2021 SENATE HUMAN SERVICES

SB 2087

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

SB 2087
1/6/2021

A BILL for an Act to amend and reenact subsection 3 of section 50-24.6-04 of the North Dakota Century Code, relating to the medical assistance prior authorization program.

Madam Chair Lee opens the hearing on SB 2087 at 2:30 p.m. All members present; Senator Lee, Senator K. Roers, Senator O. Larsen, Senator Hogan, Senator Clemens, Senator Anderson.

Discussion Topics:

- Line extension products
- Pharmacy budget
- Prescription drug rebates
- Prior authorization

Brendan Joyce, Pharmacy Administrator, Medicaid. Introduced SB 2087 and provided testimony #49 in favor. **(2:31)**

Gabriella Balf, Psychiatrist, University of North Dakota Faculty. Provided neutral testimony #125. **(2:51)**

Senator Anderson moved **DO PASS**.
Senator Hogan 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 SB 2087

Madam Chair Lee closes the hearing on SB 2087 at 2:59 p.m.

Justin Velez, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2087: Human Services Committee (Sen. Lee, Chairman) recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2087 was placed on the Eleventh order on the calendar.

Testimony
Senate Bill 2087 - Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairman

January 6, 2021

Chairman Lee and members of the Human Services Committee, I am Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services (Department). I appear today to provide testimony on Senate Bill 2087, which was introduced on behalf of the Department.

Senate Bill 2087 is addressing the medical assistance pharmacy prior authorization program. Senate Bill 2087 will complete some minor clean-up in the language and will allow the Department to react, if necessary, when federal final regulations regarding line extension products go into effect.

Page 1, Line 9 and Page 2, line 2 involves striking through the phrase “in the aggregate, or.” This language is not necessary in this section of the law as the Department ensures compliance with Federal Upper Limit in the aggregate requirements outside of the prior authorization program. Therefore, if implementation of prior authorization on a product would put compliance with the federal requirement at risk, it would not be brought to the Drug Use Review (DUR) Board for consideration.

The remaining changes in the bill on page 1, lines 11 and 12 and page 2, lines 4, 25, and 26 are in response to final regulations posted on December 21, 2020 by the Centers for Medicare and Medicaid Services (CMS). (Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482-F) Final Reg).

Recent federal regulations that were finalized may have a drastic impact on the pharmacy budget. The federal regulations have finalized the definition of line extensions for covered outpatient drugs. In one of many impacts from this final regulation, the rebates for injectables could be based on the costs of the oral version of the medication, and any increases in said rebate would be 100% federal dollars.

For instance, Abilify is an antipsychotic medication. The Abilify tablet was approved in 2002 and has been generic for a number of years. Abilify Maintena is a long acting injectable version of the same drug. Abilify Maintena was approved in 2013 and is not available as a generic. With the new rules, the 2002 price of the tablet (< $17) will be used in the calculation of the rebate for the injectable in 2022 (currently > $1700). Any increase in rebate amount that results from this change will be 100% federal funds, otherwise known as the Quarterly Rebate Offset Amount (QROA).

QROA has existed since 2010 and has generally averaged less than 6% of total rebates since 2017. To summarize, the Department pays $1000 to the pharmacy for a medication. When we were 50/50 FMAP, $500 of that payment was federal dollars and $500 was state dollars. If the rebate was $500 prior to 2010, the Department would send 50% of the rebate ($250) back to CMS for their share and the Department would keep 50% of the rebate ($250) so the net cost to the state for that $1000 medication was $250 in state dollars ($500 payment to pharmacy minus $250 rebate collected). After 2010, with the QROA, the Department would send 50% ($250) plus 6% ($30) to CMS, so the net cost to the state for that $1000 medication was now $280.

It is unknown at this point exactly how significant these changes will be when they become effective in 2022, but given some dramatic differences in prices between products that are considered line extensions in the new rule, it has severe potential to significantly impact the amount of drug rebates states will be able to retain.

Using the same $1000 medication example, if the new calculations change the rebate for that drug to increase from $500 to $800, that means the $300 difference in rebate would be the QROA. Still assuming 50/50 FMAP, the payment to the provider would still be $500 federal funds and $500 state funds. The rebate amount would be $800, with then new $300 of that being 100% federal funds plus the previous existing QROA of 6% also being 100% federal funds, and the remaining being 50/50 federal and state funds. This results in the net cost for CMS to be $500 minus $300 minus $280 - CMS will MAKE $80 every time ND Medicaid pays for this medication. The state cost would be $500 minus $220 for a total of $280.

