSM do not have FDA approved medicines** (Rothschild, 2021), some with a huge societal prevalence and cost: Borderline Personality Disorder, Lewy Body Dementia, etc). Well-known databases like Cochrane or textbooks like Stephen Stahl's "Prescriber's Guide" delineate the uses and the studies published in peer-reviewed journals that support the use of those medications. Some psychiatric disorders have **gold-standard treatments that are not readily available in our state**: ECT (Electro Convulsive Treatment) or TMS (Transcranial Magnetic Stimulation) for treatment refractory depression, DBT (Dialectical Behavioral Therapy) for borderline personality disorder or CBT (Cognitive Behavioral Therapy) for insomnia, yet we psychiatrists still want to bring relief and safety to our patients and their families.

While our prescribers' collaboration with ND Medicaid has historically been the best collaboration with insurers in this state, it is only fair to bring to light the reality that we face in our nation regarding the paucity of data in psychotropics' trials and of means to treat our patients in a rural state.

The other situation worth mentioning is the 21-year age limit that requires a regimen to be discussed with "a board-certified child and adolescent psychiatrist approved by the

department." (page 4, line 29) Child and adolescent psychiatrists transfer the care of a person to their adult counterparts at age 18, when the person reaches legal majority. While we salute the safety goal to avoid polypharmacy in young adults, I am afraid the regular child adolescent psychiatry practice does not include persons aged 18 and older, and adult psychiatrists are the de facto treaters of this age group. I also wonder about the availability of a board-certified child adolescent psychiatrist for those situations – when the current board's composition does not have one, and/or the treatment situation may occur at a time other than business hours (weekend, holidays, etc.)?

In sum, I salute the efforts to streamline care and contain costs, and I respectfully bring to your attention the known gaps that providers have experienced, where our state's patients care suffers.

Looking forward to working together with our colleagues in ND Medicaid for policy solutions that respect our patients' safety and reflect the reality of mental health care in our state.

Thank you for the opportunity to testify today. I would be happy to answer any questions.

Respectfully yours,

Gabriela Balf, MD, MPH
Clin Assoc Prof – UND Dept of Psychiatry and Behavioral Science

Hefner, G., Wolff, J., Toto, S., Reißner, P., & Klimke, A. (2022). Off-label use of antidepressants, antipsychotics, and mood-stabilizers in psychiatry. *Journal of Neural Transmission (Vienna, Austria : 1996)*, *129*(11), 1353–1365. https://doi.org/10.1007/s00702-022-02542-0

Rothschild, A. J. (2021). Why Is There No Food and Drug Administration-Approved Medication for Major Depression With Psychotic Features? *Journal of Clinical Psychopharmacology*, *41*(4), 359–361. https://doi.org/10.1097/JCP.0000000000001433

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Testimony
Senate Bill No. 2156
Senate Human Services Committee
Senator Judy Lee, Chairman
January 16, 2023

Chairman Lee, and members of the Senate Human Services Committee, I am Brendan Joyce, PharmD, Clinical Services Director with the Department of Health and Human Services (Department). I appear before you in support of Senate Bill No. 2156.

Many of the changes within Senate Bill No. 2156 are to address updates to names or issues that became apparent during the change to remote meetings. On page 2, Line 7, the name for the association that represents generic manufacturers has changed to the Association for Accessible Medicines. Also on page 2, there are 3 references to chairman that are being changed to presiding officer.

On page 2, line 18, the definition of quorum for the purposes of the Drug Use Review (DUR) Board is being proposed to ensure the meetings can continue when there are times of significant vacancies. We have had several meetings either cancelled or delayed due to not meeting the attendance needed. Vacant positions have been the primary cause, with some no-shows as is anticipated with clinicians trying to fit public service into their already tight schedules. Specifically defining a quorum for the purposes of the DUR Board will ensure meetings can still proceed and will prevent wasted clinician time.

Page 2, lines 19-21 address the necessary ability for remote attendance of meetings. Page 2, lines 21-23 provides clarification that the allowed

per diem compensation for qualifying DUR Board members can be paid by the department's vendor.

Page 2, lines 26-27 are being added to allow the two manufacturer appointees on the board to not have to meet the state resident requirements that exist for boards within section 44-03-04 of the North Dakota Century Code.

The remaining changes in Senate Bill No. 2156 are to align the Medicaid program with Medicare Part D formulary requirements. This includes all changes on pages 3 through 5.

The changes on page 4, lines 1 through 6, 19, and 20, involves removing restrictions on the prior authorization of stimulants and replacing that with immunosuppressants. This change would align Medicaid restricted drug classes with Medicare restricted drug classes. It is important to remember that many of our most vulnerable transition to Medicare coverage and aligning these policies with Part D will assist with changes that occur with the transition.

