2013 SENATE HUMAN SERVICES

SB 2066

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2066
1/14/2013
Recording Job Number: 17160

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to prior authorization of antineoplastic agents.

Minutes: You may make reference to "attached testimony."

Chairman Lee opens hearing for SB 2066.

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division of the Department of Human Services, is first to testify in support of SB 2066.

See attached testimony #1.

Floor is open for questions from the committee.

Senator Dever inquires about the delay patient's experience receiving medication or not receiving medication that their doctors prescribe.

Dr. Joyce indicates that any delay is partially self-imposed due to not providing enough information until a response from the authorization is received. Any authorization letter that is received is answered as soon as possible. However, it is difficult to answer because he is unaware of how the process on the administrative end works and is hopeful the delays don't fall there. It would be accurate to say that it would be more streamlined if there was a process that was already in place.

Senator Anderson indicates that in the oncology business, more drugs are used off label than in any other class of drugs and asks if a doctor can use a particular drug that is not formally approved by the FDA if there is evidence that is was successfully used for another treatment.

Dr. Joyce explains that compendia within the Social Security Act are where that comes into place. It isn't FDA approved indications that these medications can be used for and covered. Medicaid dollars don't go to experimental, however, when it has some justification for use within the official compendia (e.g. DRUGDEX, Micromedics) they have what is classified as strength of evidence. The general threshold between experimental and non-experimental is 2b (Roman numeral's followed by a lower case letter b). The Social

Security Act was modified a few years ago to where they included peer-reviewed studies and peer-reviewed journal publications to where they will allow these studies and publications to be included. As long as there is some evidence for its use in any official compendia as allowed by the act there will not be a problem.

Chairman Lee asks what the likely circumstances would be for an individual who is privately insures compared to the way the process is now in place for a Medicaid covered individual in North Dakota.

Dr. Joyce states that anyone with private insurance needs prior authorization for medication when it goes over a certain dollar amount. This is more of a protection for the insurance company to ensure they aren't paying for things that aren't necessary or justified. More evidence is required therefore they lean more towards on-label medications. North Dakota is not even getting to the point where they do it like the private sector. It is not being asked that prior authorization be enforced; it is being asked that there be an efficient communication process to help with these requests. It is not our goal to step in between the doctor and patient. Dr. Joyce then gives an example of an authorization request. Clinics are against this bill at the moment but they are hopeful they would find it beneficial to help ensure that these medications are being use properly. The clinics are the ones that have to pay if there in an audit.

Senator Larson asks for examples of the medications that prior authorization is needed for.

Dr. Joyce explains that there are no specific brand name drugs because all prior authorization requirements are run through the Drug Utilization Review Board (DURB). If any specific medications are brought forth it is going to be based on the cost and the risk involved.

Chairman Lee asks Dr. Joyce for a summary of the DURB.

Dr. Joyce explains that the DURB it is made up of two psychiatrists, six doctors, six pharmacists, a PhRMA representative, a generic pharmaceutical company representative, both the pharmacy director and medical director for Medicaid, and a community member. Medications are reviewed based on the analysis of utilization trends and that they meet the criteria as approved by the FDA. It would be fair to say that the DURB's mission is not to deny people access to appropriate care but rather to assure that what they are getting is appropriate care.

Senator Dever asks if pharmacies stock the expensive medications and if there is a delay in getting ahold of them.

Dr. Joyce explains that pharmacies can order medications and receive them the next day (which isn't considered a delay), even the really costly meds. Expensive medications will not be ordered by the pharmacists until a paid claim is received from the payer.

No further questions for Dr. Joyce from the committee and no further testimony in favor of SB 2066.

Courtney Koebele, representing the North Dakota Medical Association, is first up to testify in opposition of SB 2066.

See attachment testimony #2.

Floor is opened for questions from the committee.

Chairman Lee asks Ms. Koebele to discuss the issues involved with prior authorization with health providers that interfere with the relationship between the patient and the doctor.

Ms. Koebele is not personally aware of any problems pertaining to cost but would like to talk with the provider BCBS to do some more research.

Senator Axness refers to Dr. Joyce's testimony when he mentions that there were approximately 30 other states that have gone through this process and asks Ms. Koebele if she has heard from any of those states/medical associations if there has been a problem with the Medicaid prior authorization.

Ms. Koebele indicates that she has not contacted them and is not aware of any problems.