$1000 Drug with $500 Rebate	Pre-QROA (Pre-2010)	With QROA (2010 to Present)	New Rules ($1000 drug with $800 rebate)
State Share	$250	$220	($80)
CMS Share	$250	$280	$280

The Department has always taken the QROA into account when calculating net prices for medication reviews, and we will continue to do the same going forward. The most significant impacts will be in medication classes that the Department is prohibited by state law from prior authorizing (e.g. antipsychotics like the Abilify example above). The final rule is large and there are other areas that have the potential to impact individual state programs. If these rules result in existing rebates to change, that would increase the amount of existing rebates that would be considered part of the QROA. One thing is certain, the Department needs the flexibility to react to any changes that do occur, and to work with the Drug Use Review Board when necessary for all of the Medicaid program.

This concludes my testimony, and I am happy to answer any questions you may have.

NORTH DAKOTA PSYCHIATRIC SOCIETY

A District Branch of the American Psychiatric Association

January 6th, 2021
From: ND Psychiatric Society
Re: Commentary on SB 2087

Esteemed Madam Chairman Lee and members of the Human Services Senate Committee,

We salute ND Medicaid's efforts to curb the escalating costs of healthcare. As a member of their DUR Board, I am painfully familiar with some medications' exorbitant cost (usually they are not psychiatric meds).

We also salute Dr. Joyce's efforts, because he has demonstrated, time and again, that he is a rational debater who respects the medical facts.

I am writing today to express my concern that, in our intellectual and/or passionate dialogue, we seem to **overlook the most important person's opinion: our patient.** I sometimes feel like Dr. Joyce and I talk over a child's head about their well-being. All the while, the child knows nothing about all this work that goes behind the scenes. It takes me between 20 and 60 min to gather the whole history of some failed medication trials, from far past records of course, since most of our patients do not carry around lists with details about the 25 past failed trials. Even then, it is not for sure that I can convince the pharmacist that it is a good choice. At times, I was even told that "You don't meet the criteria to talk directly with our physician." I have to say, though, this has never happened to me with ND Medicaid. The patient only knows that I, the doctor, the only face she knows from the healthcare system, failed "to get me my medication." As a psychiatrist who treats treatment-refractory depression, schizophrenia, OCD, etc., in a city where basic psychiatric procedures like ECT are not available, pretty much every single medication I prescribe will need prior authorization (PA). At the end of each day, I will have at least 6-7 PAs sitting on my desk and frantic calls from pharmacies that, even with the "battle" done for prior authorization, the patient's copay is still $400/month. “Can't you prescribe something easier, like Zoloft?!” I call them back, and I stay on hold for a while, only to tell them: "You mean, to prescribe something this patient has been through many moons ago and did not work or had adverse reactions?!"

In AMA's most recent physician survey in Dec 2019[1], the average number of PAs is 33/week and costs about 14.4 hrs of staff/doctor's time. 86% of the physicians said that the PA burden is "high" or "extremely high." Enough about a doctor's experience. How about the most important person in the room? 90% note that PA has a negative impact on

patients' clinical outcomes, and 74% say PA delays have led to patients abandoning their recommended course of treatment.

The most recent bill addressing a part of this problem was HR 3107[2], introduced in Congress in June 2019; it had 221 bipartisan cosponsors. It went nowhere.

I often fantasize about how a **more transparent discussion** would take place, where we three parties sit and decide together, as adults: the patient, the pharmacist, and myself. I wish my patient would tell the pharmacist why she does not want to take again a medication that made her gain 40 lbs in 4 months years ago, just to prove that it will make her gain weight again, and then will be able to switch to the one I prescribed. And I would stay silent while the pharmacist would explain to her that it is in her best interest. Or would **simply recognize that it's all about costs**.

To be fair, ND Medicaid and Dr. Joyce have listened intently to our stories before, and I am sure they will continue to do so. The 2021 ND Medicaid PDL, unlike other insurances', contains all the medications that I would think are desirable in terms of benefit/harm ratio. A select few of them even without prior authorization!

On behalf of our patients, we thank the Human Service Senate Committee for listening to our comments.

Gabriela Balf-Soran, MD, MPH
Assoc Clin Prof – UND School of Medicine – Behavioral Sciences and Psychiatry Dept
ND Psychiatric Society Immediate Past-President

[1] https://www.ama-assn.org/practice-management/sustainability/prior-auth-survey-findings-underscore-need-legislative-action

[2] https://www.congress.gov/bill/116th-congress/house-bill/3107/all-actions?overview=closed#tabs

2021 HOUSE HUMAN SERVICES

SB 2087

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2087 AM
3/10/2021

Relating to the medical assistance prior authorization program

Chairman Weisz opened the committee hearing at 9:47 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	A
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Federal regulations
- Supplemental rebates
- Drug Use Review Board

Brendan Joyce, Administrator Pharmacy Services Department of Human Services (9:47) testified in favor and submitted testimony #8398.

Dr. Gabriela Balf-Soran, UND School of Medicine Behavioral Sciences and Psychiatry Department (10:02) testified in favor and submitted testimony #8576.

Vice Chair Rohr adjourned at 10:08 a.m.

