MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

1422

2007 HOUSE HUMAN SERVICES

HB 1422

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: January 24, 2007

Recorder Job Number: 1753

Committee Clerk Signature Judy Schock

Minutes:

Chairman Price: We will open the hearing on HB 1422.

Representative Robin Weisz, District 14: We had this bill 2 years ago, we added a sunset clause.

Dr. McLean, practicing psychiatry for 15 years: I primarily work with the seriously mentally ill individuals. I have been a strong advocate for individuals with seriously mentally ill and very interested in all the medications. The main concern I have is making sure that they get the right medications at the right time. Many with these disorders have a suicide rate of up to 10%. The state has done a very good job of helping to educating prescribers. The cost issue is something you will be looking at. I caution you when looking at the fiscal amount to look at the whole picture. The medications are very costly, but not treating is very costly as well. I am in favor of this bill.

Susan Rae Hegeland, Executive Director of the Mental Health Association in ND: See attached testimony, also brochure enclosed. I am leaving testimony with you from **James Moench , Executive Director of ND Disabilities Advocacy Consortium**, who was unable to be here.

Deborah Knuth, Government relations director for the American Cancer Society: See attached testimony.

Dr. Albert Samuelson, physiatrist practicing in Bismarck for the past 40 plus years: I have a particular interest in sever mental disorders, and the schizophrenia population. We really don't know the cause of schizophrenia. We know there are many chemical systems in the brain. The treatments are complex. They have the freedom to try different medications. We often have to negotiate with patients to stay on medications and out of hospitals. Those with chronic disease usually end up on Medicaid or Medicare.

Chairman Price: A real concern of the committee is a Medicaid patient who was currently on a drug that seemed to be working. They did not want them changed for financial reasons. What I am asking you is let's say they have been on a drug generic or brand and it is really not working. What would be the impact on the patient if at that point, on a current Medicaid, on a current drug, you are going to change the drug that would say prior authorization that was required than. How would you feel about that? The drug is not working and you want to change it.

Dr. Samuelson: If you had the mechanism to negotiate these things. I can't answer that question. I think we feel torn on the preauthorization. There are all kinds of pressures.

Carlotta McCleary, executive Director for the ND Federation of Families for Children's Mental Health: See attached testimony. Being the parent of a child with disorder, we had to go out of state for his care. We needed Medicaid for him and we were denied, because he was not on a generic. We ended up trying them because we had no choice. Fortunately it worked for him. Children should have access to drugs with out barriers.

Chairman Price: anyone else if favor? Is there any opposition?

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services: See attached testimony with several added attachments.

Chairman Price: Anyone else in opposition? If not we will close the hearing on HB 1422

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

House Human Services Committee

☐ Check here for Conference Committee

Hearing Date: January 24, 2007

Recorder Job Number: 1856

Committee Clerk Signature	Judy Schock

Minutes:

Chairman Price: Take out HB 1422.

Representative Porter: It seems to be working and I move a due pass, **Representative Kaldor** seconds the motion. The vote is 10 yeas 0 nays and 2 absent. **Representative Weisz** will carry to the floor.

Date: 1/24
Roll Call Vote #:

2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

House HUMAN SERVICES HB 1422 Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass

Motion Made By Rep Porter Seconded By Rep Kaldor

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price – Chairman	✓		Kari L Conrad		
Vonnie Pietsch – Vice Chairman	✓		Lee Kaldor	✓	
Chuck Damschen	✓		Louise Potter	✓	
Patrick R. Hatlestad	✓		Jasper Schneider		
Curt Hofstad	✓				
Todd Porter	✓				
Gerry Uglem	✓				
Robin Weisz	✓				

Total (Yes) "Click here to type 10 Yes Vote" No "Click here to type 3 No Vote"

Absent 2

Floor Assignment Rep. Weisz

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

REPORT OF STANDING COMMITTEE

HB 1422: Human Services Committee (Rep. Price, Chairman) recommends **DO PASS** (10 YEAS, 0 NAYS, 2 ABSENT AND NOT VOTING). HB 1422 was placed on the Eleventh order on the calendar.

2007 SENATE HUMAN SERVICES

HB 1422

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 2-26-07

Recorder Job Number: 3847

Committee Clerk Signature Mary K Monson

Minutes:

Chairman Senator J. Lee opened the hearing on HB 1422 relating to the prior authorization program.

Representative Chet Pollert (District #29) introduced HB 1422 in support.

Dave Peske (ND Medical Association, Executive Director the ND Psychiatric Society) HB 1422 is a simple bill dealing with the removal of the sunset clause. He explained how that works (meter 2:20).

He distributed "Limiting Medicaid Patients' Access to Mental Health Medications Is Not Fiscally Responsible" (attachment #1) and explained it.

Testimony from the president of the ND Psychiatric Society, Terry Johnson, MD, was distributed (attachment #2). This was testimony prepared for the House hearing and Mr. Peske was given permission to use it.

Attachment #3, testimony from Andrew McLean, MD, Psychiatrist, was distributed and read by Mr. Peske.

Mr. Peske introduced Bismarck Psychiatrist, Cheryl Huber, MD.

Dr. Huber testified in support of HB 1422. She reviewed the testimony presented and read by Mr. Peske and agreed with those comments. She said that prior authorization already exists for a number of other medications so why not psychotropic medications. (Meter 13:20)

Senator J. Lee asked Dr. Huber to give her insight about the review of drugs in particular and psychotropic drugs in general, if that was a part of the DUR board responsibility.

Dr. Huber said it hasn't been at this point because of the previous exemptions in 2005. (Meter 15:50)

Senator J. Lee asked if a physician can write "dispense as written" to make sure that drug is provided.

Dr. Huber said not without prior authorization at this point.

Senator J. Lee asked her to explain the difference between the way a drug would be addressed for the private insured patient and the Medicaid patient

Dr. Huber said she would like to see it be no different. Part of the difference is going to be those people who have other private insurance. They have whatever resources they can to keep their illness under control. Unfortunately, Medicaid patients are missing some of those resources. They tend to be sicker and less able to use other means to help control their illnesses.

(Meter 18:53) Discussion continued on patients with close to identical conditions on Medicaid verses privately insured.

Senator Warner asked Dr. Huber to discuss what is special about the adolescent mind and how it responds differently to drugs.

Dr. Huber said her own theory was that adolescents and young adults have a little more immature nervous system in general and there are certain side effects that can occur with classes of medicine that tend to be more prevalent in younger people.

Senator Dever said he didn't understand why the DUR board couldn't address the arguments about the medication. It was his understanding that this bill had a sunset clause to allow the DUR board the opportunity to address it and then see where it was at this session.

Senator J. Lee gave some background on that (meter 22:35).

Representative Robin Weisz (District #14) testified in support of HB 1422.

Susan Rae Helgeland (Executive Director, Mental Health Association, ND) provided testimony in favor of HB 1422 (attachment #4) and a copy of Issue Brief Series: Access to Medications, (attachment #5).

Senator Dever said the carve-out for Medicaid does not exist for private insurance. He asked if there were any statistics or any way of evaluating how the two are different.

Ms. Helgeland did not have the difference between private insurance and Medicaid and prior authorization and formularies (meter 31:55).

Senator J. Lee asked if people who are denied medication are denied because of prior authorization or because they don't have access to the health care system.

(Meter 34:17) Ms. Helgeland said that people who are enrolled in Medicaid are already on access to medication but they don't have the supports in place to help them stay on their meds and to help and support them.

Senator J. Lee wanted to know if prior authorization has a big role to play in denying people medication.

Ms. Helgeland said that denying meds and staying on meds and staying in a recovery mode are different things. Sometimes meds need to be changed.

Ms. Helgeland read testimony in favor of HB 1422 from Carlotta McCleary (Executive Director, NDFFCMH) (attachment #6).

Ms. Helgeland said that when people are unable to get their medication, the typical protocol for a person on Medicaid is ending up in the emergency room. A person on private insurance usually does not end up in the emergency room.

Senator Warner asked Ms. Helgeland to explain the difference between SCHIP and Medicaid coverage.

Ms. Helgeland replied that the CHIP is for children whose family income is just higher than Medicaid eligibility. If they don't qualify for Medicaid because there is too much income, then they move into CHIP which is at 140% of poverty. CHIP is covered under BC/BS.

Senator Warner – Is there a formulary under this?

Ms. Helgeland – I don't know – That's what we need to find out.

Senator Dever said he understood there was a problem with Medicaid under the present situation but the bill asks to keep the situation the same.

(Meter 46:00) Discussion followed on prior authorization of prescription refills.

Deborah Knutt (American Cancer Society) testified in support of HB 1422 because of the cancer medications.

Senator J. Lee asked if she had any examples of times when somebody has been denied a cancer medication.

Ms. Knutt – No, they would be concerned when that would happen. They are finding that with cancer patients the treatment is becoming highly individualized. That is where the concern is.

James Moench (Executive Director, NDDAC) provided written testified in support of HB 1422. (Attachment #7)

Maggie Anderson (Director, Division of Medical Services, DHS) testified in opposition to HB 1422 (attachment #8).

Senator J. Lee asked if there has been any real evidence nationally or prior to '05 that would have raised concerns.

Ms. Anderson said what they are aware of are the efforts with Part D where they did subject them to prior authorization. They are aware of similar bills and legislation being introduced in other states. (Meter 58:00)

Senator J. Lee asked if there have been challenges to getting medication for those people who have moved from Medicaid to Medicare Part D.

Ms. Anderson said she didn't have that specific information.

Senator Heckaman referred to the Medicaid drug spending detail in her testimony and about the top four.

Ms. Anderson replied that they are the top four because they are the current drug needs of the Medicaid population. They are post Part D drug spends. (Meter 60:00)

Senator Heckaman asked if this bill is not passed if it would change these top four.

Ms. Anderson said that for '07-'09 the Dept. had no intentions of prior authorizing those drugs. What this bill does is take their ability away from doing that in the future. (Meter 60:34)

Senator Warner asked her to comment on the ability to create an objective system of evaluating the responses between the two populations of Medicaid and the private sector.

Ms. Anderson responded that she couldn't indicate what availability they would have to that data within the private insurance group. They have very little to access to the Part D information. They could provide the Medicaid information.

Senator Pomeroy referred to the Medicaid drug spending detail and asked if it would be much more individualized with the first four than with the others.

Ms. Anderson replied that, depending on an individual's diagnosis and specific condition, any of those medications can be individualized.

Rod St. Aubyn (BC/BS) testified in a neutral position on HB 1422 and provided a copy of their formulary (attachment #9).

He provided some general information in regards to the prior authorization (meter 68:30).

He said they would object, in terms of their plan, if they were told that they couldn't have prior approval for a certain classification. Even though they don't prior approve any of the drugs right now, there are always new drugs coming out. Their formulary committee adds and removes drugs from their formulary ongoing.

The hearing on HB 1422 was closed.

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-05-07

Recorder Job Number: 4393

Committee Clerk Signature Mary K Monson

Minutes:

Chairman Senator J. Lee opened HB 1422 for discussion and more information from the Dept. of Human Services.

Dr. Brendan Joyce (Dept. of Human Services, Pharmacy Administrator) explained the history of prior authorization (01:15).

Senator J. Lee asked Dr. Joyce to explain what prior authorization is and how it works.

(Meter 02:58) Dr. Joyce explained that it all depends on what insurance is used and gave examples.

(Meter 05:30) He went back to talking about the history of prior authorization of medications with ND Medicaid. He showed that for certain classes of medications there was a great savings after prior authorization. There actually was an increase in the number of prescriptions but more cost effective ones were used such as over the counter prilosec. There are no studies that show that the prilosec over the counter to be less effective than any of its counterparts and there are no studies that show any of the prescription products to be more effective than the prilosec over the counter.

He talked about the samples people get in the doctors office. Samples are a push for brand loyalty by the drug manufacturers. They are a promotion.

Senator J. Lee pointed out that over the counter drugs are paid for by Medicaid which are not paid by private.

(Meter13:00) Dr. Joyce talked about claw-back which is the amount of money they have to pay back to the feds to help pay for Medicare Part D.

This bill, to his understanding, only applies to Medicaid. He pointed out that BC/BS does already prior authorize cancer drugs. It is a certification process and is what is done by the majority of payers--that is to make sure that these drugs are being used as they are most cost effective. It is not to deny medications to patients but to certify and prove that it should be used for that patient.

(Meter 17:20) He addressed concerns the department had with psych medications.

This bill will keep Medicaid from having somebody who is stable on one medication move to another one. This bill will do nothing to keep PHARMA from doing that (Meter 20:50). He gave examples.

Senator J. Lee asked if the switching by the industry would be that perhaps somebody has been taking a medication twice a day and now is just once a day but the compound is identical. Is that a way somebody would switch from one brand name drug name to another—dosage.

Dr. Joyce said those are some issues. Medicaid isn't as worried about things that are going to change compliance. They are more concerned with Paxil, a generic antidepressant (meter 25:10). He explained why.

He explained that some medications are loosing their patents in the next few years.

Senator J. Lee asked him to compare Medicaid to private insurance in respect to two people having identical prescriptions issued for identical conditions.

Dr. Joyce gave an example of an anti psychotic. (Meter 30:45) On Medicaid the patient would get the medication with a $3 co-pay. On BC/BS this medication was recently taken off their formulary. Because it is a non formulary medication they will be paying 30% extra.

He gave another example pertaining to Paxil CR.

Senator J. Lee asked if there are carve outs in Part D.

Dr. Joyce said there are no carve outs (meter 33:45)

(Meter 35:10) (Attachment #10) Dr. Joyce talked about Georgia Medicaid doing prior authorization.

Senator J. Lee asked if it was correct that a prescription has to be reauthorized every time it is refilled.

Dr. Joyce replied that was not correct. The medications they do prior authorizations for are given a one year prior authorization allowance (meter 36:45).

Senator Dever said two years ago when they passed this bill it was with the understanding that the DUR Board would look at it, sunset now to allow them to do that. What would it take to get the DUR Board to come out with a policy on this?

(Meter 39:30) Dr. Joyce answered that he could put it on the June agenda and they could probably hash out a policy on it after two meetings. There aren't many medications classes they are still looking at.

Discussion continued on that legislation from last session.

Senator Pomeroy asked if a person who is fragile where medication is concerned needs not to be worried about being forced to go on a generic when he needs an adjustment.

(Meter 46:00) Dr. Joyce talked about a variety of issues that come into play, some being physician specific.

Senator J. Lee asked if generics would have actually been different from brand names 15-20 years ago.

Dr. Joyce replied that around the 70's – 80's there was some non regulation of some of the generics (meter 52:10).

Senator J. Lee recognized Dave Peske (ND Medical Association). He provided information from Dr. Cheryl Huber about the costs for a patient who switched from an anti psychotic drug and had to go into the emergency room of a hospital. (Attachment #11) This was followed by discussion about destabilization.

Chet Pulver (ND Mental Health Association) said he didn't think they could compare people with medical insurance and without. He gave examples of people on Medicaid. People with severe mental illness who are on Medicaid are there because they have run out of options.

(Meter 63:20) Discussion followed about the parts of the bill on page 2 that were over struck. Options for amending were discussed. There was interest in extending the sunset.

Senator J. Lee said their main concern is that the health outcome of the individual is a good as it can be. She said they also need to be fiscally responsible about what they are doing on the budget outcome.

(Meter 73:30) Discussion continued on different options with Dr. Joyce giving a suggestion. Senator J. Lee asked him if he would put together a proposed amendment that the committee could consider. He agreed to do so.

Senator J. Lee closed discussion on HB 1422.

2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

Senate Human Services Committee

☐ Check here for Conference Committee

Hearing Date: 3-12-07

Recorder Job Number: 4867, 4931, 4934

Committee Clerk Signature Mary K Monson

Minutes:

Chairman Senator J. Lee opened HB 1422 for discussion and consideration of amendments provided by Dr. Brendan Joyce.

Dr. Brendan Joyce (Pharmacy Administrator, Medicaid) distributed the amendments and explained one was just a hog-house version (attachment #12) but just rewriting the language back into it and adding a section 2 giving directive for the drug use review board to review the categories and provide recommendations. (Meter 3:00) He talked about the reporting process, deadlines for reporting recommendations, and suggested the finalization not be required until October 2008.

Senator J. Lee – If we had semi annual reports to the appropriate interim committee, would that be a logical thought?

Dr. Joyce said that would be fine.

Senator J. Lee said she had some enthusiasm for this concept. (Meter 5:00)

(Meter 6:20) Discussion took place on specific drugs being linked to specific conditions but also used for other conditions. That is why the language in the amendment is fairy general.

Ted Kleiman (Dr. of the Day from the Fargo area) (meter 8:00) offered comments on using medications for behavior problems in children. He also talked about uninsured people who are

severely disturbed and are put on the older medications that do make a difference. He urged the committee to look at long term studies. "What does make a difference?"

Dave Peske (ND Medical Association) suggested a change to Section 2 with regards to the reporting requirement. On line two the suggestion was to change it to read, "...review the *utilization, costs, and effectiveness of the* drugs...". He said they would agree to the suggestion to move the report to October 31.

Chet Pulver (ND Mental Health Association) reported that they had not had time to examine the amendment but it seemed like they were on the right track.

(Meter 17:15) There was discussion on what the best date would be for the reporting.

JOB #4931

The discussion continued on amendments and the recommendations for the reporting deadline and who they should report to. They wanted the report to go to a committee of the Legislative Council semi-annually with a final report due by October 1, 2008.

JOB #4934

The amendments were reviewed.

Senator Warner moved to accept the hog-house amendment which includes a new section 2.

The motion was seconded by Senator Heckaman.

Roll call vote 6-0-0. Amendment accepted.

Senator Warner moved a Do Pass as amended.

Senator Heckaman seconded the motion.

Roll call vote 6-0-0. Motion accepted. Carrier is Senator J. Lee.

Date: 3-12-07

Roll Call Vote #: 1

2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1422

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Amend Hog. House & new section 2

Motion Made By Sen. Warner Seconded By Sen. Heckaman

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee, Chairman	✓		Senator Joan Heckaman 2	✓	
Senator Robert Erbele, V. Chair	✓		Senator Jim Pomeroy	✓	
Senator Dick Dever	✓		Senator John M. Warner 1	✓	

Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

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

Date: 3-12-07

Roll Call Vote #: 2

2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1422

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass as Amended

Motion Made By Sen. Warner Seconded By Sen. Heckaman

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee, Chairman	✓		Senator Joan Heckaman 2	✓	
Senator Robert Erbele, V. Chair	✓		Senator Jim Pomeroy	✓	
Senator Dick Dever	✓		Senator John M. Warner 1	✓	

Total (Yes) 6 No 0

Absent 0

Floor Assignment Senator J. Lee.

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

REPORT OF STANDING COMMITTEE

HB 1422: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1422 was placed on the Sixth order on the calendar.

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to amend and reenact section 50-24.6-04 of the North Dakota Century Code, relating to the prior authorization program; to provide for review by the drug utilization review board; to provide for a report to the legislative council; to provide an effective date; and to provide an expiration date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 50-24.6-04 of the North Dakota Century Code is amended and reenacted as follows:

50-24.6-04. (Effective through July 31, ~~2007~~ 2009) Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:

   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;

   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or

   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.

2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.