Senator Anderson is under the impression, upon review of Ms. Koebele's testimony that she is making the contention that the DURB could provide information and education to physicians about which drugs they could properly use without the DUR authorization.

Ms. Koebele agrees and states that there is opportunity to get information out so that they wouldn't need to put it in the statute.

No more questions from the committee for Ms. Koebele.

Deborah Knuth, Director of Government Relations for the American Cancer Action Network (ACS CAN), is next up to testify in opposition of SB 2066.

See attached testimony #3.

Floor is opened for questions from committee.

Chairman Lee states that after hearing Dr. Joyce's testimony, it is clear that they are not looking at generic alternatives.

Ms. Knuth agrees and would like the opportunity to go back and do more research about the regulations and oversights Dr. Joyce was referring to in order to ensure that the doctors have the ability to treat their patients with the best treatment out there. Ms. Knuth indicates that she also wants to look more closely into the prior authorization that private insurance policies have at this time.

Senator Larson asks Ms. Knuth to provide an example of when she stated that prior authorization took 72 hours when Dr. Joyce testified that the most an authorization would take was a day.

Ms. Knuth stated that she will get back to the committee with some specific examples. Ms. Knuth also indicates that she was referring more towards national statistics with the 72 hours.

Chairman Lee expresses that although those numbers are important and beneficial to know, it is best to stick with what will specifically impact patients in North Dakota to ensure those people are getting the appropriate treatment and that the necessary provisions are put in place. Ms. Knuth will speak to ND oncologists and clinics and appreciates the opportunity to be able to come back with more information and examples.

No further questions from the committee for Ms. Knuth.

Sharon Brigner, a state policy employee for the Pharmaceutical Research and Manufactures of America (PhRMA) and an ER RN in northern Virginia, is next to testify in opposition of the bill.

See attachment #4, a statement from PhRMA.

Ms. Brigner read from her own written testimony and was asked to supply a copy of it to the clerk after but it was never received.

Chairman Lee indicates that Ms. Brigner's testimony relates to something completely different to Dr. Joyce's testimony about the actual procedure of making the process more streamlined.

Ms. Brigner states that her testimony was prepared based off the bill and that her concern was to deliver testimony as the bill was written. She would like to work more closely with counsel as far as procedures are concerned.

No further questions from the committee for Ms. Brigner and no further testimony in opposition.

Chairman Lee closes the hearing on SB 2066 and welcomes any further follow-up and recommendations for amendments.

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2066
1/14/2013
Recording Job Number: 17177

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to prior authorization of antineoplastic agents.

Minutes: You may make reference to "attached testimony."

Committee discussion of SB 2066.

Chairman Lee believes there is a way to amend the bill to allow this procedure to be followed that proceeds threat that treatment would be denied. She proceeds to explain how PhRMA operates and how they do not like prior authorization. Millions of dollars are spent on drug spend for Medicaid and a lot less can be spent if providers were asked to look at the possibility of equally effective generic drugs as an option. She is a strong supporter of prior authorization if it is done properly. There is a benefit to the process without creating problems for the provider.

Senator Larsen wants to know who gets stuck with the cost if the prior authorization does not go through.

Chairman Lee explains that the drugs will not be approved for administration until the insurance companies authorize the use of the drug and the insurance company picks up the cost. The difference with Medicaid is that the risk is with the provider.

Senator Anderson states that Dr. Joyce is a straight shooter and is just trying to facilitate the appropriate protocol. The research protocol's need to support the authorization. This bill is good to go as is and does not need an amendment.

Chairman Lee suggests that the committee consider a sentence be added that indicates that it is not only for cost containment, for example, the legislative intent is not that the prior authorization be used to choose the least expensive drug but rather the purpose be to determine the appropriate drug to be used.

Senator Axness feels that the individuals testifying in opposition were not prepared. He is comfortable with the bill as is but would be would be in favor of adding the amendment Chairman Lee suggested.

Senator Dever agrees and feels that adding a sentence about cost would only raise concern about the cost. Prior authorization is the most cost effective way.

Committee agrees that Dr. Joyce is a credible source and has never led the committee astray.

Senator Larsen asks for clarification about the drugs needed for prior authorization.

Chairman Lee states that if there is a question about the propriety of the medication being used for a particular patient by the pharmacy and/or Dept. of Human Services and the physician states that it's the best treatment then it will pretty much get approved.

Senator Anderson explains the change in the Affordable Care Act in regards to the recovery of fraud and abuse. Provider knows up front whether or not procedure will be paid for therefore proceeding with come quicker. PhARMA is not concerned with cost since they don't pay for it.