Page 3, line 31, and page 4 line 18 are changes to match the language to the Part D language. The other changes on page 3, line 26, page 4, line 13, and page 5, lines 5 through 12, are all related to the definition of "substantially all," which is also from the law covering Part D formulary requirements. This can be better understood with some examples. Please note that no products would ever be prior authorized without the proposals first going through the DUR Board review process. Also, just because state law allows the Department to prior authorize a drug class or a specific drug doesn't mean that the Department would implement

prior authorization for them. For instance, in the 20 years of the Department's drug prior authorization program, no immunosuppressants have been subject to prior authorization.

Multisource brands of the identical molecular structure: this would allow the Department to prior authorize a brand drug when a generic is available, or vice versa. Not all equivalent products would have to be offered without prior authorization.

Extended-release products when the immediate-release product is included: this would allow the Department to prior authorize extended-release products provided the original immediate release product was offered without prior authorization.

Products that have the same active ingredient or moiety: this would allow the Department to prior authorize different marketed products that perhaps only differ in their salt form (e.g. paroxetine HCl and paroxetine mesylate) or strength (e.g. venlafaxine ER 225 mg capsules).

Dosage forms that do not provide a unique route of administration: this would allow the Department to prior authorize follow-on products that are marketed in a different form for a different price (e.g. venlafaxine ER tablets).

This concludes my testimony. I would be happy to try to answer any questions the committee may have. Thank you.

PROPOSED AMENDMENTS TO SENATE BILL NO. 2156

Page 2, after line 27, insert:

"7. A board member appointed under subdivision a through d of subsection 2 is not subject to the bona fide resident of the state requirement under section 44-03-04 if the board member is providing services to residents of the state receiving medical assistance through telemedicine or telepharmacy and the board member position has been vacant for at least six months. The affected association shall continue to recruit in-state board members for that board member position and will replace the non-resident board member once the affected association has enough appointees for all of their board member positions."

Page 3, line 14, after the period insert "The department shall work with the medical assistance recipient's health care provider to assure treatment can be found for diagnoses with no compendia supported medications."

Page 3, line 20, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 7, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 21, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 24, overstrike "twenty-one" and insert immediately thereafter "eighteen"

Page 4, line 29, overstrike "pediatric" and insert immediately thereafter "child and adolescent"

Renumber accordingly

Testimony
Engrossed Senate Bill No. 2156
House Human Services Committee
Representative Robin Weisz, Chairman
March 6, 2023

Chairman Weisz, and members of the House Human Services Committee, I am Brendan Joyce, PharmD, Clinical Services Director with the Department of Health and Human Services (Department). I appear before you in support of engrossed Senate Bill No. 2156.

Many of the changes within engrossed Senate Bill No. 2156 are to address updates to names or issues that became apparent during the change to remote meetings. On page 2, Line 7, the name for the association that represents generic manufacturers has changed to the Association for Accessible Medicines. Also on page 2, there are 3 references to chairman that are being changed to presiding officer.

On page 2, line 18, the definition of quorum for the purposes of the Drug Use Review (DUR) Board is being proposed to ensure the meetings can continue when there are times of significant vacancies. We have had several meetings either cancelled or delayed due to not meeting the attendance needed. Vacant positions have been the primary cause, with some no-shows as is anticipated with clinicians trying to fit public service into their already tight schedules. Specifically defining a quorum for the purposes of the DUR Board will ensure meetings can still proceed and will prevent wasted clinician time.

Page 2, lines 19-20 address the necessary ability for remote attendance of meetings. Page 2, lines 22-23 provides clarification that the allowed per diem compensation for qualifying DUR Board members can be paid by the Department's vendor.

Page 2, lines 26-30 and page 3, lines 1-2 will allow board members to not have to meet the state resident requirements that exist for boards within section 44-03-04 of the North Dakota Century Code provided they are still practicing in North Dakota. The associations responsible for these appointed positions would continue to recruit members who do reside within North Dakota.

Page 3, lines 3-4 are being added to allow the two manufacturer appointees on the board to not have to meet the state resident requirements that exist for boards within section 44-03-04 of the North Dakota Century Code.

Page 3, lines 20-22 place into statute what has always occurred. The change helps ensure that treatment will be found for all Medicaid members.

Page 3, line 28, page 4, line 16, page 5, lines 2 and 4 change the age definition of a child from the Medicaid definition of under 21 to the psychiatry practice definition of under 18. Related to this, page 5, line 9-10 fixes the language to match the proper term of the physician specialty of board certified child and adolescent psychiatrist.

The remaining changes in engrossed Senate Bill No. 2156 are to align the Medicaid program with Medicare Part D formulary requirements.