3. Except for quantity limits that may be no less than the pharmaceutical manufacturer's package insert or AB-rated generic equivalent drug for which the cost to the state postrebate is less than the brand name drugs, in the aggregate, the department may not prior authorize or otherwise restrict single-source or brand name antipsychotic, antidepressant, or other medications used to treat mental illnesses, such as schizophrenia, depression, or bipolar disorder, and drugs prescribed for the treatment of:

   a. Acquired immune deficiency syndrome or human immunodeficiency virus; and

   b. Cancer.

4. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.

5. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:

   a. Establish policies and procedures necessary to implement the prior authorization program.

   b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.

   c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

(Effective after July 31, ~~2007~~ 2009) Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:

   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;

   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or

   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.

2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.

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   a. Establish policies and procedures necessary to implement the prior authorization program.

b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.

c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

SECTION 2. DRUG UTILIZATION REVIEW BOARD REVIEW - REPORT TO LEGISLATIVE COUNCIL. During the 2007-08 interim, the drug utilization review board shall review the utilization, cost, and effectiveness of the drugs identified in subsection 3 of section 50-24.6-04 and make recommendations for managing the utilization of the identified drugs or of any other drugs for the conditions identified in that subsection. The drug utilization review board shall make semiannual reports of its progress and a final report, due by October 1, 2008, of its findings and recommendations for legislative changes to a committee of the legislative council, including any legislation necessary to make the suggested changes. The legislative council shall receive the board's report and report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixty-first legislative assembly."

Renumber accordingly

2007 HOUSE HUMAN SERVICES

CONFERENCE COMMITTEE

HB 1422

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

House Human Services Committee

☒ Check here for Conference Committee

Hearing Date: March 28, 2007

Recorder Job Number: 5594

Committee Clerk Signature	Judy Lehoch

Minutes:

Rep. Weisz: I guess beings the senate made a few changes I would like to hear why you made the changes if that is ok. I would just like to get an overview.

Sen. Lee: It looks like a long amendment but it really was a result of re drafting it so it was a little more presentable. The change that we made was to extend the time frame for another couple of years here. During that time the DUR board would be called upon to study and review and submit proposed rules as they might think would be necessary. It might be that there were none on those excluded categories which are oncology, psychotropic drugs, and HIV/Aids. The idea being that the people who hear this are expressing concern to get those drugs out. Our committee thought the way to deal with that is to ask the DUR board to look at them even though they had no plans to do any kind of prior authorization work in the next two years on this. We wanted to ask them to study these and see if they would conclude that there would be some rules that would apply. Instead of fearing an unknown at least we would know whether or not there is something that would be of concern with us. Nothing would change in the next two years. Those categories would still be exempted. As we all know the written possibility is still there. It seems like a good idea to the Senate Human Services committee that we have something in front of us so we know whether or not there would be a concern about it.

If there are proposed rules as a result of their study then two years from now we decide whether or not those would be appropriate or should we continue to exempt those from consideration. I think that is the summary of what we did.

Sen. Dever: Did you mention the report of the legislative council?

Sen. Lee: No I didn't and thank you. They would make semi annual reports so that we would know how they are coming along through the legislative council. That would allow us as we go through the interim to know how it's coming and see if they are finding a need. We know for example that oncology drugs are unique to the patient and we don't want to interfere in any way with the division's ability to properly manage the medical conditions of Medicaid patients. Since the rest of us have that in our insurance policies, it doesn't seem unreasonable that we might consider it put in. Medicare part B doesn't card any of this stuff out. That was discussed in congress before part B was passed. It seemed like a way for the legislators to become better informed about it.

Rep. Weisz: As far as the study, what do you envision that you would receive in the semi annual reports? I'm curious as to what kind of information that we would be getting on these reports as we go through the interim to make that determination.

Sen. Dever: First of all it is not a study it is a report by the DUR board. One of the concerns that I had in the Senate was one of the people that testified said that the DUR board had not considered these drugs because the law was in place. Well the law had a sunset on it and now we are considering whether we should remove that sunset or not. I guess if we extend the sunset I think the purpose in the report is to ensure that there was consideration given to that.

Rep. Weisz: But if we didn't extend the sunset then they would have information to make the decision on whether to continue the current practice or to put it into formulary.

Sen. Lee: The idea was just that we would really have something more concrete than so material to deal with. I think there was also some confusion among our committee members and I think it is possible that in the department that was true as well. My understanding of what we did two years ago is that we were told we couldn't do anything. There was some feeling that they should have been looking at it but not making any changes. This clarity that we thought that this brought forward is that we would like the DUR board to do the homework required and it is a fair amount of additional work for this group. They are volunteers. I was just told yesterday that Dr. Huber who is a psychiatrist has just been elected Chair of the DUR board. So a Psychiatrist is going to be the chair of that board. There is at least one other psychiatrist that can fill you in on all of the participants of the DUR board. There are experts that are on that board in medication. Both positions including psychiatrists and pharmacists. If they reviewed it and do homework that we aren't capable of doing. They can bring that information to us in two years. That is something that we can figure out if we want to keep this going or change it.

Rep. Weisz: I think that in the house that was one of the things that we passed it as is, was because there didn't appear to be any information that came before our committee that showed if there was an issue or a problem. I understand from your prospective that nobody did anything that would have supported it. I think that was one of the reasons the house passed out as it did was there didn't appear to be a problem. There wasn't any testimony that showed up that they were having problems. Maybe we weren't clear two years ago.

Sen. Lee: I misunderstood. I thought they were told not to do anything. That they should focus on other things that they weren't supposed to do, and focus on other things. I may not be the only one under that impression. I may be the only one. I didn't understand it that way.

Rep. Potter: This doesn't sound like a bad plan right off the bat. I'm kind of curious if anybody has an idea of what kinds of things that they will be looking at in the next couple of years with drug utilization review board, as to what kinds of things that they will be trying to look at and take under any kind of consideration?

Sen. Lee: There are people in the room that you could ask.

Dr. Brenden Joyce: Pharmacy Administrator for ND Medicaid. The DUR board is going to approach this in a step by step fashion. In June they are going to look at HIV/AIDS and cancer. They will have as many meetings as they need to. They typically meet every three months. I have been told now that they may be meeting every 2 months to get through these things in the next two years if this bill passes out as amended. So they will be looking at HIV/AIDS. There is only one drug that ever would have a potential for being restricted and that is because it has been shown that it causes more resistance. If that drug is used as they progress through their therapies it is totally appropriate. The first line is a bad idea, the second line is fine. Then they are going to look at Cancer. We are pulling information now about the gestation. We are told Blue Cross Blue Shield have authorized 8 or 10 cancer drugs right now. Looking at different things from other states, it is typically the same thing. First line second line and what it is approved for. It's just getting interpretation for what kind of cancer it is for. That is what they are going to be looking at. We chose to have those two done first because they are simplest forms. People don't do things with HIV/AIDS. Cancer is pretty basic. We just have to make sure that we use the right drugs with the right cancers that prove effective. We plan on presenting exactly what they come up with like if they have criteria for coverage or prior authorization. We plan on presenting that to legislative council. We will be coming straight to them.

Sen. Dever: In the report of October 1, I understand that we need to bring legislation forward and we need to have it there prior to that.

Dr. Brenden Joyce: Yes.

Rep. Potter: When you go through the HIV/AIDS drugs and cancer and find something that you aren't expecting. What do you do? What does that show you?

Dr. Brenden Joyce: We being the department and the vendor that works on this, we know what is going on outside of Medicaid in ND. We know what is being done, what strategies are being successful, what strategies are not being successful, and we try to manage utilization appropriately. We use all of that information to try and figure out the best way to approach this. If we find something that hasn't been notices elsewhere or something new and different, we will be surprised because we aren't the first ones doing this by any means. We are anticipating using the experience of others, other states, and other insurance companies to figure out the best way to approach it where you aren't causing prioritization and increasing efficiency.

Rep. Potter: But really it is just research?

Dr. Brenden Joyce: Yes.

Sen. Lee: Do you have a little information that you could share with us about the other experiences with DUR boards and prior authorizations? Do most states carve out?

Dr. Brenden Joyce: It's all over the board out there. Some say it is carving out the psychotics and anti depressants. It all varies quite a bit throughout the nation. As far as Medicare there was an attempt to carve out and it failed in Congress. They ended up requiring coverage of all or substantially all of the medications in those categories. They can still require prior authorization for those categories but they at least have to have them on the information. You may have to do paperwork but you will still have access to it. In private insurance companies it varies quite a bit. It all depends upon how they are trying to manage the premium levels and

such. It varies quite a bit. Recently there have been quite a few more states that have done that. As opposed to the ones that were done a number of years ago which had a bad outcome when there weren't so many options for medication. They had a bad outcome and tried to do something that caused increased hospitalizations. Georgia actually cut down on hospitalizations because they were able to pick the more efficient products and the more effective ones. We hope to model any recommendations that come out of the DUR board.

Rep. Weisz: When you look at costs in this report to do you take the costs of the drug itself? Do you take into account the increased hospitalizations?

Dr. Brenden Joyce: That is definitely one of the things that we take a look at. For instance the average cost is $398 per prescription if it's an antipsychotic if it keeps people out of the hospital. There is some noise out there which we have to investigate to see if it actually is anything besides noise. We plan on doing that when antipsychotic come up to take a review. People gain 10 pounds in a month quite typically. Some gain more and more. Then the instance of Diabetes goes up in that population. They are investigating adding a medication to that to avoid the long term consequences. If an antipsychotic is proven to cause anything, we need to make sure this is proven to cause something deter mental down the road. That is the investigation that has to be done. You cannot just look at the dollars of that prescription. You can't just say that it is more expensive. Those dollars don't mean anything.

Rep. Hofstad: My question was the cost too and how that plays in.

Dr. Brenden Joyce: The DUR board meetings may interest some of you if you wish. You can be included on the mailing list to be notified when the meetings are and such. We have some legislators on the list already. June is the next meeting.

Rep. Weisz: Are there any further questions or comments from the committee? Are we ready to settle this?

2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1422

House Human Services Committee

☑ Check here for Conference Committee

Hearing Date: March 28, 2007

Recorder Job Number: 5595

Committee Clerk Signature Judy Lahoda

Minutes:

Rep. Weisz: I will entertain a motion.

Rep. Hofstad: I will move that we accede to the Senate side.

Rep. Weisz: The motion would be that the house accedes to the Senate on HB 1422.

Rep Potter: I second that.

Rep. Weisz: That is the proper motion. We don't concur we have to accede. I think the house was comfortable with this. We do understand the concerns that the Senate side had with trying to ensure that we will continue this in the future. We will take the roll call vote on a Do pass on the motion. The motion passed 6-0-0. I will carry this bill.

REPORT OF CONFERENCE COMMITTEE
(ACCEDE/RECEDE)

Bill Number HB 1422 (, as (re)engrossed): Date: 3/28/07

Your Conference Committee House Human Services

For the Senate:	YES / NO	For the House:	YES / NO
Sen Lee	✓	Rep Weiss	✓
Sen Dever	✓	Rep Hogstad	✓
Sen Warner	✓	Rep. Potter	✓

recommends that the (SENATE/HOUSE) (ACCEDE to) (RECEDE from)

the (Senate/House) amendments on (SJ/HJ) page(s) 168 -- 1070

✓, and place 1422 on the Seventh order.

___, adopt (further) amendments as follows, and place _____ on the Seventh order:

___, having been unable to agree, recommends that the committee be discharged and a new committee be appointed.

((Re)Engrossed) _____ was placed on the Seventh order of business on the calendar.

DATE: 3/28/07
CARRIER: Rep Weiss

LC NO.	of amendment
LC NO.	of engrossment
Emergency clause added or deleted	
Statement of purpose of amendment	

MOTION MADE BY Rep Hogstad

SECONDED BY: Rep Potter

VOTE COUNT 6 **YES** 0 **NO** 0 **ABSENT**

Revised 4/1/05

REPORT OF CONFERENCE COMMITTEE

HB 1422: Your conference committee (Sens. J. Lee, Dever, Warner and Reps. Weisz, Hofstad, Potter) recommends that the **HOUSE ACCEDE** to the Senate amendments on HJ pages 1068-1070 and place HB 1422 on the Seventh order.

HB 1422 was placed on the Seventh order of business on the calendar.

2007 TESTIMONY

HB 1422

MENTAL HEALTH ASSOCIATION IN NORTH DAKOTA

Works for a world free from discrimination against mental illness

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United Way

North Dakota 2-1-1 Get Connected. Get Answers.

Visit our website at **www.mhand.org**

A private, non-profit [illegible]1(c) 3 agency. The [illegible]on-governmental [illegible]ization concerned with all aspects of mental health for all citizens of North Dakota.

Testimony
Mental Health Association in North Dakota

HB1422 - Relating the Medicaid Drug Prior Authorization Program

House Human Services Committee
Representative Price, Chairman

January 24, 2007

Chairman Price and members of the House Human Services Committee, My name is Susan Rae Helgeland, the Executive Director of the Mental Health Association in North Dakota. I am here to testify in support of HB1422.

The Mental Health Association in North Dakota is a nonprofit organization whose mission is to promote mental health through education, advocacy, understanding and access to quality care for all individuals.

In 2005, the 59th Legislative Assembly passed legislation that changed the membership of the Drug Utilization Review (DUR) board and provided for an important change to the medication prior authorization program for Medicaid recipients. Mental health drugs, along with cancer and HIV drugs were exempted from the DUR prior authorization program. The bill included a sunset clause of July 31, 2007. HB1422 would remove that sunset clause.

MHAND believes that medications for treatment of mental health issues should continue to be exempt or "carved out" from the prior authorization process because of the following:

- Over the last decade, science has significantly advanced the understanding and treatment of mental illness. Thanks to the development of new medications people with mental disorders can lead full and productive lives.

- Unlike other medications that treat other illnesses, medications that are used to treat mental illness cannot be used interchangeably because each medication has a different mechanism of action and affects each person's brain in a different way. Medication for mental illness have a longer response time (3-6 weeks) and more difficult side effects

- There are no laboratory tests to gauge the effectiveness of medications for treatment of mental illness.

- Mental Health clinicians work hard with their patients to choose a medication that takes into account the individual's health history, physical health issues, co-occurring physical health conditions, range of systems, race and ethnicity and treatment goals. In some cases, a combination of medications for mental illness must be prescribed.

- MHAND feels that it is impossible to regulate, by policy, the full range of therapeutic alternatives to account for each individual's needs.

- Changing psychiatric medications is very difficult. Each failed trial results in suffering and possible worsening of the person's conditions, including the risk of suicide.

- Requiring prior authorization for mental health medications delays proper care, creates more time spent suffering and increases the risk of a history of negative outcomes, including suicide.

- Studies have shown that restricting access to medications for mental illness to achieve cost containment often had the opposite outcome due to increased state expenditures for costly hospitalization, emergency room and/or physician clinic visits.

The North Dakota Mental Health Planning Council supports this bill.

I have attached some information for the committee. The brochure entitled *"Pennywise and Pound Foolish – Restricting Access to Psychotropic Drugs"*. The brochure produced by the National Mental Health Association (NMHA) explains the pitfalls for states considering restricting access to mental health drugs. Also attached is a fact sheet from NMHA entitled "*Preserving Open Access to Mental Health Medications*".

The Mental Health Association in North Dakota respectfully requests that your committee gives this bill a "Do Pass" recommendation.

Chairman Price, I will be glad answer any questions that you might have. If the committee needs more information on this matter or others please feel free to contact me.

Over the last decade, science has significantly advanced the understanding and treatment of mental illnesses and made possible new worlds of opportunities for individuals and families living with mental illness. With proper treatment and support, people with mental disorders can now lead full and productive lives.

For many people with mental illness, the newest, most effective medications are a critical component of a continuum of services that enable these individuals to succeed and become fully integrated into their communities. As healthcare expenditures continue to grow, however, state public health programs (such as Medicaid and the Children's Health Insurance Program) may respond by imposing restrictions on medications to cut costs.

Unfortunately, many of the new policies being implemented—including restrictive formularies, prior authorization requirements and dosage limits—not only risk the health of mental health consumers, but can actually increase total healthcare costs and negatively impact state budgets.

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For more information and supporting studies...
Contact the National Mental Health Association's Advocacy Resource Center at 800-969-NMHA (6642), email shcrinfo@nmha.org or visit our Web site at www.nmha.org.

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1021 Prince Street
Alexandria, VA 22314-2971
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www.nmha.org

PENNY-WISE & POUND-FOOLISH:

Restricting Access to Psychotropic Medications

Restricting Access to Medications...

1. Increases Costs

- A 1998 federally-funded study conducted by the Lewin Group found that reducing pharmaceutical budgets by excluding effective drugs from coverage is usually more than offset by increases in spending in other services elsewhere in the system, such as increased hospitalization.
- The *New England Journal of Medicine* reported in one study that limiting access to psychotropic medications and forcing people to switch from one medication for schizophrenia to another increases overall costs 17 fold due to hospital costs incurred (1994).
- Administrative costs increase when doctors are required to spend more time filling out and processing paperwork and less time with patients.

"When you deny access to needed medication, you are playing with people's lives. Ironically, you also cost the system far greater resources in increased hospitalization, emergency room visits, and other expensive interventions."

—Indiana State Representative Susan Crosby
44th District
Deputy Speaker Pro Tem

2. Impedes Proper Care

- Healthcare providers often do not prescribe newer, more effective medications due to excessive paperwork required by insurers.
- Insurers often require consumers to "fail first" on formulary medications—sometimes repeatedly—before granting access to more appropriate medications.
- Requiring prior authorization for needed medications delays proper care, creates more time spent suffering, and increases the risk of a host of negative outcomes, including suicide.

3. Jeopardizes Personal Health and Productivity

- Not all medications work for all people—side effects, efficacy, dosing, and effects on cognitive functions vary by individual and disorder.
- Without access to newer medications, including atypical antipsychotics and SSRIs, many consumers live with unnecessary side effects, have greater medical complications, and face more obstacles to achieving full and productive lives.
- Consumers may unknowingly be switched to generic medications, which can often have adverse effects on their treatment.
- The severity of mental illnesses often increases and requires more costly interventions because of inappropriate treatments or inability to access needed medications.

So What Should States Do?

To ensure open access to all medications determined medically necessary by providers and consumers, policy makers should:

- **Oppose formulary restrictions** in public health programs such as Medicaid and the Children's Health Insurance Program. Such restrictions can include: limiting the types or number of medications covered; requiring consumers to "fail first" on cheaper medications; demanding higher copayments for some medications; imposing cumbersome and time-consuming preauthorization requirements; and other measures that restrict access to effective treatment.
- **Expand funding and availability** of community-based mental health services that complement medication treatment.

"The states must address the issue of access to medications, whether it is cost, Medicaid eligibility or availability. Aggressive legislative efforts are needed to ensure that mental health care recipients have access to these medications that can dramatically improve their health."

—New York State Assemblyman Martin A. Luster
125th District, Chairman, Committee on Mental Health, Mental Retardation and Developmental Disability

National Mental Health Association

Preserving Open Access to Mental Health Medications

"American's must understand and send this message: mental disability is not a scandal – it is an illness. And like physical illness, it is treatable, especially when the treatment comes early."

– President George W. Bush, April 2002

For most mental health consumers, access to the range of the newest and most effective medications is crucial to their successful treatment and recovery. New advances in medications, combined with other therapies, allow people to lead healthy and productive lives in their communities. Research shows that newer medications are more effective, have fewer side effects and save money over time.