Committee is comfortable with bill but is willing to wait a day to get any additional information from the opposing sides before voting.

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2066
1/22/13
Recording Job Number: 17463

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to prior authorization of antineoplastic agents.

Minutes:

You may make reference to "attached testimony."

Committee discussion #2 on SB 2066.

Committee reviews proposed amendment from the lawyers in the Department of Human Services and has discussion on the reason for the amendment. See attachment #5.

Senator Dever moves to adopt the amendment.

Senator Larsen seconds.

Roll call vote: 5-0, motion to adopt amendment passes.

Senator Anderson moves Do Pass as Amended.

Senator Larsen seconds.

Roll call vote: 4-1, Do Pass as Amended.

Senator Anderson carries Bill to the floor.

13.8113.01001
Title.02000

Adopted by the Human Services Committee

January 21, 2013

1-22-13

PROPOSED AMENDMENTS TO SENATE BILL NO. 2066

Page 2, line 16, after the underscored period insert "The department may not prefer one antineoplastic agent over another. If an antineoplastic agent prior authorization shows that the agent meets the definition of medically accepted indication under section 1927 of the Social Security Act [42 U.S.C. 1396r-8] and title 42 of the Code of Federal Regulations, the department shall approve the agent."

Renumber accordingly

Date: 1/21/13
Roll Call Vote #: 1

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2066

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 13.8113.01001

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

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Sen. Dever Seconded By Sen. Larsen

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

Total (Yes) 5 No 0

Absent 0

Floor Assignment

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

Date: 1/21/13
Roll Call Vote #: 2

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2066

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 13.8113.01001

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

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Sen. Anderson Seconded By Sen. Larsen

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

Total (Yes) 4 No 1

Absent 0

Floor Assignment Sen. Anderson

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

REPORT OF STANDING COMMITTEE

SB 2066: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (4 YEAS, 1 NAYS, 0 ABSENT AND NOT VOTING). SB 2066 was placed on the Sixth order on the calendar.

Page 2, line 16, after the underscored period insert "The department may not prefer one antineoplastic agent over another. If an antineoplastic agent prior authorization shows that the agent meets the definition of medically accepted indication under section 1927 of the Social Security Act [42 U.S.C. 1396r-8] and title 42 of the Code of Federal Regulations, the department shall approve the agent."

Renumber accordingly

2013 HOUSE HUMAN SERVICES

SB 2066

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2066
March 26, 2013
Job #20481

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

Relating to prior authorization of antineoplastic agents.

Minutes: *See Testimonies #1-3*

Chairman Weisz opened the hearing on SB 2066.

Maggie Anderson: Director of the Medical Services for the DHS testified in support of the bill. (See Testimony #1)

6:52
Chairman Weisz: Based on what you have said, what are the concerns this bill is going to pivot certain medications?

Anderson: Sen. Lee shared an e-mail with us when the bill was introduced on the Senate side and that resulted in the amendments being added on Lines 16-20 that it made it clear we cannot prefer one agent over another. If the prior authorization shows up and the agent meets the definition of medically accepted indication and provides a citation, the department shall approve the agent. By adopting those amendments the Senate Human Services Committee felt they were addressing the concerns.

Rep. Silbernagel: Do you get prior authorization for an either or drug or is it usually well defined.

Anderson: It is usually well defined.

Rep. Mooney: Why wouldn't they have this in place before?

Anderson: There existing code today has some exceptions to drugs that the department can prior authorize. This is one of the categories. On page 2 of the bill it lists the areas where the department may not prior authorize medication. So that was based on previous policy decisions. We identified this as one that could make things more efficient and hopefully avoid recovery audit.

OPPOSITION

9:55
John Vastag: I represent the Health Policy Consortium which is Trinity Health Systems in Minot, Altru Health Systems in Grand Forks, and the Sanford Health Systems and we stand in opposition of the bill today and I want introduce Dr. Edward Wos who is with the Sanford Medical Center here in Bismarck.