The changes on page 4, line 3, lines 9-15, line 22, and lines 27-29, involves removing restrictions on the prior authorization of stimulants and replacing that with immunosuppressants. This change would align Medicaid restricted drug classes with Medicare restricted drug classes. It is important to remember that many of our most vulnerable transition to Medicare coverage and aligning these policies with Part D will assist with changes that occur with the transition.

Page 5, lines 15-22 are changes to match the language to the Part D language and are all related to the definition of "substantially all," which is also from the law covering Part D formulary requirements. This can be better understood with some examples. Please note that no products would ever be prior authorized without the proposals first going through the DUR Board review process. Also, just because state law allows the Department to prior authorize a drug class or a specific drug doesn't mean that the Department would implement prior authorization for them. For instance, in the 20 years of the Department's drug prior authorization program, no immunosuppressants have been subject to prior authorization.

Multisource brands of the identical molecular structure: this would allow the Department to prior authorize a brand drug when a generic is available, or vice versa. Not all equivalent products would have to be offered without prior authorization.

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Products that have the same active ingredient or moiety: this would allow the Department to prior authorize different marketed products that perhaps

only differ in their salt form (e.g. paroxetine HCl and paroxetine mesylate) or strength (e.g. venlafaxine ER 225 mg capsules).

Dosage forms that do not provide a unique route of administration: this would allow the Department to prior authorize follow-on products that are marketed in a different form for a different price (e.g. venlafaxine ER tablets).

This concludes my testimony. I would be happy to try to answer any questions the committee may have. Thank you.

NORTH DAKOTA PSYCHIATRIC SOCIETY

A District Branch of the American Psychiatric Association

House Human Services Committee

Re: In Support of Senate Bill 2156

March 6th, 2023

Esteemed Chairman Weisz and Committee Members,

I am Gabriela Balf, a Bismarck psychiatrist and member of the NDMA, ND Psychiatric Society, as well as a Medicaid Drug Utilization Review Board Member for four years.

It is with great delight that I testify in support of the amended SB 2156. This bill was first heard in January in the Senate Human Services Committee. Madam Chair Lee listened to our concerns and recommended I work with Dr. Joyce on addressing those in the bill's text. So we did. I was delighted to see, again, how **professional** and **collegial** this process can be.

I will briefly recap, for the record, and for hopefully mapping future collaborations with commercial insurers, the deep concerns we had, that were fully addressed in our collaborative work. Over the years, NDMA and NDPS expressed concern about the dangerous **gaps in patient care** that the Prior Authorization process has been proven to bring. I have so many stories about people being discharged from the hospital where they were prescribed the only medication that stabilized them, the insurance did not approve or delayed the approval of that medication, and they ended up back in the hospital, or, like it has been documented, they died.

Sometimes, the preferred drug list and the Prior Authorization process ignore **several situations in real medical practice** that appear daily, at least in my experience as a specialist in treatment-refractory conditions like depression, bipolar disorder, schizophrenia, dementia with behavioral disturbances, personality disorders, etc. It is my daily reality as a psychiatrist, since psychotropic data in trials reflects the pharma's interests, and not the prevalence or importance of psychiatric conditions, and we have scarce means to treat our patients in a rural state. In psychiatry, it is a well-known fact that 85% of the prescribed medications are prescribed for an "off-label" use (Hefner et al., 2022). Conversely, **more than 80% of conditions in DSM do not have FDA approved medicines** (Rothschild, 2021), some with a huge societal prevalence and cost: Borderline Personality Disorder, Lewy Body Dementia, etc). Well-known databases like Cochrane or textbooks like Stephen Stahl's "Prescriber's Guide" delineate the uses and the studies published in peer-reviewed journals that support the use of those medications. Some psychiatric disorders have **gold-standard treatments that are not readily available in our state**: ECT (Electro Convulsive Treatment) or TMS (Transcranial Magnetic Stimulation) for treatment refractory depression, DBT (Dialectical Behavioral Therapy) for borderline personality

disorder or CBT-I (Cognitive Behavioral Therapy for Insomnia), yet we psychiatrists still strive to bring relief and safety to our patients and their families.

In sum, I salute the opportunity to testify today about the reality of a good collaboration with an insurer. It happened because **our legislators care and take feedback from the people and organizations they affect with their decisions**. It also happened because the organizations and their people understand where the other is coming from, and work together for the benefit and safety of our patients.

Thank you, I would be happy to answer any questions.

Respectfully yours,

Gabriela Balf, MD, MPH
Clin Assoc Prof – UND Dept of Psychiatry and Behavioral Science

Hefner, G., Wolff, J., Toto, S., Reißner, P., & Klimke, A. (2022). Off-label use of antidepressants, antipsychotics, and mood-stabilizers in psychiatry. *Journal of Neural Transmission (Vienna, Austria : 1996)*, *129*(11), 1353–1365. https://doi.org/10.1007/s00702-022-02542-0

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