Unfortunately, in response to budget cuts, some states are imposing dangerous restrictions on access to these essential medications. Although NMHA understands that states are facing major budget shortfalls, cutting full access to the most effective mental health medications is an ill-conceived quick-fix that will endanger consumer health and ultimately cost states more money in the long-term.

Most States Have Exempted Mental Health Medications from Restrictions

- The Kaiser Commission on Medicaid and the Uninsured recommends that "all psychotherapeutic, anti-viral and anti-convulsive medications" be exempt from restrictions.[i]
- Twenty-nine states have laws or regulations that exempt mental health medications from restrictions in their Medicaid programs, including Indiana, North Carolina, Kansas, Missouri and Virginia. Unfortunately, there are increasing threats to those exemptions in South Carolina, Tennessee and Florida.
- Most states, including California, Texas and Michigan, approve well over 90 percent of prior authorization requests.[ii] This demonstrates that most physicians have medically necessary reasons for prescribing certain medications.

Each Mental Health Medication is Unique

- Unlike many medications that treat other illnesses, medications that treat mental illness cannot be used interchangeably because each medication has a different mechanism of action and affects each person's brain in a different way.[iiiiv]
- Clinicians work hard with their patients (or consumers work with their doctors) to choose a medication that takes into account the individual's health history, physical health issues, co-occurring physical health conditions, range of symptoms, race and ethnicity, and treatment goals. It is impossible for policies that universally restrict access to the full range of therapeutic alternatives to account for each individual's unique needs.
- The wrong choice of medicine may not only fail to work but also can have intolerable side effects, such as significant weight gain, muscle spasms, blurred vision, severe insomnia or fatigue, or kidney malfunction.[v]
- Changing psychiatric medications is very difficult. It can take between six and 12 weeks to determine if a medication works, and each failed trial results in suffering and a possible worsening of the person's condition.

Restricting Access to Mental Health Medications Costs More

- Although budget cuts are the catalyst for restrictions on access, ironically, states will see no real cost savings from Medicaid cuts that limit medication choices and services for people who have mental illnesses. Without the right medication, people who have mental illnesses may stop taking their medicine or halt their treatment program. This would drastically increase their likelihood of suffering a serious episode, and, in turn, lead to emergency room visits, in-patient hospitalization, and crisis services.

- According to the California Office of Statewide Health Planning and Development, the average bill for a psychiatric hospital in 2002 was $2,222 per day, whereas even the *most expensive* medication to treat mental illness costs far less. Access to the right medications can reduce wasteful spending.[vi]

- Patients who switch from one SSRI medication to another during their care are in treatment 50 percent longer and cost approximately 50 percent more to treat—and in **more** costly treatment settings—than patients who do not switch drugs mid-treatment.[vii]

Mental Health Treatment Works

- A 2003 study from the *National Bureau of Economic Research Reporter* found that newer medications generally increase longevity, decrease activity limitations and reduce total medical expenditures.[viii]

- According to the National Institute of Mental Health, treatment success rates for many mental health disorders surpass those of other medical conditions. For example, the treatment success rate for schizophrenia is 60 percent, depression is 70-80 percent and panic disorder is 70-90 percent, whereas the treatment success rate for heart disease is 45-50 percent.

States Should Improve Best Practices in Mental Health Services

- Rather than limit access to medications, states needs to focus on practices that would improve patient health and contain costs such as:
  - *Provider-peer education initiatives that improve clinical practice.*
  - *Closer review and retroactive intervention in cases of polypharmacy or other inappropriate prescribing.*
  - *Case management of chronic illness to improve coordination of all medical and mental health care, including medications.*
  - *Closer data review to identify fraud, deviation from clinical best practices, outlier prescribers, and clinicians that are "under"-dosing.*

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[i] Somers, S., Perkins, J., and the National Health Law Program, Inc. (April 2003). Model Prescription Drug Prior Authorization Process for State Medicaid Programs. Kaiser Commission on Medicaid and the Uninsured. Available at http://www.kff.org.

[ii] Kaiser Family Foundation on Medicaid and the Uninsured. (January 2004). Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003. Available at http://www.kff.org/medicaid/4164.cfm.

[iii] American Psychiatric Association (final draft pending). Maximizing Pharmacotherapy in the Treatment of Severe and Persistent Mental Illness: The Case for Maintaining Open Access to Medically Indicated Medications for Schizophrenia. Prepared for the Office of Healthcare Systems and Financing, American Psychiatric Association. American Psychiatric Association (final draft pending).

[iv] Maximizing Pharmacotherapy in the Treatment of Depression: The Case for Maintaining Open Access to Medically Indicated Medications. Prepared for the Office of Healthcare Systems and Financing, American Psychiatric Association.

[v] American Psychiatric Association (final draft pending). Maximizing Pharmacotherapy in the Treatment of Severe and Persistent Mental Illness: The Case for Maintaining Open Access to Medically Indicated Medications for Schizophrenia. Prepared for the Office of Healthcare Systems and Financing, American Psychiatric Association.

[vi] California Office of Statewide Health Planning and Development (June 17, 2004). Hospital Annual Financial FAQs. Available at http://www.oshpd.cahwnet.gov/hid/HID/hospital/faqs_hospital_fin.htm.

[vii] Hensley and Nurnberg, Pharmacoeconomics 2001; 19(10): 973-982

[viii] Lichtenberg, F. R. (Winter 2003). New Drugs: Health and Economic Impacts. *National Bureau of Economic Research Reporter*. Available at www.nber.org/reporter/winter03/healthandeconomic impacts.html.

Testimony

North Dakota Disabilities Advocacy Consortium

HB 1422
Prior Authorization Program

Same given to Senate

House Human Services Committee
January 24, 2007

Chairperson Price, members of the House Human Services Committee, I am James M. Moench, Executive Director of the North Dakota Disabilities Advocacy Consortium (NDDAC). The Consortium is made up of 22 organizations concerned with addressing the issues that affect people with disabilities. We are very interested in adding funding for support of home and community based care initiatives. Not only is home and community based care the right thing to do for people who require some assistance to manage their daily lives, it is the most cost effective way to provide services. We applaud the efforts of the Legislature and the Department of Human Services to keep North Dakota citizens in their homes and communities as long as possible.

The Consortium supports removing the sunset clause on section 50-24.6-04 of the North Dakota Century Code relating to the drug prior authorization program. By removing the sunset clause, the state would retain the "carve out" for medications for mental illness that are different from other medications. Finding the correct psychiatric medication can be very difficult. Any delay in treatment results in suffering and possible worsening of the person's conditions, including the risk of suicide. The program has worked without problem and should be continued. Simply removing the sunset clause would continue the current situation.

The organizations in the North Dakota Disabilities Advocacy Consortium urge to House Human Services Committee to support removal of the sunset clause as proposed in HB 1422.

I appreciate this opportunity to testify on behalf of the NDDAC and look forward to working with you over the course of this legislative session.

Thank you.

NORTH DAKOTA DISABILITIES ADVOCACY CONSORTIUM

2006 Membership

1. AARP
2. Dakota Center for Independent Living
3. Family Voices of North Dakota
4. Freedom Resource Center for Independent Living
5. Independence Center for Independent Living
6. ND APSE: The Network on Employment
7. ND Association of the Blind
8. ND Association of the Deaf
9. ND Association for the Disabled
10. ND Center for Persons with Disabilities (NDCPD)
11. ND Children's Caucus
12. Fair Housing of the Dakotas
13. ND Fed. of Families for Children's Mental Health
14. ND Human Rights Coalition
15. ND IPAT Consumer Advisory Committee
16. ND Mental Health Assn.
17. ND Statewide Living Council
18. Options Resource Center for Independent Living
19. Protection & Advocacy Project
20. The Arc of Bismarck
21. The Arc of Cass County
22. The Arc of North Dakota

Updated: July 10, 2006

Testimony

House Bill 1422

House Human Services Committee

Wednesday, January 24, 2007

Deborah Knuth
Government Relations Director, American Cancer Society

Good morning, Chairperson Price and members of the House Human Services Committee. My name is Deborah Knuth, and I am the government relations director for the American Cancer Society. I am here today to testify in support of House Bill 1422, and ask for a "do pass" recommendation from this Committee.

I represent an organization committed to preventing disease and improving public health. We have set ambitious goals for significantly reducing the rates of cancer incidence and mortality along with measurably improving the quality of life for all people with cancer. We are also concerned with addressing the needs of the uninsured, under insured and disparate population of North Dakota. I urge you to support HB 1422 so that cancer patients aren't deprived of open access to the necessary drug products needed to treat their disease.

Thank you once again, Chairperson Price and members of the Committee, for this time to speak with you this morning. I would be happy to endeavor to answer any questions you may have.

TESTIMONY: HOUSE BILL 1422
SENATE APPROPRIATIONS COMMITTEE

REPRESENTATIVE PRICE, CHAIRMAN

January 24, 2005

Chairman Price and members of the Committee: my name is Carlotta McCleary. I am the Executive Director for the ND Federation of Families for Children's Mental Health (NDFFCMH). The NDFFCMH is a parent run organization that focuses on the needs of children with emotional, behavioral and mental disorders and their families. On behalf of the Federation, I am here to testify in support of House Bill 1422.

According to the Presidents New Freedom Commission on Mental Health, "early detection, assessment, and linkage with treatment and supports can prevent mental health problems from compounding and poor life outcomes from accumulating. Early intervention can have a significant impact on the lives of children and adults who experience mental health problems.

Emerging research indicates that intervening early can interrupt the negative course of some mental illnesses and may, in some cases, lessen long-term disability. New understanding of the brain indicates that early identification and intervention can sharply improve outcomes and that longer periods of abnormal thoughts and behavior have cumulative effects and can limit capacity for recovery"

In a letter to the President, the President's New Freedom Commission on Mental Health wrote" Today's Mental Health system is a patchwork relic—The result of disjointed reforms and policies. Instead of ready access to quality care, the system presents barriers that all too often add to the burden of mental illnesses for individuals, their families, and our communities."

We believe that children and their families should have access to the medication that they need without the barriers.

Thank you for your time.

Carlotta McCleary, Executive Director
ND Federation of Families for Children's Mental Health
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Testimony
House Bill 1422 – Department of Human Services
House Human Services Committee
Representative Clara Sue Price, Chairperson
January 24, 2007

Chairman Price, members of the committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services. I appear before you to provide testimony in opposition of House Bill number 1422.

There is no fiscal note for this bill as the Department has no plans to pursue DUR Board recommendation for prior authorization of any of the drug categories affected by this bill. Even so, the Department is opposed for the following reasons.

First, medications used for mental illnesses accounts for a minimum of 40.7 percent of our drug spend. Four drug classes (see Attachment A) account for the majority of this spend and they are the top four drug classes for ND Medicaid. It takes the next 22 drug classes to account for the same amount of spend as these first four drug classes. It is not possible to manage pharmacy expenditures without the ability to manage the driving factors of those expenditures.

Second, the most vulnerable patients – the aged and / or disabled – transferred to Medicare Part D and are subjected to prior authorization rules for their prescription drugs. Attempts were made when Medicare Part D was enacted to not allow insurance companies (Part D plans) to prior authorize these medication classes; but these attempts failed due to the associated costs. Part D currently requires that these medication

classes be on the formulary, but Part D plans can require prior authorization.

Third, these restrictions on prior authorization can have some significant unintended consequences. For instance, the Code of Federal Regulations requires that state Medicaid agencies will not cover experimental therapy. However, a physician could choose to use Sutent® in combination with Gleevec® for a cancer where there is no proof that the combination would be effective as part of an experimental protocol. This therapy could exceed $100,000 and the Federal government could interpret their regulation to mean that the entire amount would have to be 100 percent state funds with no qualification for Medicaid rebates.

Also, there are times when there is extremely strong evidence favoring the use of one product over another. Please see Attachment B for an example of this with HIV therapy. If this bill passed, the Department could not safely assure that this medication was used appropriately.

Fourth, there has been a large amount of recent evidence proving that many of the mental illness medications are equally effective. For instance, the CATIE trial has shown that older generic medication is as effective as the newer, more expensive medications for schizophrenia. Information from STAR*D continues to provide interesting results regarding the treatment of depression. Also, the previous top antidepressants Prozac®, Paxil®, Celexa®, Zoloft®, Remeron®, Wellbutrin® and others are now available generically, plus they have years of experience of use behind them.

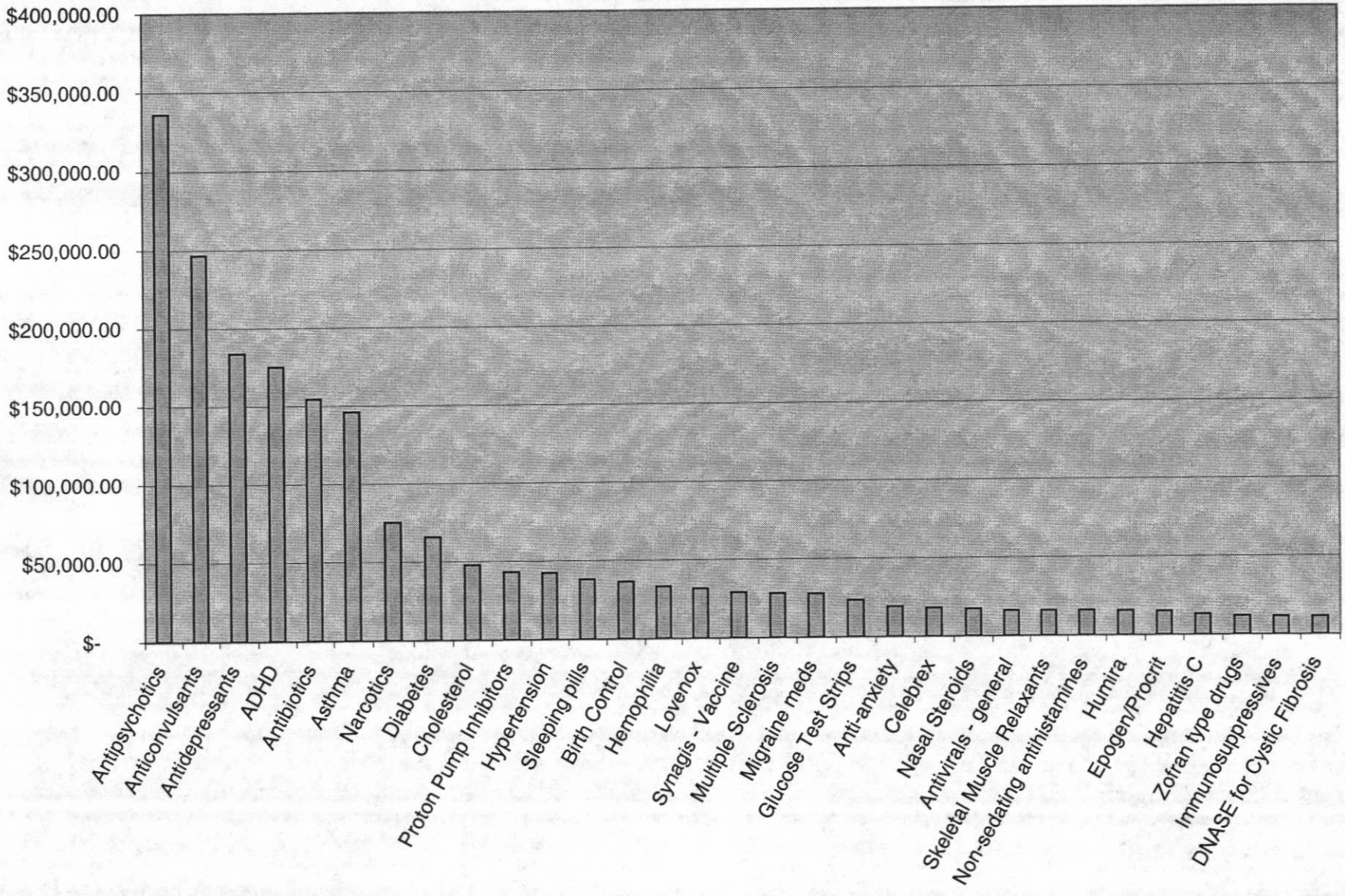
Fifth, a consistent concern is that the Medicaid agency would try to change people who are stabilized on a medication to a different medication. Grandfathering can take care of this concern 100 percent, but we must remember, pharmaceutical companies are continuously trying to migrate patients from one medication to another. Recent examples include Celexa® to Lexapro®, Paxil® to Paxil CR®, and Wellbutrin SR® to Wellbutrin XL®. Future examples include Risperdal® to Invega®. Please see Attachment C for a recent story regarding this issue. Most quotes regarding this practice are found in stockholder meetings and the financial reports from the companies.

Finally, carving out exceptions can be a very slippery slope. There have been attempts in many states to exempt a variety of drug classes and patient classes. We believe the clinicians on the DUR Board are there for a very important purpose and should be trusted to make these types of decisions.

I would be happy to answer any questions the committee would have.

Drug Class Code Description	# of Claims	Amt Paid	% Spend	Cumulative % Spend
Antipsychotics	1,632	$ 336,221.89	14.5%	14.5%
Anticonvulsants	2,524	$ 246,596.94	10.7%	25.2%
Antidepressants	2,785	$ 183,804.50	7.9%	33.1%
ADHD	2,114	$ 175,227.83	7.6%	40.7%
Antibiotics	4,583	$ 154,581.90	6.7%	47.4%
Asthma	2,599	$ 145,945.55	6.3%	53.7%
Narcotics	2,841	$ 75,313.64	3.3%	57.0%
Diabetes	1006	$ 65,835.13	2.8%	59.8%
Cholesterol	630	$ 47,942.32	2.1%	61.9%
Proton Pump Inhibitors	954	$ 43,315.67	1.9%	63.7%
Hypertension	1990	$ 42,475.15	1.8%	65.6%
Sleeping pills	564	$ 38,057.29	1.6%	67.2%
Birth Control	1048	$ 36,433.20	1.6%	68.8%
Hemophilia	4	$ 33,138.34	1.4%	70.2%
Lovenox	33	$ 31,548.18	1.4%	71.6%
Synagis - Vaccine	24	$ 28,908.63	1.2%	72.8%
Multiple Sclerosis	23	$ 28,193.73	1.2%	74.1%
Migraine meds	172	$ 27,755.17	1.2%	75.3%
Glucose Test Strips	275	$ 23,602.84	1.0%	76.3%
Anti-anxiety	1,663	$ 19,186.38	0.8%	77.1%
Celebrex	844	$ 18,204.94	0.8%	77.9%
Nasal Steroids	276	$ 17,361.99	0.8%	78.6%
Antivirals - general	227	$ 16,161.87	0.7%	79.3%
Skeletal Muscle Relaxants	593	$ 16,126.58	0.7%	80.0%
Non-sedating antihistamines	508	$ 15,930.27	0.7%	80.7%
Humira	15	$ 15,641.16	0.7%	81.4%
Epogen/Procrit	12	$ 15,150.13	0.7%	82.1%
Hepatitis C	11	$ 13,120.15	0.6%	82.6%
Zofran type drugs	114	$ 11,860.51	0.5%	83.1%
Immunosuppressives	54	$ 11,625.36	0.5%	83.6%
DNASE for Cystic Fibrosis	17	$ 11,438.64	0.5%	84.1%
Growth Hormones	5	$ 11,388.24	0.5%	84.6%
HIV-AIDS	17	$ 11,328.65	0.5%	85.1%
Antifungal agents	202	$ 10,095.11	0.4%	85.6%
Pulmonary HTN	3	$ 9,911.55	0.4%	86.0%
Detrol & Ditropan	128	$ 9,198.84	0.4%	86.4%
Antiplatelet	86	$ 8,349.43	0.4%	86.7%
Ophthalmic antibiotics	329	$ 7,907.25	0.3%	87.1%
Neulasta and Neupogen	4	$ 7,415.18	0.3%	87.4%
Topical Antibiotics	179	$ 6,663.68	0.3%	87.7%
Bone Resorption Inhibitors	103	$ 6,376.28	0.3%	88.0%
Topical immunosuppresants	63	$ 6,357.05	0.3%	88.2%
Thyroid hormone	532	$ 6,300.49	0.3%	88.5%
Otic anti-inflamatory agents	78	$ 6,153.65	0.3%	88.8%
Exjade	1	$ 6,042.17	0.3%	89.0%
Anticancer	4	$ 6,001.78	0.3%	89.3%
ANTIDIURETIC AND VASOPRESSOR HORMONES	49	$ 5,982.50	0.3%	89.6%
ANTIMETABOLITES	42	$ 5,853.30	0.3%	89.8%
TOPICAL ANTI-INFLAMMATORY STEROIDAL	333	$ 5,778.57	0.2%	90.1%
PANCREATIC ENZYMES	19	$ 5,605.33	0.2%	90.3%
ANTIHISTAMINES - 1ST GENERATION	313	$ 5,333.24	0.2%	90.5%
TRICYCLIC ANTIDEPRESSANTS & REL. NON-SEL. RU-INHIB	373	$ 5,105.43	0.2%	90.8%

Attachment A



ATTACHMENT B

AIDS HEALTHCARE FOUNDATION

January 13, 2006

Mr. David Zentner, Director
Medical Services, DHS
600 E. Boulevard Avenue
Bismark, ND 58505

RE: Implementation of TAR Procedures for HIV Drug Trizivir

Dear Mr. Zentner,

In light of recent clinical trial results, AIDS Healthcare Foundation would like to re-submit our request for treatment authorization request ("TAR") procedures to be placed on Trizivir, a product used to treat HIV/AIDS.