Dr. Edward Wos: I can tell you of the experiences I have had with my patients regarding preauthorization. Oncology drugs are in a state of rapid flux. We have guidelines called NCCN guidelines where we actually have groups of drugs changing month by month. These are drugs that have been approved. NCCN is a consortium of cancer centers throughout the country including MD Anderson, Sloan Kettering, all these major centers approve these combinations and most oncologists will look at that and decide what the appropriate treatment is. The problem with this system is that it is obsolete. You are looking at one drug for one system. If FDA approval was the sole criteria, no one would get Adriamycin for breast cancer. Eighty percent of people get this drug for breast cancer. If you have an obsolete system looking for a drug on a one drug per system, I would not be opposed if a more integrated system that is integrated with the oncology community. I don't think this can be assimilated into that without some major changes.

12:16
Chairman Weisz: Can you go back to statement and clarify where you said, under this scenario 80% of them wouldn't get that?

Dr. Wos: FDA does not approve Adriamycin for breast cancer. It is a well-known accepted treatment for breast cancer.

Chairman Weisz: Under the current system you are getting reimbursed.

Dr. Wos: Yes because everyone knows it is an acceptable treatment based on other systems. My concern is with this committee looking at certain FDAs and there will be a lot of delay.

12:59
Dr. Wos: (Continued testimony) We get patients from out of town that may need chemotherapy right away. Do we have to wait weeks to get this approved? I would submit that this system would cause disparities. It would be the poorest people who do not have insurance that will be delayed in their treatment.

Chairman Weisz: What about recovery audit if something isn't approved? Is that an issue for you currently?

Dr. Wos: I've never run into that.

Rep. Silbernagel: Are some of these drugs we are discussing biosimilars?

Dr. Wos: I'm talking about directed therapies?

Rep. Silbernagel: Right.

Dr. Wos: I'm talking about standard chemotherapy. These directed therapies are a little bit different. That is another area altogether.

Rep. Laning: I read the bill the antineoplastic agents are now removed from the not prior authorized list to the prior authorized list. Wouldn't that make it faster to approve it?

Dr. Wos: I think as the system stands now we get the drug and if it is not approved, it is given to us later on. They are asking us to hold treatment until approved.

Ken Tuba: From American Cancer Society read the testimony of Deborah Knuth, Director of Government Relations for the American Cancer Society Cancer Action Network (ACS CAN) in opposition of the bill. (See Testimony #2)

Sharon Brigner: Pharmaceutical Research and manufacturers of America testified in opposition of the bill. (See Testimony #3)

23:05
Rep. Silbernagel: Are there any other states that have this type of legislation in place currently?

Brigner: Many other states have the protected class of cancer medications and also have protected classes of antirejection medications and mental health medications. We have seen of them try to repeal the legislation as we are looking at now with engrossed SB 2066, but thankfully most of those states have not succeeded in doing that. The patient and health providers' voices are being heard.

Rep. Mooney: Do you mean by saying protected that it is left as not being required for pre-authorization?

Brigner: Yes.

Dr. Michael Booth: A practicing cardiovascular surgeon in Bismarck and I'm here representing the ND Medical Association of which I am president testified in opposition of the bill. Prior authorization is to save money and a good program. The basic premise is to get providers to go to generic drugs which are generally less expensive than brand name drugs. With oncology you deal with a total different group of providers and set of problems. This bill has a fundamentally disconnect in its premise and solution. The rack issue that was brought up by Dr. Brendan Joyce who came up with this plan is a straw man. Racks for oncology are extremely rare in this state and basically done retrospectively to verify the charges and the accuracy of charges and whether or not it is the right drug. The motive behind that is not appropriate. I think the motive is to try and control cost. The amendment that was put into this bill on the Senate side eliminating preference over one class of drugs over another basically takes out the prior authorization process' teeth. It makes the prior authorization process ineffective. From a fiscal standpoint I don't think it will save money. In fact it will drive up costs in the Medicaid program by the creating delays between making decisions on treatment plans for the patient and then actually carrying out the treatment; which would be delayed until approval for the drugs. More office visits and

more charges. It impacts us as providers by interfering our ability to deliver timely and efficient care in cancer patients of which many are running on short time frames. I think the department should look at setting up a case management system to look at the selection of drugs and the appropriateness and monitor it along. This is already being done by the Blues plan. I think this bill is ineffective achieving its purpose and there are better ways to do it.

Chairman Weisz closed the hearing on SB 2066.

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2066
March 26, 2013
Job 20505

☐ Conference Committee

Lynell Thueson

Explanation or reason for introduction of bill/resolution:

Minutes:

Chairman Weisz: Discussion on SB 2066.

00:50 Representative Porter: This bill has been discussed many times and is difficult for us and the Century Code to get between the physician and the patient. This does exactly that. I **move a Do Not Pass** on SB 2066.