Tamara Krause, Committee Clerk

Testimony
Senate Bill 2087 - Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman

March 10, 2021

Chairman Weisz and members of the Human Services Committee, I am Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services (Department). I appear today to provide testimony on Senate Bill 2087, which was introduced on behalf of the Department.

Senate Bill 2087 updates language and will allow the Department to react, if necessary, when federal final regulations regarding line extension products go into effect.

Page 1, Line 9 and Page 2, line 2 involves striking through the phrase “in the aggregate, or.” This language is not necessary in this section of the law as the Department is federally required to comply with Federal Upper Limit in the aggregate requirements outside of the prior authorization program. If implementation of prior authorization on a product would put compliance with the federal requirement at risk, it would not be brought to the Drug Use Review (DUR) Board for consideration.

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These federal regulations have the potential to impact the pharmacy budget due to their definition of line extensions for covered outpatient drugs. This could result in significant increases in the state share for injectables due to changes in rebate calculations for line extensions.

For instance, Abilify is an antipsychotic medication. The Abilify tablet was approved in 2002 and has been generic for a number of years. Abilify Maintena is a long acting injectable version of the same drug. Abilify Maintena was approved in 2013 and is not available as a generic. With the new rules, the 2002 price of the tablet (< $17) will be used in the calculation of the rebate for the injectable in 2022 (currently > $1700). Any increase in rebate amount that results from this change will be 100% federal funds, otherwise known as the Quarterly Rebate Offset Amount (QROA).

QROA has existed since 2010 and has generally averaged less than 6% of total rebates since 2017.

To summarize through an example, let us assume that the Department pays $1000 to the pharmacy for a medication. When we were 50/50 FMAP, $500 of that payment was federal dollars and $500 was state dollars. If the federal rebate was $500 prior to 2010, the Department would send 50% of the rebate ($250) back to CMS for their share, and the Department would keep 50% of the rebate ($250) for the state share, so the net cost to the state for that $1000 medication was $250 in state dollars ($500 payment to pharmacy minus $250 rebate collected).

After 2010, with the QROA, the Department would send 50% of the rebate ($250) plus 6% for the QROA ($30) to CMS, so the net cost to the state for that $1000 medication was now $280 ($500 minus $220 for state share of rebates).

Supplemental rebates for ND started after the 2015 legislative session. Assuming a $300 supplemental rebate was received for the example with the same 50% FMAP, the new split of the rebates would be as follows.

$1000 cost of the drug ($500 federal and $500 state dollars)

$280 federal rebate federal share (50% of $500 rebate plus 6% QROA)

$220 federal rebate state share ($500 federal rebate minus federal share)

$150 federal share of supplemental rebate (50% of $300 supplemental rebate)

$150 state share of supplemental rebate (50% of $300 supplemental rebate)

Net federal cost = $70 ($500 - $280 - $150)

Net state cost = $130 ($500 - $220 - $150)

If the new federal regulations for line extensions changes the federal rebate to $800, the $300 difference between the original federal rebate and the new federal rebate is included in the QROA, so it would be 100% federal funds. Also, with the higher federal rebate, the less room there is for a manufacturer to offer a supplemental rebate, which results in this:

$1000 cost of the drug ($500 federal and $500 state dollars)

$280 federal rebate federal share (as above)

$220 federal rebate state share (as above)

$300 federal rebate new QROA due to line extension rule

Supplemental rebate is gone as manufacturer no longer has margin to offer

Net federal cost = $500 - $280 - $300 = ($80)

Net state cost = $500 - $220 = $280

It is unknown at this point exactly how significant these changes will be when they become effective in 2022, but given some dramatic differences in prices between products that are considered line extensions in the new rule, it has the potential to significantly impact the amount of drug rebates states will be able to retain.

The Department has always taken the QROA into account when calculating net prices for medication reviews, and we will continue to do the same going forward. The most significant impacts will be in medication classes that the Department is prohibited by state law from prior authorizing (e.g. antipsychotics like the Abilify example above). One thing is certain, the Department needs the flexibility to react to any changes that do occur, and to work with the Drug Use Review Board when necessary for all of the Medicaid program.

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2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2087
3/10/2021

Relating to the medical assistance prior authorization program

Chairman Weisz opened the committee meeting at 3:38 p.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	A
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	A
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Line extension drugs
- Rebates

Rep. Karen Rohr (3:40) moved **Do Pass**

Rep. Mary Schneider (3:40) second

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

Representative Greg Westlind	Y

Motion Carried Do Pass 11-1-2

Bill Carrier: Rep. Karen Rohr

Chairman Weisz adjourned at 3:44 p.m.

Tamara Krause, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2087: Human Services Committee (Rep. Weisz, Chairman) recommends **DO PASS** (11 YEAS, 1 NAY, 2 ABSENT AND NOT VOTING). SB 2087 was placed on the Fourteenth order on the calendar.