Our original request was based on the interim results from the Adult AIDS Clinical Trial Group (AACTG) 5095 study. The study was a comparison between Trizivir alone, and a four-drug (Trizivir + efavirenz) and a three-drug (Combivir + efavirenz) regimen. It revealed that subjects given Trizivir alone experienced accelerated virologic failure. To minimize the hazardous effects on subjects, these interim results led to discontinuation of the Trizivir-only arm of the trial, as well as a "Notice to Physicians" from the National Institute of Allergy and Infectious Diseases citing the dangers of prescribing Trizivir as a stand alone therapy in treatment naïve patients.

In December 2005, final results for AACTG 5095 revealed still more information regarding patient response to Trizivir, in this case in combination with efavirenz. Dr. Gulick's study revealed no additional benefit from the use of the four-drug regimen (Trizivir + efavirenz) when compared to the three-drug regimen (Combivir + efavirenz). *"After a median of 3 years of follow-up, the 3-drug efavirenz regimen proved similar to the 4-drug efavirenz combination with regard to virologic failure rate, time to virologic failure, CD4+ cell count gains, and frequency of grade 3 or 4 side effects."*

The AACTG 5095 final results underscore the need for TAR procedures to be placed Trizivir, given the drug's ineffectiveness. We continue to be concerned that physicians not expert in HIV medicine may continue to prescribe it to naïve patients, and that such prescriptions will have an adverse fiscal impact on the state.

JAN 24 2006

Medical Services

JAN 22 2007

Medical Services

For the above reasons, AHF, a non-profit organization that provides HIV/AIDS medical services to some 17,000 people in the United States, requests that California place appropriate TAR procedures on Trizivir for ARV naïve patients. By implementing these procedures, you would ensure that treatment naïve patients receive Trizivir only when absolutely medically necessary, and guarantee that better medication regimens are used for the vast majority of patients (thereby increasing health outcomes and maximizing the value of state Medicaid expenditures). At the same time, Trizivir would continue to be readily available for patients already taking HIV/AIDS medications.

Thank you for your attention in this matter. If you have any questions, or require additional information, please do not hesitate to contact my office at 323-860-5200. I look forward to hearing from you.

Sincerely,

Michael Weinstein
President

Cc: Ms. Karin Mongeon, North Dakota State ADAP Director

AIDS HEALTHCARE FOUNDATION

October 21, 2004

Mr. David Zentner
Director
Medical Services, DHS
600 E. Boulevard Avenue
Bismark, ND 58505
(701) 328-1544

RE: Implementation of TAR Procedures for HIV Drug Trizivir

Dear Mr. Zentner,

This is to request that the North Dakota Medicaid program place treatment authorization request procedures ("TAR") on Trizivir, a product of GlaxoSmithKline ("GSK") used to treat HIV/AIDS.

Based on recent tests and studies, AIDS Healthcare Foundation ("AHF"), the nation's largest AIDS treatment organization believes that Trizivir, a fixed dose combination drug containing three separate medications used to treat HIV/AIDS, is not appropriate in most cases for treatment naïve HIV patients. We are concerned that physicians not expert in HIV medicine may continue to prescribe to naïve patients, and that such prescriptions will have an adverse fiscal impact on the state.

We therefore urge that the TAR process be implemented to restrict Trizivir's use for patients who are naïve to ARV therapy.

Trizivir is a fixed dose combination ("FDC") tablet that contains the following HIV/AIDS medications: AZT, 3TC, and abacavir. One of the presumed benefits of Trizivir - taking these three drugs in one pill – is that, because it purportedly lowers the pill burden, there will be better compliance and adherence to a medication regimen. This, the theory goes, will result in increased health outcomes for patients, as well as increased ease of use and treatment by doctors. For these reasons, FDC products have experienced a growth in use and popularity and are now produced in various forms by a number of pharmaceutical companies.

The problem with Trizivir is that, while the individual medications comprising it may be effective in treating HIV/AIDS, the specific

AIDS HEALTHCARE FOUNDATION

combination has been shown to have minimal effectiveness. The National Institutes of Health ("NIH") conducted a study to measure the effectiveness of various AIDS drug combinations, including Trizivir (ACTG 5095). In March of 2003, however, the NIH suspended a portion of its study comparing Trizivir to other regimens.

The NIH study compared treatment naïve patients on Trizivir alone with patients who took a combination of Trizivir and Bristol-Myers Squibb Co.'s ("BMS") Sustiva, or Sustiva and a two-drug tablet called Combivir, also made by GSK. Twice the number of Trizivir-only patients saw their HIV levels climb again within about eight months of starting therapy. According to a Kaiser Daily HIV/AIDS Report on the issue, the researchers stopped one arm of the study because patients taking Trizivir experienced virologic failure - defined as having a viral load level above 200 copies/ml at least four months after beginning the treatment—sooner and more often than patients in the other two arms of the study.

The finding that Trizivir is less effective for treatment naïve patients with HIV/AIDS recently was stated again in a study published in the April 29, 2004 issue of *The New England Journal of Medicine* (Volume 350, Number 18, pages 32-43).

Trizivir's lack of effectiveness renders it unsafe for treatment naïve patients. It is apparent that Trizivir may be effective only if it taken with other HIV/AIDS drugs. However, Trizivir is marketed and used to treat HIV alone. The potential harm to these patients is increased as many are treated by general practitioners who may not be aware of the most recent findings and continue to prescribe Trizivir to treatment naïve patients. This will result in reduced health outcomes for those who take the promise of the FDC to heart and use only Trizivir.

While Trizivir may be effective when taken in combination with other HIV/AIDS medications, the necessity of taking additional medications appears to defeat the purpose and benefit of fixed dose combination therapy – reducing pill burden to increase regimen adherence and compliance. Therefore, the chief benefit of Trizivir is lost.

The end result of the continued presence of Trizivir on the market is confusion, decreased health outcomes, and drug resistance. Given the effectiveness of the three drugs comprising Trizivir, and the existence of numerous other AIDS medications, including other FDC's, the continued use of Trizivir for treatment naïve patients presents a real danger to those people afflicted with HIV/AIDS.

For the above reasons, AHF, a non-profit organization that provides HIV/AIDS medical services to some 12,000 people in the United States, requests that your state place appropriate TAR procedures on Trizivir for ARV naïve patients. By

AIDS HEALTHCARE FOUNDATION

implementing these procedures, you would ensure that treatment naïve patients receive Trizivir only when absolutely medically necessary, and guarantee that better medication regimens are used for the vast majority of patients (thereby increasing health outcomes and maximizing the value of state Medicaid expenditures). At the same time, Trizivir would continue to be readily available for patients already taking HIV/AIDS medications.

Thank you for your attention in this matter. If you have any questions, or require any additional information, please do not hesitate to contact my office at 323 860 5200. I look forward to hearing from you.

Sincerely,

Michael Weinstein
President

Cc: Ms. Karin Mongeon, North Dakota ADAP Director

Print Page

News Report

Final results from ACTG 5095 report no additional benefit from use of 4-drug vs 3-drug efavirenz-based regimen in first-line therapy

December 16, 2005

First-line therapy with abacavir, efavirenz, and fixed-dose zidovudine/lamivudine did not control HIV replication better than the latter 3 drugs alone in a double-blind, placebo-controlled trial. This conclusion was drawn from AIDS Clinical Trials Group (ACTG) study 5095 and reported at the 45th Interscience Conference on Antimicrobial Agents and Chemotherapy in Washington, DC.[1]

In 2003, a review panel stopped 1 of the treatment arms of this trial—a nucleoside-only arm consisting of abacavir/zidovudine/lamivudine—because of inferior virologic response relative to that observed in a pooled analysis of the 2 efavirenz-containing regimens.[2]

After a median of 3 years of follow-up, the 3-drug efavirenz regimen proved similar to the 4-drug efavirenz combination with regard to virologic failure rate, time to virologic failure, CD4+ cell count gains, and frequency of grade 3 or 4 side effects. Black patients had a higher risk of failure than whites or Hispanics, a finding that did not appear to be related to differences in adherence between the 3 groups.

Roy Gulick, MD, of Cornell University, and ACTG colleagues tested the 3 regimens in antiretroviral-naive patients with viral loads ≥ 400 copies/mL and any CD4+ cell count. After the triple-nucleoside regimen was closed, the ACTG team continued to follow 765 patients randomized to either of the 2 efavirenz arms. Participants in these groups began therapy with similar viral loads (averaging 72,444 copies/mL) and CD4+ cell counts (averaging 240 cells/mm^3). Fifty-seven per cent of participants had a viral load < 100,000 copies/mL at baseline.

After a median of 144 weeks of follow-up, Dr. Gulick and colleagues found no difference between the 4-drug regimen and the 3-drug regimen with regard to the trial's primary endpoint—the proportion of patients with a confirmed viral load > 200 copies/mL at study Week 16 or later: 99 (26%) taking efavirenz/zidovudine/lamivudine and 94 (25%) taking efavirenz/abacavir/zidovudine/lamivudine met that failure definition.

Time to virologic failure did not vary between treatment arms, either in the whole study population or after stratification for baseline viral load above or below 100,000 copies/mL. Time to treatment discontinuation and the proportions of study participants who achieved a viral load < 50 or 200 copies/mL also proved similar in the 2 groups. More than 80% of patients in each study arm maintained a viral load < 50 copies/mL throughout follow-up in an intent-to-treat analysis. CD4+ cell counts increased by 250-300 cells/mm^3 with both the 3-drug regimen and

Related Content:

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- Novel NNRTI TMC125 demonstrates efficacy in patients with NNRTI resistance in salvage setting
- Addition of enfuvirtide to a multiclass 4-agent regimen results in faster viral decay in therapy-naive patients
- HCV genotype 3 associated with greater risk of liver enzyme elevations in HIV/HCV-coinfected patients
- Two serum markers identified that correlate with biopsy staging of fibrosis in HCV/HIV-coinfected patients
- TNX-355, a novel HIV attachment inhibitor retains activity in multiclass-experienced patients
- Investigational PI brecanavir (GW640385) demonstrates activity in patients with and without PI resistance
- Four-drug NRTI-only regimens remain under investigation in first-line and salvage therapy settings
- HIV-infected patients appear less likely to reach lipid targets than uninfected counterparts
- Metformin reduces abdominal fat in HIV-lipodystrophy and improves lipid parameters
- Low-dose rifabutin safe with fosamprenavir/ritonavir, but rifampin cannot be coadministered with atazanavir/ritonavir

Of Related Interest

- Dublin: HIV/AIDS Update
- Dublin: HIV/AIDS Update
- Thymidine Analogue Mutations Detected in One Half of Treatment-Naive Patients Experiencing Virologic Failure on Once-Daily 4-NRTI Regimen
- Pilot study shows dual PI regimen appears as safe and effective as 2-class HIV therapy
- Safety and Efficacy of Lopinavir/Ritonavir Plus Saquinavir Similar to Lopinavir/Ritonavir Plus NRTIs in Antiretroviral-Naive Patients at 48 Weeks

the 4-drug regimen.

Multivariate analysis identified 2 factors that predicted virologic failure: Blacks had a 1.67 times higher risk of virologic failure than whites (95% confidence interval: 1.19-2.35; $P = .0003$), and HCV coinfection increased the risk of failure 1.57 times (95% confidence interval: 1.02-2.40; $P = .04$).

Blacks, whites, and Hispanics reported similarly high rates of adherence throughout the follow-up period, with approximately 85% saying they had not missed a dose in the past 4 days, a validated measure of antiretroviral adherence.

Earlier work indicated that blacks have a higher rate of genetic polymorphisms in genes that code for the enzyme which metabolizes efavirenz. Those genetic mutations have been correlated with higher efavirenz levels, which may cause more side effects. In fact, Dr. Gulick reported, blacks in ACTG 5095 did have a significantly shorter time to discontinuation of their assigned regimen and significantly higher rates of grade 3 or 4 side effects than did whites or Hispanics. However, he noted that this hypothesis explaining the higher risk of failure of these efavirenz regimens in black participants in study 5095 remains speculative.

References

1. Gulick R, Ribaudo H, Shikuma C, et al. ACTG 5095: zidovudine/lamivudine/abacavir vs. zidovudine/lamivudine + efavirenz vs. zidovudine/lamivudine/abacavir + efavirenz for initial HIV therapy. Program and abstracts of the 45th Interscience Conference on Antimicrobial Agents and Chemotherapy; December 16-19, 2005; Washington, DC. Abstract H-416a.

2. Gulick RM, Ribaudo HJ, Shikuma CM, et al. Triple-nucleoside regimens versus efavirenz-containing regimens for the initial treatment of HIV-1 infection. N Engl J Med. 2004;350:1850-1861.

ATTACHMENT C

REUTERS

Print this article

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UPDATE 4-FDA OKs J&J's next-generation schizophrenia pill

Wed Dec 20, 2006 4:55 PM ET

(Recasts first sentence, adds interview, analyst comments)

By Julie Steenhuysen

CHICAGO, Dec 20 (Reuters) - U.S. regulators have approved a longer-lasting version of Johnson & Johnson's <JNJ.N> blockbuster schizophrenia drug, Risperdal, the company said on Wednesday.

But while the timing of the approval was as expected, the drug's label included an unexpected warning that it could increase the risk of a potentially fatal heart side effect, raising concerns among investors.

Morgan Stanley analyst Glenn Reicin said the Invega approval should be viewed as a "mixed" event by investors, noting the labeling issues.

Prudential analyst Larry Biegelsen in a research report noted Pfizer's antipsychotic drug, Geodon, carries a similar warning and that "has hampered its uptake." But Biegelsen said the J&J warning was less severe than Pfizer Inc.'s <PFE.N> and said he still believed the drug would be successful.

Invega is designed to deliver paliperidone -- the active ingredient in Risperdal -- through a technology that allows the drug to remain in the body over a longer period of time.

Analysts said J&J is hoping to switch a large portion of Risperdal sales to Invega in advance of Risperdal's patent expiration in 2008.

But the drug's label notes a modest increased risk of QT prolongation, a disorder of the heart's electrical system that could lead to life-threatening form of ventricular tachycardia in which the heart is unable to pump blood throughout the body.

"With the exception of Geodon, it does not appear that this QT prolongation warning is present in other similar drugs," Morgan Stanley's Reicin said.

"We continue to believe that Invega will not be viewed as a best-in-class drug since it is relatively undifferentiated from current products and the label warning on the risk of QT prolongation might be used as a marking weapon by competitors," Reicin said.

'APPLES TO ORANGES'

Janssen president Janet Vergis, in an interview, said she does not believe the labeling will present a major hindrance to the drug's acceptance.

She said the drug is the first antipsychotic to be approved since the FDA issued new guidelines in 2005 for a specific type of QT study for all new drug approvals.

"The warnings are very different," added Dr. Mary Kujawa, senior director for Janssen's medical affairs, referring to the Pfizer product.

"The Geodon warning was with prior criteria and considerations. What we are talking about with Invega is the new standard for the FDA. It's like comparing apples to oranges."

Vergis said Invega is the first drug for schizophrenia to include information in its label about improvements in a patient's personal and social functioning, which are key issues for these patients and their families.

Schizophrenia is a chronic, disabling mental disorder that affects more than 2 million Americans. Symptoms include hallucinations, delusions, disordered thinking, movement disorders, social withdrawal and cognitive deficits.

Invega is part of a class of drugs known as atypical antipsychotics, which are associated with weight gain and an increased risk of diabetes. Introduced in the 1990s, the drugs now account for some $10 billion in U.S. sales.

Wall Street analysts have said Invega was key to J&J's drug portfolio.

JP Morgan analyst Michael Weinstein said the approval gives J&J 18 months to market the drug before the start of generic competition for Risperdal. In a note to clients, Weinstein forecast Invega sales of $488 million in 2007, growing to $1.78 billion by 2009.

New Brunswick, New Jersey-based J&J will market Invega in the United States through its Janssen LP unit.

The company studied the drug in more than 1,600 patients in 23 countries. Invega improved symptoms compared with placebo in all doses studied. Side effects included restlessness, movement disorders, rapid heart beat and sleepiness.

The FDA said the drugs have an increased rate of death compared with placebo in elderly patients with dementia-related psychosis. The drug is not approved for dementia-related psychosis.

Invega has not undergone rigorous study for longer than six weeks and the FDA recommends that patients who use the drug for extended periods be checked periodically by their doctors.

J&J shares fell 45 cents, or less than 1 percent, to close at $66.43 Wednesday on the New York Stock Exchange. (Additional reporting by Toni Clarke in Boston)

Close This Window

Attachment # 1

Limiting Medicaid Patients' Access to Mental Health Medications Is Not Fiscally Responsible

More than half of mental illness specialty care programs surveyed found that **prior authorization barriers** and denials of drug coverage **caused problems** for patients, including hospitalization, missed dosages and increased side effects.

International Patient Advocacy Association
1999 Study by the Michigan Mental Health Association and the Michigan Psychiatric Society

Every $1.00 invested in mental health early treatment and prevention programs yields a savings of $2.00 to $10.00, thus highlighting the fact that investment lowers healthcare costs. Conversely, **cutting access to the proper medication and services increases overall costs.**

National Mental Health Association
"Labor Day 2001 Report – Untreated and Mistreated Mental Illness and Substance Abuse Costs U.S. $113 Billion a Year"

In the case of treating depression, **only 30% of patients respond to the first anti-depressant prescribed** to them, and 70% may eventually require a change in medications.