Seconded by Representative Oversen.

A Do Not Pass Roll Call vote on SB 2066: yes = 12, **No = 0**, **Absent = 1**. Carrier: Representative Oversen

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

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2066

House Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

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

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Porter Seconded By Rep. Oversen

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

Total (Yes) 12 No 0

Absent 1

Floor Assignment Rep. Oversen

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

REPORT OF STANDING COMMITTEE

SB 2066, as engrossed: Human Services Committee (Rep. Weisz, Chairman) recommends **DO NOT PASS** (12 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). Engrossed SB 2066 was placed on the Fourteenth order on the calendar.

2013 TESTIMONY

SB 2066

Attachment #1

Testimony
Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairman
January 14, 2013

Chairman Lee, members of the Senate Human Services Committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division of the Department of Human Services. I am here to provide support of Senate Bill 2066, which was introduced at the request of the Department.

Current state law (N.D.C.C. 50-24.6-04.3.e) specifically prohibits the Department of Human Services from utilizing a prior authorization process for antineoplastic agents (oncology/cancer medications). This prohibition has resulted in two areas of concern for the Medicaid program:

1. Many oncologist offices submit prior authorization requests for the medication they administer as they do not wish to administer medications costing $10,000 or more without confirmation that they will be reimbursed. Requesting prior authorization is their standard business procedure for all insurance coverage.
   As there is no prior authorization allowed for oncology medication for North Dakota Medicaid, these requests cannot be routed through the prior authorization vendor who responds to 98 percent of requests within four hours and 100 percent within one business day. The prior authorization vendor cannot be used for these requests as their contract is only to handle drugs that are prior authorized. Also, if the vendor was to be used, they would need guidelines for processing the requests (e.g. approval and denial

criteria), and since current law prohibits prior authorization of these meds, no criteria can be used.

Currently, these requests come in a general letter format (not on a prior authorization form, because there is no such form for antineoplastics) and are routed based on the content of the letter (They may go to the out-of-state prior authorization team, the medical coders, or a member of the utilization review staff.) Obviously, depending upon the schedules of the staff, response times are not as predictable as the vendor prior authorization staff.

2. North Dakota Medicaid receives federal matching funds for Covered Outpatient Drugs as defined in the Social Security Act Section 1927. [42 U.S.C. 1396r-8]. Covered Outpatient Drugs do not include those used for a medical indication which is not a medically accepted indication. The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i). The compendia specifically includes the DRUGDEX Information System, which the Department utilizes. Without prior authorization of antineoplastic agents (oncology/cancer medications), the Department cannot ensure that the drugs are being used for medically accepted indications.

   Nationwide, Medicaid Recovery Audit Contractors are tasked with ensuring Medicaid programs are following state and federal policies in the payment of services. This includes reviewing paid claims and

the associated medical records to determine if medications are being used for medically accepted indications.

Because of the current restriction on prior authorization of these agents, the Department finds itself in an untenable situation where we are unable to provide efficient, fast and direct answers for providers, and we are unable to ensure claims paid by the Department will not be reversed through a recovery audit.

The Department is proposing a solution through this bill that would allow ND Medicaid to implement indication (diagnosis) based prior authorization, so all requests from physician offices can be processed in the same efficient manner, and payments will not be made outside of federal or state policies.

There is no anticipated fiscal impact from this proposed change since the prior authorization would be limited to ensuring that the medication is being used for the appropriate indications as outlined by the Food and Drug Administration or compendia (DRUGDEX Information System) allowed by the Centers for Medicare and Medicaid Services (CMS). The prior authorization would not try to steer utilization to another product due to cost.

The Department requests your favorable consideration of SB 2066 as it addresses the attention CMS has placed on Program Integrity, and offers an efficient solution for the prior authorization requests already submitted by providers for these medications.

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

Attachment #2

NDMA
Est.1887 NORTH DAKOTA MEDICAL ASSOCIATION

Senate Human Services Committee
Senate Bill 2066
January 14, 2013

Madam Chairman Lee and Committee Members, I'm Courtney Koebele and I serve as executive director of the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents and medical students. The North Dakota Medical Association is opposed to Senate Bill 2066.

Human Services is asking for authority to preauthorize antineoplastics. This language allows them to routinely require pre-authorization and then piggy-back their approval based on federal and other third party indications for usage of a given agent, which are typically very conservative and usually not state of the art. DHS may feel cancer chemotherapy is being over-utilized and that they need to get the costs under control, especially with some of the new recombinant agents that have come on the market.