Kaiser Commission on Medicaid and the Uninsured
"Case Study: Michigan's Medicaid Prescription Drug Benefit"

Medications comprise only 3% of costs for mental illnesses, and some experts contend that they may be responsible for more than 50% of positive treatment outcomes.

National Mental Health Association
NMHA Policy Positions on Restrictive Formularies

Attachment #2

Testimony before the
Senate Human Services Committee
House Bill 1422

February 26, 2007

The practice of psychiatry is both very challenging and exciting. We are able to successfully treat people with severe disorders such as schizophrenia and the most severe depression and bipolar disorders, as well as many other psychiatric illnesses. The use of medications for these disorders has advanced greatly in the past 40 or 50 years, and even more dramatic results became available as we moved into the newer generation of antipsychotics, antidepressants, and anti-epileptics (used as mood stabilizers).

Mentally ill patients, formerly warehoused in the State Hospital with no hope of improvement, have been given hope. Schizophrenic patients treated with some of the newer antipsychotics are now sometimes able to complete their education and/or hold down full time jobs with benefits. For some a more realistic goal is for them to have a better life with their family, avoid hospitalizations for the condition, and to be less tormented with voices, delusions and mood swings.

These patients do best if their mood disorder is treated until they are in full remission. If not, they are more prone to a relapse of their condition. The more they relapse the more treatment resistant they become, and the more likely they are to continue relapsing. Conversely, the longer they stay healthy or are in remission, the more likely they are to remain safe and productive.
If we are required to go through a step-wise progression of drug treatment, starting with the lower-priced medications, only to have the patient relapse before we can go to another medication, we may be causing increased illness and morbidity and much more suffering and expense in the long run. If I can do what I determine to be the best treatment for the patient at the outset of their care, I have an increased likelihood of success and decreased likelihood of making their illness worse. It was for these reasons that numerous other states, as well as the ND Legislature in 2005, wisely protected the fragile treatment process for these mentally ill Medicaid patients by preserving the psychiatrists' ability to utilize the drugs that they determine are necessary to achieve the most beneficial treatment of these patients. NDCC 50-24.6-04 has allowed this patient-physician relationship to remain intact, and should remain in the statute.

Some of the benefits and cost savings of having the needed drugs available to treat those patients who are mentally ill are:

- Decrease in the utilization of other medical services;
- Decrease in the number of emergency room visits and hospitalizations;
- Often a decrease in severity or even existence of co-morbid illnesses and physical pain;
- Decrease in death through suicide or inadvertent death through associated problems; and
- Increase in the patients' productivity and quality of life.

Some patients need multiple medications to get the best results. The best results, I believe, are attained when an experienced physician can take into account the multiple variables and then determine the best treatment for that patient at that time. Some of the variables include: the diagnosis, which we must recognize is not usually black and white, with many variations, shades and blending of diagnoses that can make a difference in what treatment is chosen; co-morbid conditions; family history; the patient's preconceived ideas about their illness or certain treatments; compliance issues; the psychological dynamics going on between patient, treating professional, family and others, and many more. With some patients, it may take months and even years to find the right combination to keep them out of the hospital and decrease their suffering, and in some cases get them back to work. This is often done with multiple medications, carefully combined, often along with some psychotherapy, and always taking into account their other co-morbid illnesses and medications.

The bottom line is that psychiatric treatment is a complex process, and to get the best results the practitioner, always acting as the patient's advocate, must be able to choose the best treatment medication for the situation, to quickly make necessary adjustments, and not have roadblocks preventing that sensitive response. House Bill 1422 preserves our ability to respond to Medicaid patients' complex mental health treatment needs, and in doing so will continue to minimize further treatment costs to the state of North Dakota.

We respectfully request the support of the Committee for passage of HB 1422.

Attachment #3

Testimony before the Senate Human Services Committee House Bill 1422

February 26, 2007

Chairperson Lee and Senators of the Committee:

Thank you for the opportunity to present my written testimony. I would prefer to be there in person. Unfortunately I don't have enough heads for the number of hats I'm wearing these days.

I have been treating individuals with serious and persistent mental illness for over 20 years. The issue of prior authorization and other practices of managing prescription costs is based on cost-benefit ratios. And I could communicate for some time on the fact that cost-benefit is not simply dollars and cents, but also a quality of life issue, however I will leave that up to others. The up front cost of psychotropic medication is quite high. There is ample evidence however, that limiting access to medications results in increased visits to emergency rooms, primary care physicians, and mental health clinics, all adding substantially to the costs of caring for the patient. Individual interactions between doctors and their patients, (and not pharmacy benefit management averages) allows for the right medication getting to the right person at the right time. This is the most cost effective interaction. It is also the art of medicine.

If this were simply a question of generic equivalents there would be no issue. In almost all cases I support using generic equivalents over brand name drugs. However, many of the brand medications have similar, but not generic, equivalents. For instance, some will argue that a pharmaceutical company has developed a "me too" medication that is similar to what is currently on the market generically. It might be an extended release version, a metabolite version, or a racemic isomer (mirror image) version. To give an example, there is a substance called carvone. One mirror image version gives the flavor of caraway. The other *exact mirror image* gives the flavor of spearmint. This occurs even though it is an exact mirror image compound. "Similar to" is not the same as "generic equivalent," and "similar to" is often not adequate for our patients.

For some of the major mental illnesses, such as schizophrenia and bipolar affective disorder, the suicide rate for inadequately treated individuals is as high as 10%. Insight into need for treatment and issues of compliance are major concerns. A patient with schizophrenia who has trouble remembering his daily dose, should be able to get, without barriers, an extended release brand medication. A patient with bipolar affective disorder should not have to first try a generic that is only "close enough" to what the prescriber knows is in their best interest. The illnesses themselves are enough of a barrier to adequate treatment. Let's not compound these barriers. The current system we have is a good one, working well. I would ask that you continue to allow psychotropic medications to have exemption from prior authorization and other barriers to access.

Respectfully submitted, Andrew McLean, MD, Psychiatrist

Attachment #4

MENTAL HEALTH ASSOCIATION IN NORTH DAKOTA

Works for a world free from discrimination against mental illness

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PSYCHOSOCIAL REHABILITATION CENTERS

MYRT ARMSTRONG CENTER
1419 1st Avenue South
Fargo, ND 58103
Phone: 701-293-7716
Fax: 701-293-7716

MOUNTAINBROOKE CENTER
North 3rd Street
Forks, ND 58201
Phone: 701-746-4530
Fax: 701-775-8645

United Way

North Dakota 2-1-1 Get Connected. Get Answers.

Visit our website at **www.mhand.org**

A private, non-profit 501(c) 3 agency. The only non-governmental organization concerned with all aspects of mental health for all citizens of North Dakota.

Testimony
Mental Health Association in North Dakota

HB1422 - Relating the Medicaid Drug Prior Authorization Program

Senate Human Services Committee
Senator Lee, Chairman

February 26, 2007

Chairman Lee and members of the Senate Human Services Committee, My name is Susan Rae Helgeland, the Executive Director of the Mental Health Association in North Dakota. I am here to testify in support of HB1422.

The Mental Health Association in North Dakota is a nonprofit organization whose mission is to promote mental health through education, advocacy, understanding and access to quality care for all individuals.

I come before your committee to speak in behalf of those individuals with mental illness in our communities that must rely on the Medicaid program for their health care needs.

Over the last decade, science has significantly advanced the understanding and treatment of mental illness. Thanks to the development of new medications, people with mental disorders can lead full and productive lives

The Mental Health Association in North Dakota believes that mental health drugs should continue to be exempt from the prior authorization program of the Drug Utilization Review board as they have been since 2005.

Unlike medications for other illnesses, medications used to treat mental illness cannot be used interchangeably because each medication has a different mechanism of action and affects each person's brain in a different way. It can take between six and twelve weeks to determine if a medication works for a particular individual. There are no laboratory tests to determine if mental drugs are effective. Only physicians working closely with their patients can make that determination. Physicians must take into consideration such things as patient history, race and ethnicity, co-occurring disorders, and treatment goals when prescribing medication for mental illness.

Studies have shown that restricting access to medications for mental illness to achieve cost containment often has the opposite outcome due to increased state expenditures for costly hospitalization, emergency room and/or physician clinic visits. The Kaiser Commission on Medicaid and the Uninsured recommends that "all psychotherapeutic, anti-viral, and anti-convulsive medications" be exempt from restrictions. Under the guidelines of the prior authorization program in North Dakota, a patient must fail first on approved medication before permission can be obtained to use unapproved drugs. Requiring prior authorization for mental health medications delays proper care, creates more time spent suffering and increases the risk of a history of negative outcomes, including suicide.

On behalf of the Mental Health Association in North Dakota and North Dakotans with mental illness, I request that your committee give this bill a do pass recommendation.

The North Dakota Mental Health Planning Council also supports this bill.

Madam Chairman, I will be glad to answer any questions. If the committee needs more information on this matter or others, please feel free to contact me.

Attachment # 5

National Mental Health Association

Issue Brief Series: Access to Medications

Issue Brief # 2:

State Policy Mechanisms That Restrict Access to Care

"While various forms of drug limitation may save the government money in the short term, the accumulated costs to patients and taxpayers over time can be high. Serious costs result from potentially ineffective treatment, treatment delay, the inevitable worsening of mistreated medical conditions and repeated visits to doctors or medical specialists."[1]

Introduction

It is no secret that states face ongoing revenue shortfalls, increasing Medicaid budgets and rising prescription drug costs. Long-term care costs remain the program's most expensive budget line items, but medication costs are continuing to grow at a faster pace than others. Many states are seeking ways to contain prescription drug costs to help reduce their budget shortfalls.

Among the strategies states are employing to reduce drug costs are supplemental rebates, drug importation and even price controls. The overarching problem is that the *entire* healthcare industry—not merely the pharmaceutical sector—is profit-driven. Any discussion of pharmaceutical pricing must be viewed within this context. Managing pharmaceuticals costs as isolated spending components, an approach often followed European models, fails to address valid systemic issues and may jeopardize both people who need prescription drugs and state budgets.[2]

States are implementing these dramatic changes in the form of policies quickly and often without obtaining significant input from the people who are affected by them. Federal regulation requires pharmaceutical companies to offer the "best price" for all products the states distribute through their Medicaid programs and to offer rebates to further reduce the programs' drug costs. Increasing numbers of states are also negotiating supplemental rebates and employing other mechanisms to reduce the prices they pay for medications, by, for example, requiring doctors or patients to secure "prior authorization" (this term is defined in the next section of this document). to obtain medications made by pharmaceutical companies that refuse to offer these additional rebates. They are, in effect, using Medicaid beneficiaries as a bargaining tool in these negotiations. Although NMHA supports state efforts to negotiate cheaper prices for prescription drugs, the association is seriously concerned that through such policies, the states have crossed the line by interfering with medical practices that affect patient health and are forcing Medicaid beneficiaries to pay the price by restricting their access to lifesaving therapies.

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[1] Hunter, D. (2003). Government Controls on Access to Drugs and What Seniors Can Learn from Medicaid Drug Policies. *The Heritage Foundation Backgrounder*, No. 1655. Available: www.heritage.org/research/healthcare/bg1655.cfm.

[2] Towse, A. (May/June 2003). The Efficient Use of Pharmaceuticals: Does Europe Have Any Lessons for a Medicare Drug Benefit? *Health Affairs*, Vol. 22, No. 3, pp. 42-45.

Forty-one states have instituted or plan to institute preferred drug lists that require prior authorization for non-preferred medications and many have used other techniques to reduce drug costs.

State Strategies That Restrict Access

In the early 1990s, states used drug formularies—lists of medications they devised—to limit Medicaid beneficiaries' access to medications. Many of these formularies contained only one or two mental health medications and rarely did they include the newest or most effective drugs available. In 1992, federal guidelines made it illegal for states to impose such "closed formularies," requiring Medicaid programs to make available all Federal Drug Administration (FDA) approved medications to enrollees.[3]

Formularies are now called preferred drug lists (PDLs), but the term's definition remains unchanged; a PDL is a list of medications that consumers can access. A physician who wishes to prescribe medications that do not appear on the PDL (or formulary) must obtain ***prior authorization*** from the Medicaid agency (or its subcontractor) to allow the patient to obtain the drug medications through the Medicaid program. As a rule, a Pharmacy and Therapeutics Committee (P&T) or another workgroup is responsible for developing the list of approved medications. Theoretically, Medicaid consumers have access to all FDA-approved medications, but in practice, program administrators can make it difficult for people to enjoy so broad a choice of drugs. The provider must prove that the medications in the PDL aren't effective or have side effects to justify their request for a non-PDL-listed drug.

The prior authorization requirements are intended to make it more difficult for Medicaid beneficiaries to access certain (more expensive) medications and to change the behavior of the prescribing physician by making it time-consuming for them to prescribe medications that are not listed in the PDL. Many health providers, for example, simply do not have staffing capacity to complete the prior authorization forms and make all of the necessary phone calls to ensure that a consumer gets the medications he or she needs. Unfortunately, as a result, patients may get a less effective medication or none at all and the providers may waste time that they could otherwise have used improving their patients' health.

If a state does institute a prior authorization process, a 24-hour-a-day, 7-day-a-week call center must be established and function at full capacity before the prior authorization process can be implemented. In addition, further protocols for approving prior authorization requests must be established. The Kaiser Foundation on Medicaid and the Uninsured suggests three criteria Medicaid programs could adopt as automatic justification for approval of a prior authorization request:

1. Patient allergy.
2. Patient has been stabilized on a name brand medication and a switch to a generic is unadvisable.
3. Prescription is for a name-brand medication and consumer developed side effects while taking the generic alternative.[4]

Fail First or "Step Therapy"

Some states require that people "fail" to respond favorably to a medication, sometimes more than once, before they can access "non-preferred" medications (those that do not appear on the PDL). This type of policy does not take into account consumers' individual needs and can put their health at risk. This type

[3] 42 U. S. C. § 1396r-8 (d)(4).

[4] Somers, S., Perkins, J., and the National Health Law Program, Inc. (April 2003). Model Prescription Drug Prior Authorization Process for State Medicaid Programs. Kaiser Commission on Medicaid and the Uninsured. Available: www.kff.org.

of policy is dangerous and fiscally unwise when applied to a person whose condition has stabilized through adherence to an already prescribed medication regimen. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who don't and their treatment typically costs about 50 percent more than it would have if they'd been allowed to continue taking a medication that has already been deemed appropriate.[5] In addition, identifying an effective medication therapy for people who have mental health disorders can be challenging and, frequently, it simply does not make sense to change an already successful form of treatment.

In some states, consumers will be asked to substitute a medication from a specific class to another within that class. In the treatment of some diseases, variation in the effects—or effectiveness—of two or more drugs within a certain class may be nominal, making such substitutions a relatively straightforward and risk-free process. But it is not advisable to assume that all or most mental health medications within a particular class, or those that are used to treat many other chronic diseases, are similar enough to submit one for another. The choice of which medication to prescribe to treat mental disorders—even within a single therapeutic class—is based heavily on each consumer's individual condition and other potentially unique factors.[6] It's also important to keep in mind that people who use mental health medications must wean themselves from them slowly or risk developing major side effects or health risks, which makes any decision to switch abruptly from a name-brand drug to a generic alternative, potentially dangerous.

When treating people who are seeking treatment for the first time, providers may find that some guidance on both the variation in medications and previous consumer responses will help improve patient health and outcomes. However, the choice of medications must remain with the provider and consumer, so that they can identify the therapy that takes into account the consumer's specific needs.

Prescription Limits

States have also attempted to restrain budget costs by limiting the total number of prescriptions a person can receive each month. As of fall 2003, at least 14 states had put in place a monthly prescription limit ranging from three to 10 per month. But research studies indicate that any program that permits fewer than six medications per month seriously risks patient health.[7]

States attempted to initiate this strategy during the 1990s, but moved away from it as evidence mounted demonstrating the harm it could inflict on patients. A series of such incidents culminated with a Mississippi-based patient's death from pneumonia in 1999. The man, who had a severe mental illness, could not afford to fill a $45 prescription for antibiotics he'd been prescribed because he had reached the Medicaid program's five-prescription limit. Just days later, he was admitted to a local hospital for pneumonia and died. The hospital costs associated with his end-of-life care were approximately $4,500.

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[5] Hensley, PL and Nurnberg, H. G. (2001). Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls. *Pharmacoeconomics*, Vol. 19, No. 10, pp. 973-982.

[6] Huskamp, 2003.

[7] Harrington, C., Scallet, L., Goplerud, E., Robinson, G.K, Gregorian, R.S., Hughes, C., Treciak, K. (1998). Health Plan Benefit Barriers to Access to Pharmaceutical Therapies for Behavioral Health. SAMHSA Managed Care Tracking System. Prepared by the Lewin Group.

Increased Copayments

Over the past two years, 32 states have increased copayments for people who are enrolled in state Medicaid programs. Federal rules currently limit to $3 or 5 percent of the amount the state paid for the service. Children and pregnant woman are exempt from any co-payments under the Medicaid program.[8]

NMHA supports the existing limits and has grave concerns about state efforts to increase Medicaid consumers' cost-sharing requirements. Unlike people who have private health insurance, Medicaid enrollees live at or below the federal poverty level. In 2003, the Federal Poverty Level was $18,400 for a family of four for every state except Alaska and Hawaii.[9] Many people with disabilities qualify for Medicaid because they receive Social Security Income (SSI), and may need multiple medications. If their expenditures increase by even a few dollars each month, these people may find themselves forced to choose between buying food and medications.

Recent literature reviews have revealed that cost-sharing requirements decrease access to services in general, especially among those who are impoverished. Cost-sharing requirements for prescription drugs, even at the most nominal levels, have been found to jeopardize the ability of people who are living in poverty to afford the medications they need. Those who were most ill and most impoverished were the least likely to fill prescriptions that required them to make. Finally, these studies revealed that in states whose programs required copayments, patients had worse health outcomes than those in states that had not instituted cost-sharing requirements.[10]

Evolution of Policies

To date, 41 states have passed laws or set regulations that establish preferred drug lists and all 50 states and the District of Columbia have implemented cost-containment strategies in their prescription drug programs. These policies have continued to evolve over time as fiscal conditions continue to worsen. Four main "evolutions" of medications policy are discussed below: exemptions, the singling out of medications for prior authorization, prohibition of off-label use and pill splitting.

Exemptions

In its discussion of model prior authorization programs, the Kaiser Family Foundation recommends that certain medications be exempt from prior authorization requirements. These include:

1. All psychotherapeutic, anti-viral and anti-convulsive medications.
2. All name brand drugs with narrow therapeutic indices.
3. All name brand drugs for which side effects have been linked to use of the generic equivalent.
4. All drugs administered in connection with organ transplants.[11]

Research demonstrates the importance of granting full access to mental health medications and makes a strong case for exempting mental health medications from prior authorization requirements, prescription

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[8] Hudman, J. and O'Malley, M. (2003). Health Insurance Premiums and Cost-Sharing: Findings from the Research on Low-Income Populations. Kaiser Commission on Medicaid and the Uninsured. Available: http://www.kff.org/content/2003/4071/4071.pdf

[9] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. (2003). *THE 2003 HHS POVERTY GUIDELINES.* Available: http://aspe.hhs.gov/poverty/03poverty.htm.

[10] Hudman and O'Malley, 2003.

[11] Somers and Perkins, 2003.

limits or charged to people who have mental health disorders. Currently, more than half of the states have introduced some sort of exemption for mental health medications.

Unfortunately, policies that exempt one disorder but not others do not reflect the fact that people who have mental health disorders often have other serious conditions, such as heart disease, as well. There is also significant variation in the types of exemptions Medicaid programs grant for drugs that are used to treat mental health disorders. The Kaiser Commission on Medicaid and the Uninsured recommends that **"all psychotherapeutic, anti-viral and anti-convulsive medications" be exempt**, but many states only exempt atypical antipsychotic medications or medications that are used to treat specific disorders. Other states have broad exemptions, but apply them only in the fee-for-service market, not in managed care programs.

High rates of co-morbidity also underscore the danger of exempting mental health medications from restrictive access policies. A1996 study of the impact of restricting access to medications in managed care found that more than 30 percent of the people studied had both physical and mental health conditions.[12] The National Institute of Mental Health reports that approximately one in three people who have survived a heart attack also developed major depression in a given year and that people with diabetes are nearly twice as likely as those who don't have this condition to develop depression.[13]

Unfortunately, many of these exemptions appear to be at risk as states revisit ways to hold down prescription drug benefit costs. As a result, exemptions appear to be only a temporary solution. States must identify other strategies to protect the health of Medicaid consumers while continuing to manage program costs.

Singling out Medications for Prior Authorization

States are also choosing to single out individual medications, or all new medications, for prior authorization. This creates several challenges. First, a state can no longer claim to exempt a class of medications from prior authorization if it has selected a medication from that class for prior authorization. Second, research indicates that patients who have access to new medications and new medical technology tend to have improved health outcomes and less need for expensive care.[14] States that establish policies that single out new medications are denying Medicaid beneficiaries access to potentially life-changing medications.

Off-Label Use of Medications

Although the FDA approves medications for the treatment of specific medical conditions, some have been found to confer other, unrelated therapeutic benefits. For example, some anti-depressants have been found to be effective in treating migraine headaches and anxiety disorders and anticonvulsants have been

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[12] Horn, S. (pending December 2003). Unintended Costs and Outcomes: The Fiscal Case for Open Access. *Drug Benefit Trends*, Vol. 15, Supplement 1.

[13] National Institute of Mental Health (2002). Depression and Heart Disease. National Institutes of Health, National Institute of Mental Health, Publication No. 02-5004. Available: http://www.nimh.nih.gov/publicat/depheart.cfm#sup1. National Institute of Mental Health (2002). Depression and Diabetes. National Institutes of Health, National Institute of Mental Health, Publication No. 02-5003. Available: http://www.nimh.nih.gov/publicat/depdiabetes.cfm

[14] Lichtenberg, 2003. Cullen and McCullen, 2001.

successfully in treating people with mental illnesses.[15] This "off-label" use is fairly common, although practitioners tend to prescribe medications for off-label use only when research has verified their effectiveness in treating conditions for which they were not originally developed. This practice is particularly common in the treatment of children, because few drugs are developed specifically for them and children are rarely included in clinical trials.

A few states have considered prohibiting off-label use of medications as another way to restrict access to medications and contain costs. Unfortunately, this prohibition only harms people who could benefit from these therapies and does not address any concerns regarding the *appropriate* use of such medications.

Pill-Splitting

A few states and the Veterans Administration have established administrative policies to encourage or require pharmacists to prescribe medications that are provided in pills that have large doses of the active ingredients and to instruct the consumer to split the pills by hand. Because some states pay the same amount for pills that contain more of the prescribed medication as they pay for those that contain less per pill, pill splitting allows them to purchase more medication for the same price. But pill splitting is often imprecisely conducted and can put and people who need to maintain stable medication levels at risk. Research shows that, 40 percent of pill-splitting-based administration of drugs caused a deviation in appropriate dosing levels of at least 10 percent.[16] It's also worth noting that people with disabilities and older consumers may find it difficult to split the pills. States may endanger the health of Medicaid consumers by insisting on pill-splitting to reduce costs.

Conclusion

In the face of budget shortfalls, states are pressing for a variety of strategies to reduce Medicaid prescription drug expenditures. In creating preferred drug lists, instituting prescription limits and establishing stricter prior authorization mechanisms, they are attempting to reduce the use of medications to save money. But, research shows that these strategies can harm consumers and may simply shift costs to other areas in the Medicaid budget (e.g., inpatient hospitals, emergency rooms) and to other types of state expenditure (e.g., the cost of increased prison incarceration rates). Even states that have established these policies continue to seek additional cost-cutting strategies because previous strategies have not worked. Medicaid rules require that the placement of any limitation on access to medications be "in the best interests of the recipients."[17] Ultimately, all of these efforts to cut costs are dangerous if they put cost containment ahead of patient health.

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[15] Casey, D. (March 2003). Use of Anticonvulsants as Augmenting Agents in Psychosis. *Journal of Clinical Psychiatry*, Vol. 5, No. 3. Available: http://www.psychiatrist.com/visuals/vis2003-03/visuals.pdf. Stone, K., Viera, A., and Parman, C. (August 2003). Off-Label Applications for SSRIs. *Practical Therapeutics*, Vol. 68, No. 3. American Family Physician. Available: www.aafp.org/afp.

[16] McDevitt JT, Gurst AH, Chen Y. (1998). Accuracy of Tablet Splitting. *Pharmacotherapy*, Vol. 18, No. 1, pp. 193-197.

[17] 42 U.S.C. § 1396a (a) (19)

#6

TESTIMONY: HOUSE BILL 1422
SENATE HUMAN SERVICES COMMITTEE
JUDY LEE, CHAIRMAN

February 26. 2007

Chairman Lee and members of the Committee: my name is Carlotta McCleary. I am the Executive Director for the ND Federation of Families for Children's Mental Health (NDFFCMH). The NDFFCMH is a parent run organization that focuses on the needs of children with emotional, behavioral and mental disorders and their families. On behalf of the Federation, I am testifying in support of House Bill 1422.

According to the Presidents New Freedom Commission on Mental Health, "early detection, assessment, and linkage with treatment and supports can prevent mental health problems from compounding and poor life outcomes from accumulating. Early intervention can have a significant impact on the lives of children and adults who experience mental health problems.

Emerging research indicates that intervening early can interrupt the negative course of some mental illnesses and may, in some cases, lessen long-term disability. New understanding of the brain indicates that early identification and intervention can sharply improve outcomes and that longer periods of abnormal thoughts and behavior have cumulative effects and can limit capacity for recovery"

In a letter to the President, the President's New Freedom Commission on Mental Health wrote" Today's Mental Health system is a patchwork relic—The result of disjointed reforms and policies. Instead of ready access to quality care, the system presents barriers that all too often add to the burden of mental illnesses for individuals, their families, and our communities."

I am going to share our family's personal story. My son Garrett has been diagnosed with an emotional disorder since he was four years old. We took Garrett to the University of Minnesota due to Garrett's complex medical needs along with his severe mental health needs. They have termed it neuro - psychiatrically fragile.

At one point Garrett's condition deteriorated and we desperately needed to find the right combination of medication. Garrett became very depressed and suicidal. The doctors discussed the possibility of placing Garrett in a residential facility in Minnesota or a residential facility in Wisconsin. They felt both facilities would be able to meet the complex medical needs as well as handle his extreme aggressiveness.

Garrett woke up one morning from a horrible nightmare. His body was visibly shaking and he was sobbing. He shared his dream with me. He said it was the very worst dream he had ever had. He had a dream that our entire family had taken a trip. We had gone to this place but when it was time to leave, my husband and I along with Matthew and Katie left without taking Garrett with us. He had to live in this new place without his family. I

comforted him and told him it was a bad dream. Even though I knew that dream was a very real possibility.

That very morning we were in a hotel room in Minneapolis preparing to go to his doctor's appointment. This was the morning the doctors were going to admit Garrett to the University of Minnesota's Psychiatric Hospital to stabilize him on medication.

Happily, they didn't have a hospital bed available and didn't want his medication decisions in someone else's hands due to the complex nature of his illness. We were able to take him home with medications and the new treatment worked. Garrett's doctors stressed the need for Garrett to be on brand necessary medications. They consulted with the doctors on staff at the pharmaceutical companies regarding Garrett's treatment.

Last year Medicaid denied one of Garrett's prescriptions. It was an off label use medication for his behavior. We were told that he needed to get the generic. We told the pharmacist that Garrett's doctors wanted him to take the brand name for safety reasons due to Garrett's condition. They loaned us five days of medication. We called Garrett's doctor and he got in touch with Medicaid. On a Friday afternoon our five days of pills had run out. We had been in contact with the pharmacy and Garrett's doctor and still Medicaid denied his claim. We had a call into Medicaid but the call had not been returned. We were faced with the decision of giving him the generic medication or wait until Monday. Garrett couldn't be without his medication even for a few hours. We were scared to death. We gave him the medication and thankfully he did fine.

Kids need to have access to the medications the doctors prescribe. I don't believe Medicaid or the pharmacy understands my son's medical situation better than the team of doctors at the University of Minnesota. They didn't understand how medication could have done more damage to my son neurologically.

Our trips to Minneapolis are expensive. We have to take our other children out of school because we don't have family living in the area. My husband and I are taking vacation time for these trips as well. Going back to the doctor because of medication not being approved is a hardship for our family. Not to mention the expensive doctor bills.

Garrett doesn't have the luxury of failing on his medication. When he isn't stable he will be hospitalized and may need residential treatment. This is too high of a cost for Garrett and our family.

NDFFCMH believe that children and their families should have access to the medication that they need without the barriers. Thank you for your time.

Carlotta McCleary, Executive Director
ND Federation of Families for Children's Mental Health
Phone/Fax: (701) 222-3310
Email: carlottamccleary@bis.midco.net

Attachment # 8

Testimony
House Bill 1422 – Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairperson
February 26, 2007

Chairman Lee, members of the committee, I am Maggie Anderson, Director of the Division of Medical Services for the Department of Human Services. I appear before you to provide testimony in opposition of House Bill number 1422.

There is no fiscal note for this bill as the Department has no plans to pursue DUR Board recommendation for prior authorization of any of the drug categories affected by this bill. Even so, the Department is opposed for the following reasons.

Medications used for mental illness accounts for a minimum of 40.7 percent of our drug spend. Four drug classes (see Attachment A) account for the majority of this spend and they are the top four drug classes for ND Medicaid. It takes the next 22 drug classes to account for the same amount of spend as these first four drug classes. It is not possible to manage pharmacy expenditures without the ability to manage the driving factors of those expenditures.

The most vulnerable patients – the aged and / or disabled – transferred to Medicare Part D and are subjected to prior authorization rules for their prescription drugs. Attempts were made when Medicare Part D was enacted to not allow insurance companies (Part D plans) to prior authorize these medication classes; but these attempts failed due to the

associated costs. Part D currently requires that these medication classes be on the formulary, but Part D plans can require prior authorization.

If the Legislature wishes to restrict the ability for prior authorization for these indications, we do ask that some clarity be brought into the bill. Which specific diagnoses are affected? Can other management strategies be used? Is the state to use 100 percent state funds when the physician's desired use is deemed experimental (cancer)?

Finally, carving out exceptions can be a very slippery slope. There have been attempts in many states to exempt a variety of drug classes and patient classes. We believe the physicians and pharmacists on the DUR Board are there for a very important purpose and should be trusted to make these types of decisions, just as many of these same physicians and pharmacists are trusted to make the decision in the private sector.

I would be happy to answer any questions the committee would have.

#9

BLUE CROSS BLUE SHIELD OF NORTH DAKOTA FORMULARY

January 2007

BlueCross BlueShield of North Dakota
An independent licensee of the Blue Cross & Blue Shield Association

TO INSURED

Your benefits are not limited to the drugs on this formulary list. However, choosing formulary drugs is one way to help control health care costs. The more often our members and their physicians choose formulary drugs, the more cost savings generated. This helps keep your premium rates affordable.
Thank you.

TO PHYSICIAN

This list represents the drugs included on our formulary. A committee of independent physicians and pharmacists has reviewed the products available in each class and selected them for formulary inclusion based on safety, efficacy, side effects, ease of use, potential for interactions, and cost-effectiveness. Prescribing formulary products provides your patients with the most cost-effective drug therapy offered through the prescription drug program. However, all prescribing decisions are at your discretion, based on your medical judgment. When prescribing, please consider a generic drug if medically appropriate for the patient. *Thank you.*

If you have comments or questions regarding our drug formulary, please write to the Pharmacy and Therapeutics Committee at the address shown below.

TO PHARMACIST

When dispensing a product, please consider a generic alternative, if medically appropriate for the patient. We also encourage you to dispense a product from our prescription drug formulary. We appreciate any assistance you can give our members to ensure a safe, effective product that provides cost-effective therapy. *Thank you.*

DRUG COVERAGE

Under some circumstances, formulary drugs may be excluded from coverage under the drug benefit (e.g., oral contraceptives, nicotine replacement therapy, Retin-A, various injectables, etc.). In all cases, plan inclusions/exclusions determine specific coverage regardless of formulary status. Drugs not listed are non-formulary. *Exception:* All insulin and most diabetic supplies are covered at the highest benefit level for plans that cover them. However, only the preferred products are included on this list.

PRIOR APPROVAL

Use of some products may be approved by the Pharmacy and Therapeutics committee only after specific criteria have been met. Use of these products requires prior approval. These products are identified with the symbol [PA]. A physician (or clinic personnel) should submit a written request to the Pharmacy and Therapeutics Committee at the address shown below for prior approval consideration.

ABBREVIATIONS

caps = capsules
conc = concentrate
crm = cream
DR = delayed-release
ER = extended-release
inj = injection
IR = immediate-release
lotn = lotion
NF = non-formulary
oint = ointment
pwd = powder
soln = solution
supp = suppositories
susp = suspension
tabs = tablets

COST INDEX

Dollar signs are based upon Average Wholesale Price (AWP) or Maximum Allowable Cost (MAC) and range from one ($) to five ($$$$$), ranking the drugs from least to most expensive. Within the same dollar sign, drugs are listed alphabetically. Dollar signs for maintenance drugs are typically based upon a 30 day supply at a commonly prescribed dosage. For drugs not usually taken 30 days per month, a more appropriate basis is used to determine dollar signs.

$	$20.00 or less
$$	$20.01 to $40
$$$	$40.01 to $80
$$$$	$80.01 to $160
$$$$$	More than $160

MAILING ADDRESS

Pharmacy and Therapeutics Committee
Private Claims Department
4510 13th Avenue South
Fargo, ND 58121

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PART 1: ALPHABETICAL DRUG LIST

This is an alphabetical list of the generic and brand drugs on the formulary. Generic drugs are shown in lower case; brand drugs are shown in all capital letters. **NF** means a product is non-formulary. The chapter/subchapter reference will list alternative formulary products. Drugs not listed in this index are NF.

Generic drugs are shown in lower case; brand-name drugs are shown in all capital letters. **NF** = Non-formulary

CHAPTER 1. ANTI-INFECTIVE AGENTS

1.1 Penicillins

$ amoxicillin
$ AMOXIL drops
$ ampicillin
$ penicillin v potassium
$$ amoxicillin/potassium clavulanate
$$ dicloxacillin
$$$$ AUGMENTIN – 8 hr dosing
$$$$ AUGMENTIN XR

1.2 Cephalosporins

$ cephalexin
$$ cefadroxil
$$ cefuroxime tabs
cefdinir
$$$ OMNICEF
$$$ cefprozil
$$$$ CEFTIN susp

1.3 Macrolide antibiotics

$ erythromycin DR caps
$ ERY-TAB
$ ERYTHROMYCIN FILMTABS
$ erythromycin ethylsuccinate
$ erythromycin stearate
$ erythromycin/sulfisoxazole
$$ azithromycin
$$ ZITHROMAX pwd pkt
$$$ ZMAX susp

1.4 Tetracyclines

$ doxycycline hyclate, NF = 20 mg
$ minocycline
$ tetracycline

1.5 Fluoroquinolones

$ ciprofloxacin tabs (NF = 100 mg)
$$$$ CIPRO susp
levofloxacin
$$$$ LEVAQUIN

1.6 Aminoglycosides

neomycin sulfate
tobramycin
$$$$$ TOBI

1.7 Sulfonamides

$ sulfamethoxazole/trimethoprim

1.8 Antimycobacterial agents

$ isoniazid tabs
$$ ISONIAZID syrup
$$$ rifampin
$$$$ pyrazinamide
$$$$$ ethambutol
rifabutin
$$$$$ MYCOBUTIN

1.9 Antifungals

$ fluconazole
$ ketoconazole
$$$ griseofulvin microsize susp
$$$$ GRIFULVIN V tabs
$$$$$ itraconazole caps
terbinafine
$$$$$ LAMISIL tabs
voriconazole [PA]
$$$$$ VFEND [PA]

1.10 Antiviral

$$ acyclovir
$$$$ zidovudine
abacavir
$$$$$ ZIAGEN
abacavir/lamivudine
$$$$$ EPZICOM
abacavir/lamivudine/zidovudine
$$$$$ TRIZIVIR
adefovir
$$$$$ HEPSERA
amprenavir
$$$$$ AGENERASE
atazanavir
$$$$$ REYATAZ
darunavir
$$$$$ PREZISTA
delavirdine
$$$$$ RESCRIPTOR
didanosine
$$$$$ VIDEX
$$$$$ didanosine DR
$$$$$ VIDEX EC 125 mg
efavirenz
$$$$$ SUSTIVA
efavirenz/emtricitabine/tenofovir
$$$$$ ATRIPLA
emtricitabine
$$$$$ EMTRIVA
emtricitabine/tenofovir
$$$$$ TRUVADA
enfuvirtide
$$$$$ FUZEON
entecavir
$$$$$ BARACLUDE
fosamprenavir
$$$$$ LEXIVA
ganciclovir
$$$$$ GANCICLOVIR
indinavir
$$$$$ CRIXIVAN
lamivudine
$$$$$ EPIVIR
$$$$$ EPIVIR-HBV
lamivudine/zidovudine
$$$$$ COMBIVIR
lopinavir/ritonavir
$$$$$ KALETRA
nelfinavir
$$$$$ VIRACEPT
nevirapine
$$$$$ VIRAMUNE
peginterferon alfa-2a
$$$$$ PEGASYS
peginterferon alfa-2b
$$$$$ PEG-INTRON
$$$$$ ribavirin caps, tabs, 200 mg (NF = 400, 600 mg)
ritonavir
$$$$$ NORVIR
saquinavir mesylate
$$$$$ INVIRASE
stavudine
$$$$$ ZERIT
tenofovir
$$$$$ VIREAD

tipranavir
$$$$$ APTIVUS
valacyclovir
$$$$$ VALTREX
valganciclovir
$$$$$ VALCYTE

1.11 Antimalarial

$ chloroquine phosphate
$ hydroxychloroquine
primaquine phosphate
$ PRIMAQUINE PHOSPHATE
sulfadoxine/pyrimethamine
$ FANSIDAR
$$ mefloquine
atovaquone/proguanil
$$$$ MALARONE

1.13 Anthelmintic

ivermectin
$ STROMECTOL
$ mebendazole

1.14 Misc. Anti-infectives

$ clindamycin
clindamycin palmitate hcl
$$ CLEOCIN PEDIATRIC
dapsone
$ DAPSONE
$ metronidazole tabs
$ trimethoprim
nitazoxanide
$$$$ ALINIA
$$$$$ pentamidine inj
$$$$$ NEBUPENT