However, chemotherapy is a very complicated field, and also very dynamic. It requires considerable expertise, judgment, and insight to manage it, especially when it comes to managing the pediatric cancer patients that Medicaid will be increasingly asked to fund.

NDMA's opposition reflects concern that prior authorization would interfere unfairly in the patient-physician relationship and the ability of a patient's physician to assure that the patient is receiving appropriate medical care, and that a prior authorization program may be more costly to implement than the anticipated savings. Administrative costs and extra patient visits may offset any potential savings realized under the program. Restricting access to physician-prescribed medications, particularly new and more effective treatments, may cause patients to suffer medically and require more costly treatment in the long-run.

Perhaps one alternative may be educational programs under the Drug Utilization Review (DUR) Program. Federal law is quite clear in requiring each state to institute a drug use review program to ensure that covered outpatient drugs are appropriate, are medically necessary, and are not likely to result in adverse medical results. The DUR program must include prospective drug review, retrospective drug use review, assessment of drug data against predetermined standards, and educational programs. The state has broad discretion in implementing educational programs through the DUR Board, accredited health care educational institutions, state medical societies or state pharmacists associations, or other organizations. The state must "provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices." The DUR Board is required by the federal law to provide ongoing interventions for physicians and pharmacists. *See* 42 USC 1396r-8(g).

Under the guidance of the DUR Board, the Department could develop materials identifying their concerns regarding certain categories of drugs, and provide the materials to physicians and pharmacists through direct mailings or educational forums in cooperation with those professional organizations.

For these reasons, the North Dakota Medical Association urges a DO NOT PASS on SB 2066.

Attachment #3

Testimony

Senate Bill 2066

Senate Human Services Committee

Monday, January 14, 2013
9:00 AM

Deborah Knuth
Government Relations Director, American Cancer Society Cancer Action Network (ACS CAN)

Good morning, Madam Chair Lee and members of the Senate Human Services Committee. My name is Deborah Knuth, and I am the director of government relations for the American Cancer Society Cancer Action Network (ACS CAN). I am here today to testify in opposition of Senate Bill 2066, and asking for a "do not pass" recommendation from this committee.

We support the ability of doctors to make the best medical decision for their patients in consultation with their patients. Prior authorization programs limit the ability of patients and doctors to make medical decisions in an unimpeded manner. While generic alternatives are not currently widely available for cancer patients, we are concerned that future cancer patients have timely access to the complete continuum of treatment, regardless of generic status.

We would advocate for a carve out for cancer prescriptions now and in the future. Prior authorization creates an additional administrative barrier, can discourage physicians from prescribing prior authorization drugs, even if they're the most appropriate option for the patient, and can deter beneficiaries from seeking the recommended care. Prior authorization in some cases, can take up to 72 hours. For cancer patients undergoing chemotherapy, such delays could be detrimental to their treatment success and quality of life.

We ask that the system benefit the patients, allow for the appropriate doctor/patient relationships and not impede patient quality of life and timeliness of care. The system needs to be simple for providers and patients.

In closing, the ACS CAN strongly supports the right of cancer patients and their doctors to decide what is best for the patient, based on the patient's medical and emotional needs. ACS CAN believes that Medicaid coverage should allow for timely access and coverage of the complete continuum of quality, evidence-based healthcare services. Prior authorization programs can detrimentally impact a patient's timely access to healthcare services. We encourage the state to consider all of the real costs of implementing any program and ask you to consider the total impact on patients' quality of life during a significant illness such as cancer.

Thank you for the opportunity to speak with you today. Are there any questions?

ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN works to encourage elected officials and candidates to make cancer a top national priority. ACS CAN gives ordinary people extraordinary power to fight cancer with the training and tools they need to make their voices heard. For more information, visit www.acscan.org.

Attachment #4

Statement PhRMA

Opposing North Dakota Senate Bill 2066

January 10, 2013

Position: PhRMA respectfully opposes State efforts that would remove the protected status of antineoplastic agents for the treatment of cancer in the North Dakota Medicaid Program requiring prior authorization and creating access barriers for people with serious illness.

The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes any effort by North Dakota to lift therapeutic class protections in the Medicaid program on medications because doing so would reduce patient access to medically necessary drugs. These long standing protections were specifically implemented to protect access for patients with some of the most debilitating illnesses by exempting these classes from certain restrictions. Requiring prior authorization (PA) on all antineoplastic agents could potentially result in unattended consequences for those most in need and result in significantly higher medical costs.