Chapter 3.1 Antineoplastics

Only oral and self-administered injectable cancer drugs are listed below. All cancer drugs are formulary, however, brand name oral cancer drugs are removed from the formulary after a generic version becomes available.

altretamine
HEXALEN
anastrozole
ARIMIDEX
azacitidine
VIDAZA
exarotene
TARGRETIN
bicalutamide
CASODEX
busulfan
MYLERAN
capecitabine
XELODA
chlorambucil
LEUKERAN
cyclophosphamide
dasatinib [PA]
SPRYCEL [PA]
erlotinib [PA]
TARCEVA [PA]
estramustine
EMCYT
etoposide
exemestane
AROMASIN
flutamide
fulvestrant
FASLODEX
gefitinib [PA]
IRESSA [PA]
goserelin
ZOLADEX
hydroxyurea
imatinib [PA]
GLEEVEC [PA]
interferon alfa-2a
ROFERON-A
interferon alfa-2b
INTRON A
interferon gamma-1b [PA]
ACTIMMUNE [PA]
letrozole
FEMARA
leucovorin calcium
LEUCOVORIN CALCIUM
leuprolide
ELIGARD
lomustine
CEENU
megestrol
melphalan
ALKERAN
mercaptopurine
mesna
MESNEX tabs
methotrexate
mitotane
LYSODREN
nilutamide
NILANDRON
procarbazine
MATULANE
sorafenib [PA]
NEXAVAR [PA]
sunitinib [PA]
SUTENT [PA]
tamoxifen
SOLTAMOX
temozolomide
TEMODAR
testolactone
TESLAC
thioguanine
TABLOID
toremifene
FARESTON
tretinoin
VESANOID
vorinostat [PA]
ZOLINZA [PA]

CHAPTER 4. ENDOCRINE AND METABOLIC DRUGS

4.1 Corticosteroids

$ cortisone acetate
$ fludrocortisone
$ methylprednisolone
$ prednisolone
$ prednisolone sodium
phosphate soln
$ dexamethasone
$ DEXAMETHASONE elixir, soln; tabs, 1, 2 mg
$$ DEXAMETHASONE INTENSOL
$ hydrocortisone 20 mg
$$ CORTEF 5, 10 mg
$ prednisone
$$ PREDNISONE soln, 5 mg/5 mL; tabs, 50 mg
budesonide ER
$$$$$ ENTOCORT EC

4.2 Androgen-anabolic

fluoxymesterone
$$$$ ANDROXY

testosterone
$$$$$ ANDRODERM
$$$$$ ANDROGEL
$$$$$ TESTIM
$$ testosterone cypionate
$$ DEPO-TESTOSTERONE
$$ testosterone enanthate
$$$ DELATESTRYL
methyltestosterone
$$$ METHITEST
$$$$ ANDROID
$$$$$ danazol 200 mg
$$$$$ DANAZOL 50, 100 mg

4.3 Estrogens

$ estropipate
$ estradiol patches, tabs
$$ ESTRADERM
$$ VIVELLE
$$ VIVELLE-DOT
$$$ ESTROGEL
estradiol/norgestimate
$$ PREFEST
conjugated estrogens
$$ PREMARIN
conjugated estrogens/medroxyprogesterone
$$$ PREMPHASE
$$$ PREMPRO
estradiol/levonorgestrel
$$$ CLIMARA PRO

4.4 Contraceptives

All generic oral contraceptives are formulary products and are noted by generic name along with their trade names, e.g., Apri, Reclipsen, Solia. Reference brands, noted for your information only, are non-formulary (NF) and are shown in parentheses, e.g., (Desogen, Ortho-Cept). Selected brands that are not available generically are also on the formulary and appear as: generic name followed by the TRADE NAME, e.g., drospirenone/ethinyl estradiol YASMIN.

$ medroxyprogesterone acetate inj, 150 mg/mL
$ DEPO-PROVERA
$$ desogestrel/ethinyl estradiol – Apri, Reclipsen, Solia (NF = Desogen, Ortho-Cept)
$$ desogestrel/ethinyl estradiol – Kariva (NF = Mircette), Cesia, Velivet (NF = Cyclessa)
drospirenone/ethinyl estradiol
$$$ YASMIN
$$$ YAZ
$$ ethynodiol/ethinyl estradiol – Kelnor, Zovia (NF = Demulen)
levonorgestrel
$$ PLAN B
$$ levonorgestrel/ethinyl estradiol – Aviane, Lutera (NF = Alesse)
$$ levonorgestrel/ethinyl estradiol – Enpresse, Trivora (NF = Tri-Levlen, Triphasil)
$$ levonorgestrel/ethinyl estradiol – Lessina, Sronyx (NF = Levlite)
$$ levonorgestrel/ethinyl estradiol – Levora, Portia (NF = Levlen, Nordette)
$$$ levonorgestrel/ethinyl estradiol – Jolessa, Quasense (NF = Seasonale)
$$ norethindrone – Camila, Nora-Be (NF = Nor-QD), Errin, Jolivette (NF = Ortho Micronor)
$$ norethindrone acetate/ethinyl estradiol – Junel, Microgestin (NF = Loestrin)
$$ norethindrone acetate/ethinyl estradiol/Fe – Junel Fe, Microgestin Fe (NF = Loestrin Fe)
$$ norethindrone/mestranol – Necon (NF = Norinyl 1+50, Ortho-Novum 1/50)
$$ norethindrone/ethinyl estradiol – Aranelle, Leena (NF = Tri-Norinyl)
$$ norethindrone/ethinyl estradiol – Necon, Nortrel (NF = Brevicon, Modicon, Norinyl 1+35, Ortho-Novum 1/35)
norethindrone/ethinyl estradiol
$$ NECON 10/11
$$ norethindrone/ethinyl estradiol – Necon, Nortrel (NF = Ortho-Novum 7/7/7)
$$ norgestimate/ethinyl estradiol – Mononessa, Previfem, Sprintec (NF = Ortho-Cyclen)
$$ norgestimate/ethinyl estradiol – Tri-Previfem, Trinessa, Tri-Sprintec (NF = Ortho Tri-Cyclen)
$$$ ORTHO TRI-CYCLEN LO
$$ norgestrel/ethinyl estradiol – Cryselle, Low-Ogestrel (NF = Lo/Ovral)
$$$ OGESTREL
etonogestrel/ethinyl estradiol
$$$ NUVARING vaginal ring

4.5 Progestins

$ medroxyprogesterone acetate
$ norethindrone acetate
progesterone micronized
$$ PROMETRIUM

4.6 Antidiabetic

$ glimepiride
$ glyburide
$ metformin IR, ER
$$ glipizide IR, ER
$$ glyburide/metformin
glucagon
$$$$ GLUCAGON EMERGENCY KIT
miglitol
$$$ GLYSET
rosiglitazone
$$$$ AVANDIA
rosiglitazone/glimepiride
$$$$ AVANDARYL
rosiglitazone/metformin
$$$$ AVANDAMET
exenatide
$$$$$ BYETTA
pioglitazone
$$$$$ ACTOS

pioglitazone/glimepiride
$$$$$ DUETACT
pioglitazone/metformin
$$$$ ACTOPLUS MET
pramlintide
$$$$$ SYMLIN

Rapid-Acting Insulins

insulin glulisine
$$$$ APIDRA
insulin lispro
$$$$ HUMALOG
insulin aspart
$$$$ NOVOLOG

Short-Acting Insulins

insulin regular
$$ HUMULIN R
$$ NOVOLIN R
$$ RELION R

Intermediate-Acting Insulins

insulin isophane
$$ HUMULIN N
$$ NOVOLIN N
$$ RELION N
insulin isophane/regular
$$ HUMULIN 50/50
$$ HUMULIN 70/30
$$ NOVOLIN 70/30
$$ RELION 70/30
insulin lispro protamine/lispro
$$$$ HUMALOG MIX 50/50
$$$$ HUMALOG MIX 75/25
insulin aspart protamine/aspart
$$$$ NOVOLOG MIX 70/30

Basal Insulins

insulin detemir
$$$$ LEVEMIR
insulin glargine
$$$$ LANTUS

4.7 Thyroid

$ levothyroxine – includes Levoxyl (NF = Levothroid)
$ propylthiouracil
liothyronine
$$ CYTOMEL
$$ methimazole

4.8 Oxytocics

methylergonovine
METHERGINE

4.9 Misc. Endocrine

$$ clomiphene
choriogonadotropin alfa
$$$ OVIDREL
$$$ chorionic gonadotropin
$$$ PROFASI HP
alendronate
$$$$ FOSAMAX
alendronate/cholecalciferol
$$$$ FOSAMAX PLUS D
raloxifene
$$$$ EVISTA
risedronate
$$$$ ACTONEL
risedronate + calcium carbonate
$$$$ ACTONEL with CALCIUM
$$$$$ cabergoline
cetrorelix
$$$$$ CETROTIDE
cinacalcet [PA]
$$$$$ SENSIPAR [PA]
$$$$ desmopressin inj, soln, spray, tabs
$$$$$ STIMATE
doxercalciferol
$$$$$ HECTOROL
follitropin alfa
$$$$$ GONAL-F
follitropin beta
$$$$$ FOLLISTIM AQ
ganirelix acetate
$$$$$ GANIRELIX ACETATE
lutropin alfa
$$$$$ LUVERIS
menotropins
$$$$$ MENOPUR
$$$$$ REPRONEX
$$$$$ octreotide
$$$$$ SANDOSTATIN
$$$$$ SANDOSTATIN LAR DEPOT
somatropin [PA]
$$$$$ GENOTROPIN [PA]
$$$$$ NUTROPIN [PA]
$$$$$ NUTROPIN AQ [PA]
teriparatide [PA]
$$$$$ FORTEO [PA]
urofollitropin purified
$$$$$ BRAVELLE

CHAPTER 5. CARDIOVASCULAR AGENTS

5.1 Cardiotonics

$ digoxin tabs
$$ DIGOXIN soln

5.2 Antianginal Agents

$ isosorbide dinitrate IR; NF = SL, ER
$ isosorbide mononitrate IR, ER
$ nitroglycerin patches, sublingual tabs, ER caps
$ NITRO-BID oint
$ NITROSTAT
$$$$ NITROLINGUAL

5.3 Beta Blockers

$ acebutolol
$ atenolol
$ metoprolol tartrate
$ sotalol
$$ timolol 10 mg
$$ TIMOLOL 5, 20 mg
$$ labetalol
$$ metoprolol succinate ER 25 mg
$$ TOPROL XL
$$ nadolol
$ propranolol tabs
$$ PROPRANOLOL soln
$$$ INDERAL LA
$$$ PINDOLOL
carvedilol
$$$$ COREG
$$$$ sotalol AF

5.4 Calcium Channel Blockers

$ verapamil IR, ER
$$ nifedipine ER
amlodipine
$$$ NORVASC
$$ diltiazem IR, ER – once daily

5.5 Antiarrhythmic

$$ amiodarone 200 mg
$$$ flecainide
$$$ mexiletine
$$$ disopyramide IR, ER
$$$$ NORPACE CR 100 mg
$$$ propafenone
$$$$ quinidine gluconate ER
$$ quinidine sulfate IR
$$$ QUINIDINE SULFATE ER

5.6 Antihypertensive

$ atenolol/chlorthalidone
$ benazepril
$ benazepril/ hydrochlorothiazide
$ bisoprolol/ hydrochlorothiazide
$ captopril
$ captopril/ hydrochlorothiazide
$ doxazosin
$ enalapril
$ enalapril/ hydrochlorothiazide
$ guanfacine
$ lisinopril
$ lisinopril/hydrochlorothiazide
$ methyldopa
$ propranolol/ hydrochlorothiazide
reserpine
$ RESERPINE
$ terazosin
$$ fosinopril
$$ fosinopril/ hydrochlorothiazide
$$ quinapril
$$ quinapril/ hydrochlorothiazide
$$$ hydralazine
losartan
$$$ COZAAR
losartan/hydrochlorothiazide
$$$ HYZAAR
ramipril
$$$ ALTACE
valsartan
$$$ DIOVAN
valsartan/ hydrochlorothiazide
$$$ DIOVAN HCT
$ clonidine
$$$$ CATAPRES-TTS
amlodipine/benazepril
$$$$ LOTREL

5.7 Diuretics

$ bumetanide
$ chlorthalidone 25, 50 mg
furosemide soln, 10 mg/ mL; tabs
$ hydrochlorothiazide
$ indapamide
$ spironolactone
$ spironolactone/ hydrochlorothiazide
$ triamterene/hydrochlorothiazide
amiloride
$$ AMILORIDE
$$ amiloride/hydrochlorothiazide
$$ metolazone
$ acetazolamide
$$$$ DIAMOX SEQUELS

5.8 Pressors

epinephrine
$$$ EPIPEN
$$$ EPIPEN-JR
$$$$$ midodrine

5.9 Antihyperlipidemic

$ gemfibrozil
$$ lovastatin
$$$ cholestyramine
colestipol
$$$ COLESTID tabs
atorvastatin
$$$$ LIPITOR
ezetimibe
$$$$ ZETIA
ezetimibe/simvastatin
$$$$ VYTORIN
fenofibrate
$$$$ TRICOR
niacin ER
$$$$ NIASPAN
omega-3-acid ethyl esters
$$$$ OMACOR
$$$$ pravastatin tabs, 10, 20, 40 mg
$$$$ simvastatin
colesevelam
$$$$$ WELCHOL

5.10 Misc. Cardiovascular

amlodipine/atorvastatin
$$$$ CADUET
bosentan [PA]
$$$$$ TRACLEER [PA]
iloprost [PA]
$$$$$ VENTAVIS [PA]
treprostinil [PA]
$$$$$ REMODULIN [PA]

CHAPTER 6. RESPIRATORY AGENTS

6.1 Antihistamines

$ cyproheptadine
$ promethazine supp, syrup, tabs

6.2 Systemic and Topical Nasal Products

azelastine
$$$ ASTELIN
$$$ flunisolide 25 mcg/spray
$$$ fluticasone 50 mcg/spray
mupirocin calcium
$$$ BACTROBAN nasal
triamcinolone acetonide
$$$ NASACORT AQ
mometasone
$$$$ NASONEX

6.3 Cough/Cold/Allergy

potassium iodide
$ SSKI
$ promethazine w/codeine syrup
$$ codeine/guaifenesin soln, tabs
$$$$ acetylcysteine

6.4 Antiasthmatic

$ albuterol sulfate neb soln, syrup, tabs
$$ albuterol inhaler
$$$ PROVENTIL inhaler
$$ PROAIR HFA
$$$ PROVENTIL HFA
$$ VENTOLIN HFA
$$$$ VOSPIRE ER
$$ theophylline ER
$$$ UNIPHYL
$$ terbutaline
$$$ cromolyn sodium neb soln
$$$ ipratropium bromide neb soln
$$$ ATROVENT HFA
nedocromil
$$$ TILADE
beclomethasone dipropionate
$$$$ QVAR
fluticasone
$$$$ FLOVENT HFA
formoterol
$$$$ FORADIL AEROLIZER
montelukast
$$$$ SINGULAIR

pirbuterol
$$$$ MAXAIR AUTOHALER
salmeterol
$$$$ SEREVENT DISKUS
tiotropium
$$$$ SPIRIVA HANDIHALER
triamcinolone acetonide
$$$$ AZMACORT
zafirlukast
$$$$ ACCOLATE
albuterol/ipratropium
$$$$ COMBIVENT
$$$$$ DUONEB
budesonide
$$$$$ PULMICORT RESPULES
fluticasone/salmeterol
$$$$$ ADVAIR DISKUS
$$$$$ ADVAIR HFA
omalizumab [PA]
$$$$$ XOLAIR [PA]

6.5 Misc. Respiratory
dornase alfa
$$$$$ PULMOZYME

CHAPTER 7. GASTROINTESTINAL AGENTS

7.1 Laxatives
$ lactulose
$ PEG-electrolytes for soln, generics of Colyte, Nulytely
$$ polyethylene glycol 3350

7.4 Ulcer Drugs
$ cimetidine, NF = 200 mg
$ dicyclomine
$ famotidine, NF = 20 mg
$ hyoscyamine IR, ER; NF = orally disintegrating tabs
$ ranitidine
$$ ZANTAC syrup
$$$ omeprazole DR
$$$ sucralfate tabs
$$$ CARAFATE susp
$$$$ misoprostol
pantoprazole DR
$$$$ PROTONIX
rabeprazole DR
$$$$ ACIPHEX
amoxicillin + clarithromycin + lansoprazole DR
$$$$$ PREVPAC
metronidazole + tetracycline + bismuth subsalicylate
$$$$$ HELIDAC

7.5 Antiemetics
$ trimethobenzamide caps
$ trimethobenzamide supp
aprepitant
$$$$$ EMEND
ondansetron
$$$$$ ZOFRAN ODT
$$$$$ ZOFRAN soln, tabs
$$$$$ ondansetron inj
$$$$$ ZOFRAN inj

7.6 Digestive Aids
pancrelipase
$$$$$ CREON
$$$$$ LIPRAM/PN/UL
$$$$$ PANCREASE MT
$$$$$ PANCRELIPASE IR caps, 20-4-25
$$$$$ PANCRELIPASE IR tabs, 30-8-30 – various tradenames
$$$$$ PANOKASE-16
$$$$$ ULTRASE/MT
$$$$$ VIOKASE

7.7 Misc. GI
$ lactulose – encephalopathy
$ metoclopramide
$ sulfasalazine IR, DR
calcium acetate
$$$ PHOSLO
$$$$ ursodiol
lubiprostone
$$$$$ AMITIZA
$$$$$ mesalamine enema
$$$$$ ASACOL
$$$$$ CANASA
$$$$$ PENTASA
sevelamer
$$$$$ RENAGEL

CHAPTER 8. GENITOURINARY DRUGS

8.1 Urinary Anti-infectives
$ nitrofurantoin monohydrate/macrocrystals
$$ nitrofurantoin macrocrystals
$$$$ FURADANTIN susp

8.2 Urinary Antispasmodics
$ oxybutynin IR, ER
$$$$ DITROPAN XL
$$$ hyoscyamine
tolterodine
$$$$ DETROL
$$$$ DETROL LA

8.3 Vaginal Products
$$ acetic acid gel
estradiol
$$ ESTRACE crm
$$ VAGIFEM tabs
conjugated estrogens
$$ PREMARIN crm
$$$ clindamycin crm
$$$ CLEOCIN supp
$$$ CLINDESSE
$$$ metronidazole
$$$$ METROGEL

8.4 Miscellaneous Genitourinary Products
potassium/sodium acid phosphates
$$ K-PHOS MF
$$ K-PHOS NO. 2
$$ potassium citrate ER
$$$ finasteride 5 mg
$$$ potassium citrate/citric acid
$$$ sodium citrate/citric acid
$$$ tricitrates soln
tamsulosin
$$$ FLOMAX
dutasteride
$$$$ AVODART
pentosan
$$$$$ ELMIRON

CHAPTER 9. CENTRAL NERVOUS SYSTEM DRUGS

9.1 Antianxiety Agents
$ buspirone
$ hydroxyzine pamoate
$ lorazepam
$$$ LORAZEPAM INTENSOL
$ alprazolam
$$ ALPRAZOLAM INTENSOL
$ diazepam inj, tabs
$ DIAZEPAM soln
$$ DIAZEPAM INTENSOL
$$ hydroxyzine hcl