Cancer treatments are always changing and improving. Oncologists and their patients are often faced with problems that have few approved treatment options. Treatments often use combinations of drugs that might include one or more drugs not approved for that disease. Off-label prescribing is a key factor in treating this debilitating disease. Studies have reported that about half of the chemotherapy used is given for conditions not listed on the FDA-approved drug label. In fact, the National Cancer Institute (NCI) has stated, "Frequently the standard of care for a particular type or stage of cancer involves the off-label use of one or more drugs." Currently, North Dakota follows standard of care practices by protecting antineoplastic agents, supported by the 2008 Medicare rule changes to cover more off-label uses of cancer treatment drugs. By removing this protected status North Dakota would not be acting in the best interest of some of its most vulnerable residents.

A patient's health and well–being and preserving the physician-patient decision making authority should be the focal point for all decisions regarding drug treatment regimens. Patients whose treatment is decided based on other factors may not receive the best treatment for them, and consequently result in requiring more costly treatment in the short and long term, such as hospital stays and emergency room visits. Ensuring that patients are able to access the medications prescribed without added restrictions is an important step in protecting the health of some of North Dakota's most vulnerable residents.

The patients and conditions being treated by the prescription drugs used in this class are among the most vulnerable and fragile. Patients with cancer are very sensitive to any change in medication and, therefore, need improved access to medicines not restrictions. Tampering with a delicate medication regimen that is working and has stabilized a patient's condition, could be detrimental to a patient's work and family life. Cancer is arguably among the most debilitating conditions and, therefore, the protected status of these medicines should be preserved.

A study of Maine's experience with prior authorization by Harvard Medical School professor, Stephen Sumerai, (Health Affairs, April 2008) found that there was a 29% greater risk of treatment discontinuity (30 days without medication, switching of medication, or augmentation of medication) as a result of the prior authorization requirement. There was a also an 18% greater risk of a patient going without

medication for more than 30 days as a result of the prior authorization restriction.[1] These numbers translate into real and significant costs associated with this policy change.

It is for these reasons that PhRMA respectfully urges the North Dakota legislature to maintain the current drug class protections for antineoplastic agents for the treatment of cancer and oppose Senate Bill 2066.

[1] *Estimate of the Net Cost of a Prior Authorization Requirement for Certain Mental Health Medications*, Driscoll and Fletcher, NAMI Ohio, Revised August 2008.

Attachment #5

13.8113.01xxx

PROPOSED AMENDMENTS TO SENATE BILL NO. 2066

Page 2, line 16, after the period insert "The Department may not prefer one antineoplastic agent over another; if an antineoplastic agent prior authorization shows that it meets the definition of medically accepted indication under section 1927 of the Social Security Act [42 U.S.C. 1396r-8] and title 42 of the Code of Federal Regulations, then it must be approved."

Renumber accordingly

#1

Testimony
Engrossed Senate Bill 2066 – Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman
March 26, 2013

Chairman Weisz, members of the House Human Services Committee, I am Maggie Anderson, Director of the Medical Services Division for the Department of Human Services. I am here to provide support of Engrossed Senate Bill 2066, which was introduced at the request of the Department.

Current state law (N.D.C.C. 50-24.6-04.3.e) specifically prohibits the Department from utilizing a prior authorization process for antineoplastic agents (oncology/cancer medications). The Department has noted two areas that resulted in requesting the introduction of this bill.

1. Many oncologist offices submit prior authorization requests for the medication they administer as they do not wish to administer medications costing $10,000 or more without confirmation that they will be reimbursed. Requesting prior authorization is their standard business procedure for other insurance coverage.

   As there is no prior authorization allowed for oncology medication for North Dakota Medicaid, these requests cannot be routed through the prior authorization vendor who responds to 98 percent of requests within four hours, and 100 percent within one business day. The prior authorization vendor cannot be used for these requests because their contract is only to handle drugs that are prior authorized. Also, if the vendor was to be used, they would need guidelines for processing the requests (e.g. approval and

denial criteria), and since current law prohibits prior authorization of these agents, no criteria can be used.

Currently, requests to cover antineoplastics come in a general letter format (not on a prior authorization form) and are routed based on the content of the letter. (They may go to the out-of-state prior authorization team, the medical coders, or a member of the utilization review staff.) Depending upon the schedules of the staff, response times are not as predictable as the prior authorization vendor staff.

2. North Dakota Medicaid receives federal matching funds for Covered Outpatient Drugs as defined in the Social Security Act Section 1927. [42 U.S.C. 1396r-8]. Covered outpatient drugs do not include those used for a medical indication which is not a medically accepted indication. The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i). The compendia specifically includes the DRUGDEX Information System, which the Department utilizes. Without prior authorization of antineoplastic agents (oncology/cancer medications), the Department cannot ensure that the drugs are being used for medically accepted indications.

   Nationwide, Medicaid auditors, including Recovery Audit Contractors (RAC) and Payment Error Rate Measurement Contractors (PERM), are tasked with ensuring Medicaid programs are following state and

federal policies in the payment of services. This includes reviewing paid claims and the associated medical records to determine if medications are being used for medically accepted indications. If these audits determine that a medication is not being used for medically accepted indications, the reimbursement will be recouped from the provider.

Because of the current restriction on prior authorization of antineoplastic agents, the Department finds itself in a situation where we are unable to provide efficient, fast and direct answers to providers and we are unable to ensure claims paid by the Department will not be reversed through a recovery audit.

The Department is proposing a solution through this bill that would allow North Dakota Medicaid to implement an indication-based (or diagnosis-based) prior authorization, so all requests from physician offices can be processed in the same efficient manner, and payments will not be made outside of federal or state policies.

There is no anticipated fiscal impact from this proposed change since the prior authorization would be limited to ensuring that the medication is being used for the appropriate indications as outlined by the Food and Drug Administration or compendia (DRUGDEX Information System) allowed by the Centers for Medicare and Medicaid Services (CMS). The prior authorization would not try to steer utilization to another product due to cost.

On page 2, Lines 16-20, the Senate adopted amendments to make it clear that the Department will not prefer one antineoplastic agent over another, and the Department will approve all requests when the antineoplastic agent is being used in accordance with federal guidelines for coverage of outpatient drugs.

The Department requests your favorable consideration of Engrossed Senate Bill 2066 as it addresses the attention CMS has placed on program integrity and offers an efficient solution for the prior authorization requests already submitted by providers for these medications.

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

#2

Testimony

Senate Bill 2066

House Human Services Committee

Tuesday, March 26, 2013
10:30 AM

Deborah Knuth
Government Relations Director, American Cancer Society Cancer Action Network (ACS CAN)

Good morning, Chairman Robin Weisz and members of the House Human Services Committee. My name is Deborah Knuth, and I am the director of government relations for the American Cancer Society Cancer Action Network (ACS CAN). I am here today to testify in opposition of Senate Bill 2066, and asking for a "do not pass" recommendation from this committee.

We support the ability of doctors to make the best medical decision for their patients in consultation with their patients. Prior authorization programs limit the ability of patients and doctors to make medical decisions in an unimpeded manner. While generic alternatives are not currently widely available for cancer patients, we are concerned that future cancer patients have timely access to the complete continuum of treatment, regardless of generic status.

We would advocate for a carve out for cancer prescriptions now and in the future. Prior authorization creates an additional administrative barrier, can discourage physicians from prescribing prior authorization drugs, even if they're the most appropriate option for the patient, and can deter beneficiaries from seeking the recommended care. For cancer patients undergoing chemotherapy, any delay can be detrimental to their treatment success and quality of life.

We ask that the system benefit the patients, allow for the appropriate doctor/patient relationships and not impede patient quality of life and timeliness of care. The system needs to be simple for providers and patients.

In closing, the ACS CAN strongly supports the right of cancer patients and their doctors to decide what is best for the patient, based on the patient's medical and emotional needs. ACS CAN believes that Medicaid coverage should allow for timely access and coverage of the complete continuum of quality, evidence-based healthcare services. Prior authorization programs can detrimentally impact a patient's timely access to healthcare services. We encourage the state to consider all of the real costs of implementing any program and ask you to consider the total impact on patients' quality of life during a significant illness such as cancer.

Thank you for the opportunity to speak with you today. Are there any questions?

ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN works to encourage elected officials and candidates to make cancer a top national priority. ACS CAN gives ordinary people extraordinary power to fight cancer with the training and tools they need to make their voices heard. For more information, visit www.acscan.org.

Sharon Brigner #3

Statement PhRMA

Opposing North Dakota Engrossed Senate Bill 2066
Hearing Before the House Human Services Committee
March 26, 2013

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