9.2 Antidepressants
$ amitriptyline
$ citalopram

$ doxepin
$ fluoxetine
$ nortriptyline
$ trazodone
$$ clomipramine
$$ desipramine
$$ imipramine hcl
$$ mirtazapine,
NF = orally disintegrating tabs
$$$ paroxetine hcl
$$$$ PAXIL susp
$$$$ PAXIL CR
$$$$ bupropion IR, ER, SR
$$$$ WELLBUTRIN XL
phenelzine
$$$$ NARDIL
$$$$ sertraline
$$$$ tranylcypromine
$$$$ venlafaxine
$$$$ EFFEXOR XR

9.3 Antipsychotics

$ fluphenazine hcl tabs
$$$ FLUPHENAZINE HCL elixir, soln
$ haloperidol lactate soln
$ lithium carbonate IR, ER
$ LITHIUM CARBONATE caps, 150, 600 mg; tabs, 300 mg
$$$ lithium citrate syrup
$ prochlorperazine supp
$ prochlorperazine tabs
$ thiothixene
$ haloperidol 0.5, 1, 2, 5, 10 mg
$$$ HALOPERIDOL 20 mg
$$ perphenazine
$$ thioridazine
$$ trifluoperazine
$$$ chlorpromazine
$$$ clozapine 25, 50, 100 mg
$$$$$ CLOZAPINE 200 mg
quetiapine
$$$$$ SEROQUEL
risperidone
$$$$$ RISPERDAL, NF = Risperdal M-Tab
ziprasidone
$$$$$ GEODON

9.4 Hypnotics

$ chloral hydrate syrup
$ CHLORAL HYDRATE supp
$ estazolam
$ phenobarbital
$ PHENOBARBITAL 64.8 mg
$ temazepam
$$$ RESTORIL 7.5 mg
$$$$ mephobarbital
zolpidem
$$$$ AMBIEN

9.5 ADHD/Anti-narcolepsy/ Anti-obesity/Anorexiants

$$$ dextroamphetamine IR, ER
$$$ DEXTROSTAT 10 mg
$$ methylphenidate IR, ER
$$$ METADATE ER
$$$$ CONCERTA
$$$$ METADATE CD
$$$ amphetamine/ dextroamphetamine mixed salts
$$$$ ADDERALL XR
modafinil
$$$$$ PROVIGIL

9.6 Misc Psychotherapeutic and Neurological Agents

$$$ bupropion ER – smoking deterrent
disulfiram
$$$ ANTABUSE
pimozide
$$$ ORAP
acamprosate DR
$$$$ CAMPRAL
$$$$ nicotine gum – OTC
$$$$ NICORETTE – OTC
$$$$ nicotine lozenges – OTC
$$$$ COMMIT – OTC
$$$$ nicotine patches – OTC
$$$$ NICODERM CQ – OTC
varenicline
$$$$ CHANTIX
donepezil
$$$$$ ARICEPT
$$$$$ ARICEPT ODT
glatiramer
$$$$$ COPAXONE
interferon beta-1a
$$$$$ AVONEX
$$$$$ REBIF
interferon beta-1b
$$$$$ BETASERON
memantine
$$$$$ NAMENDA

CHAPTER 10. ANALGESICS AND ANESTHETICS

10.1 Analgesics – Non-narcotic

$ butalbital/acetaminophen/ caffeine
$ salsalate
$$ butalbital/aspirin/caffeine

10.2 Analgesics – Narcotic

$ acetaminophen/codeine
$ aspirin/codeine
$ codeine sulfate 30, 60 mg
$ CODEINE SULFATE 15 mg
$ hydrocodone/acetaminophen
$ hydromorphone
$$ DILAUDID soln
$ methadone conc, tabs
$$ METHADONE soln
$ oxycodone/acetaminophen
$ ROXICET soln
$ propoxyphene hcl/ acetaminophen
$ propoxyphene napsylate/ acetaminophen 50/325, 100/650
$$ morphine sulfate soln, tabs, ER tabs, supp
$$ MORPHINE SULFATE
$$ pentazocine/naloxone
$$ butalbital/aspirin/caffeine/ codeine
$$$ oxycodone/aspirin
$$ oxycodone IR, ER
$$$$ naltrexone
buprenorphine
$$$$$ SUBUTEX
buprenorphine/naloxone
$$$$$ SUBOXONE
$$$$$ fentanyl patches
$$$$ DURAGESIC-12
$$$$$ FENTANYL CITRATE transmucosal

10.3 Analgesics – Anti-inflammatory

$ etodolac, NF = ER
$ ibuprofen
$ ketoprofen, NF = ER
$ ketorolac

$ meloxicam
$ naproxen IR, DR
[redacted] naproxen sodium, NF = ER
$ piroxicam
$ sulindac
$$ diclofenac sodium DR, ER
$$ indomethacin, NF = ER
celecoxib
$$$$ CELEBREX
adalimumab [PA]
$$$$$ HUMIRA [PA]
anakinra [PA]
$$$$$ KINERET [PA]
auranofin
$$$$$ RIDAURA
etanercept [PA]
$$$$$ ENBREL [PA]
rituximab [PA]
$$$$$ RITUXAN [PA]

10.4 Migraine Products

$ acetaminophen/isometheptene/dichloralphenazone
$$$$$ dihydroergotamine inj
[redacted] $$$$ MIGRANAL
divalproex sodium ER
$$$$ DEPAKOTE ER
sumatriptan
$$$$$ IMITREX inj, nasal, tabs
zolmitriptan
$$$$$ ZOMIG nasal, tabs
$$$$$ ZOMIG ZMT

10.5 Gout

$ allopurinol
$ colchicine
$$ probenecid
$$$ probenecid/colchicine

CHAPTER 11. NEUROMUSCULAR DRUGS

11.1 Anticonvulsant

$ clonazepam, NF = orally disintegrating tabs
$$ phenytoin susp
$$ phenytoin sodium extended
$$$ DILANTIN
phenytoin sodium prompt
$$ PHENYTOIN SODIUM PROMPT
[redacted] carbamazepine
$$$$ TEGRETOL-XR
$$$$ CARBATROL
divalproex sodium DR
$$$$$ DEPAKOTE
$$$ primidone
$$$$ ethosuximide
oxcarbazepine
$$$$ TRILEPTAL
$$$$ valproic acid
$$$$ zonisamide
diazepam rectal gel
$$$$$ DIASTAT
$$$$ gabapentin
$$$$ NEURONTIN soln
$$$$$ lamotrigine chew tabs
$$$$$ LAMICTAL chew tabs, 2 mg; tabs
levetiracetam
$$$$$ KEPPRA
topiramate
$$$$$ TOPAMAX

11.2 Antiparkinson

$ benztropine
$ trihexyphenidyl
$$ selegiline
$$$ carbidopa/levodopa IR, ER
$$$$ PARCOPA
$$$$ bromocriptine
apomorphine [PA]
$$$$$ APOKYN [PA]
entacapone
$$$$$ COMTAN
$$$$$ pergolide
pramipexole
$$$$$ MIRAPEX
ropinirole
$$$$$ REQUIP

11.3 Neuromuscular Agents

riluzole
$$$$$ RILUTEK

11.4 Musculoskeletal Therapy Agents

$ cyclobenzaprine
$$ baclofen
$$ methocarbamol
$$ orphenadrine ER
$$ orphenadrine/aspirin/caffeine
$$$$ dantrolene

11.5 Antimyasthenic agents

$$$$ pyridostigmine
$$ MESTINON TIMESPAN
$$$ MESTINON syrup

CHAPTER 12. NUTRITIONAL PRODUCTS

12.1 Vitamins

$ phytonadione inj, 1 mg/0.5 mL
$ PHYTONADIONE inj, 10 mg/mL
$ MEPHYTON
$$ ergocalciferol
$$$ calcitriol

12.2 Multivitamins

$ pediatric multivitamins/fluoride
$ pediatric multivitamins/fluoride/iron
$ pediatric vitamins ADC/fluoride
$ pediatric vitamins ADC/fluoride/iron
$ prenatal multivitamins/1 mg folic acid

12.3 Minerals & Electrolytes

$ potassium phosphate/sodium phosphates
$ potassium chloride IR, ER
$ sodium fluoride
$ SODIUM FLUORIDE soln, 0.55 mg/drop; tabs, 1.1 mg
potassium phosphate monobasic
$$ K-PHOS
potassium/sodium phosphates
$$$ URO-KP-NEUTRAL

CHAPTER 13. HEMATOLOGICAL AGENTS

13.1 Hematopoietic Agents

$ cyanocobalamin inj
$ folic acid 1 mg
darbepoetin alfa
$$$$$ ARANESP
epoetin alfa
$$$$$ PROCRIT
filgrastim
$$$$$ NEUPOGEN
oprelvekin
$$$$$ NEUMEGA
pegfilgrastim
$$$$$ NEULASTA

sargramostim
$$$$$ LEUKINE

13.2 Anticoagulants
$ warfarin
$$$ heparin sodium lock flush
$$$ heparin sodium inj
$$$$ HEPARIN SODIUM inj
enoxaparin
$$$$$ LOVENOX

13.3 Hemostatics
$$$$ aminocaproic acid

13.4 Misc. Hematological
$ pentoxifylline ER
$$$ anagrelide
$$$ cilostazol
aspirin/ER dipyridamole
$$$$ AGGRENOX
$$$$ clopidogrel
$$$$ PLAVIX

CHAPTER 14. TOPICAL PRODUCTS

14.1 Ophthalmic
$ atropine sulfate oint, soln
$ bacitracin/polymyxin B oint
$ carteolol soln
dipivefrin soln
$ erythromycin oint
$ flurbiprofen soln
$ gentamicin oint, soln
$ levobunolol soln
$ metipranolol soln
$ neomycin/polymyxin B/ bacitracin oint
$ neomycin/polymyxin B/ dexamethasone oint, susp
$ neomycin/polymyxin B/ gramicidin soln
$ pilocarpine soln
$ polymyxin B/trimethoprim soln
$ prednisolone sodium phosphate 1% soln
$ sulfacetamide sodium soln
$ SULFACETAMIDE SODIUM oint
$ sulfacetamide sodium/ prednisolone soln
$ timolol maleate soln, gel-forming soln
tobramycin soln
betaxolol
$$ BETAXOLOL soln
$$$ BETOPTIC-S
brinzolamide
$$ AZOPT
$$ cromolyn sodium soln
dorzolamide
$$ TRUSOPT
$ fluorometholone susp
$$ FML S.O.P.
loteprednol
$$ LOTEMAX
$$$ ALREX
$ prednisolone acetate susp
$$ PRED FORTE
azelastine
$$$ OPTIVAR
$$$ brimonidine 0.2% soln
$$$ ALPHAGAN P
$ ciprofloxacin soln
$$$ CILOXAN oint
diclofenac
$$$ VOLTAREN
dorzolamide/timolol
$$$ COSOPT
ketorolac
$$$ ACULAR, NF = Acular PF
$$$ ACULAR LS
$$$ ketotifen soln
latanoprost
$$$ XALATAN
loteprednol/tobramycin
$$$ ZYLET
moxifloxacin
$$$ VIGAMOX
olopatadine
$$$ PATANOL
sodium/prednisolone soln
$$$ BLEPHAMIDE
$$$ BLEPHAMIDE S.O.P.
tobramycin/dexamethasone
$$$ TOBRADEX
travoprost
$$$ TRAVATAN, NF = TRAVATAN Z
$$$ trifluridine soln

14.2 Otic
$ benzocaine/antipyrine
$ hydrocortisone/acetic acid
$ neomycin/polymyxin B/ hydrocortisone
$$$ acetic acid
ofloxacin
$$$ FLOXIN OTIC
ciprofloxacin/ dexamethasone
$$$$ CIPRODEX
ciprofloxacin/ hydrocortisone
$$$$ CIPRO HC

14.3 Mouth & Throat (Local)
$ lidocaine viscous
$ sodium fluoride dental crm, gel
$ triamcinolone paste
$$$ chlorhexidine oral rinse
$$$ nystatin susp
$$$$$ pilocarpine tabs

14.4 Anorectal
$ hydrocortisone crm, 2.5%
$ hydrocortisone acetate supp, 25 mg
$$$$$ hydrocortisone enema

14.5 Dermatological
$ aluminum chloride
aluminum chloride in alcohol
$ XERAC AC
$ betamethasone dipropionate
$ betamethasone valerate
$ clindamycin
$ clobetasol
$ desonide
$ desoximetasone
$ DESOXIMETASONE crm, 0.05%
$ econazole
$ erythromycin
$ fluocinolone
$ fluocinonide
$ gentamicin
$ hydrocortisone 2.5%
$ hydrocortisone valerate
$$$ lidocaine/prilocaine crm
$ EMLA/TEGADERM
$ nystatin
$ nystatin/triamcinolone
$ selenium sulfide 2.5%
$ silver sulfadiazine
$ triamcinolone

$ TRIAMCINOLONE oint, 0.05%
[redacted] clotrimazole/betamethasone
[redacted] diflorasone, NF = emollient crm
$$ ketoconazole
$$ permethrin crm, 5%
acyclovir
$$$ ZOVIRAX oint
$$ betamethasone dipropionate, augmented crm, gel, oint
$$$ DIPROLENE lotn
azelaic acid
$$$ FINACEA
ciclopirox
$$$ LOPROX shampoo
$$$ ciclopirox crm, lotn
$$$ LOPROX gel
clindamycin/benzoyl peroxide
$$$ BENZACLIN
$$$ doxepin
$$ mometasone
$$$ mupirocin oint, NF = Centany
mupirocin calcium
[redacted] BACTROBAN crm
pimecrolimus
$$$ ELIDEL
$$$ hydrocortisone acetate 2.5%/ pramoxine 1% crm
$$$ PRAMOSONE 2.5% lotn, oint
$$$ sulfacetamide sodium/ sulfur crm, emulsion, lotn, susp
$$$ tretinoin, NF = Avita gel [PA over age 35]
adapalene [PA over age 35]
$$$$ DIFFERIN [PA over age 35]
$$$$ erythromycin/benzoyl peroxide
$$$$ BENZAMYCIN PAK
calcipotriene
$$$$ DOVONEX
$$$ fluorouracil soln, 2%, 5%
$$$$ CARAC
$$$$ EFUDEX crm
$$$$ FLUOROPLEX
lidocaine/tetracaine
$$$$ SYNERA
lindane
[redacted] LINDANE
malathion
$$$$ OVIDE
$$$ metronidazole crm, gel, lotn, 0.75%
$$$$ METROGEL 1%
$$$$ podofilox soln
tacrolimus
$$$$ PROTOPIC
tazarotene
$$$$ TAZORAC
tretinoin microsphere [PA over age 35]
$$$$ RETIN-A MICRO [PA over age 35]
acitretin
$$$$$ SORIATANE caps
alitretinoin
$$$$$ PANRETIN
bexarotene
$$$$$ TARGRETIN
diclofenac
$$$$$ SOLARAZE
efalizumab [PA]
$$$$$ RAPTIVA [PA]
imiquimod
$$$$$ ALDARA
$$$$$ isotretinoin caps
methoxsalen
$$$$$ OXSORALEN-ULTRA caps

CHAPTER 15. MISCELLANEOUS PRODUCTS

15.2 Antidotes

deferasirox
$$$$$ EXJADE
succimer
$$$$$ CHEMET

15.3 Blood glucose test strips

ACCU-CHEK ACTIVE, ADVANTAGE, AVIVA, COMFORT CURVE, COMPACT, INSTANT ONE TOUCH FASTTAKE, II/BASIC/PROFILE, SURESTEP, ULTRA

15.6 Medical Devices

INHALER ASSIST DEVICES – SPACERS

15.8 Assorted Classes

$$$ azathioprine
$$$ sodium polystyrene sulfonate
penicillamine
$$$$ CUPRIMINE
$$$$$ cyclosporine
$$$$$ SANDIMMUNE
$$$$$ cyclosporine modified, NF = 50 mg
$$$$$ NEORAL
lenalidomide [PA]
$$$$$ REVLIMID [PA]
mycophenolate mofetil
$$$$$ CELLCEPT
mycophenolic acid DR
$$$$$ MYFORTIC
sirolimus
$$$$$ RAPAMUNE
tacrolimus
$$$$$ PROGRAF
thalidomide [PA]
$$$$$ THALOMID [PA]

Blue Cross Blue Shield of North Dakota Prescription Drug Program
Therapeutic Class Analysis
Service Dates 10/01/06 through 12/31/06

Table 1. Cost and utilization statistics by therapeutic class

Therapeutic Class	Claims	Allowed	Paid	% Claims	% Allowed	Clm PMPM	PD PMPM
Cardiovascular	148,767	[redacted]	[redacted]	21.3%			
CNS Drugs	106,082	[redacted]	[redacted]	15.2%			
Endocrine/Metabolic	97,851	[redacted]	[redacted]	14.0%			
Anti-infectives	91,223	[redacted]	[redacted]	13.0%			
Analgesic/Anesthetics	61,244	[redacted]	[redacted]	8.7%			
Respiratory	59,259	[redacted]	[redacted]	8.5%			
Topical	36,030	[redacted]	[redacted]	5.1%			
Gastrointestinal	28,714	[redacted]	[redacted]	4.1%			
Neuromuscular	24,668	[redacted]	[redacted]	3.5%			
Miscellaneous	14,821	[redacted]	[redacted]	2.1%			
Hematological	11,196	[redacted]	[redacted]	1.6%			
Genitourinary	9,023	[redacted]	[redacted]	1.3%			
Nutritional	6,291	[redacted]	[redacted]	0.9%			
Antineoplastics	3,685	[redacted]	[redacted]	0.5%			
Unclassified	885	[redacted]	[redacted]	0.1%			
Biologicals	326	[redacted]	[redacted]	0.0%			
Totals	700,065	[redacted]	[redacted]	100.0%			

Claims run out through 2/1/07

Table 5. Cost and Utilization by therapeutic class - Central Nervous System Drugs

Therapeutic class	Claims	Allowed	Paid	% Claims	% Allowed	Claim PMPM	Paid PMPM
Antidepressants	66,638	[redacted]	[redacted]	62.8%	[redacted]	[redacted]	[redacted]
CNS Miscellaneous	2,546	[redacted]	[redacted]	2.4%	[redacted]	[redacted]	[redacted]
Stimulants	13,000	[redacted]	[redacted]	12.3%	[redacted]	[redacted]	[redacted]
Hypnotics	8,328	[redacted]	[redacted]	7.9%	[redacted]	[redacted]	[redacted]
Antipsychotics	4,456	[redacted]	[redacted]	4.2%	[redacted]	[redacted]	[redacted]
Antianxiety	11,114	[redacted]	[redacted]	10.5%	[redacted]	[redacted]	[redacted]
Totals	106,082	[redacted]	[redacted]	100.0%	100.0%	[redacted]	[redacted]

Claims run out through 2/1/07

#10

Georgia Medicaid: PDL and Mental Health Drugs

Jerry Dubberly,RPh, MBA
February 10, 2005

Topics for Discussion

- Overview of the GA DCH
- Challenges facing GA Medicaid (GME)
- Preferred Drug List (PDL) and Supplemental Rebates (SR)
- Inclusion of mental health drugs in PDL
- Results to date
- Next steps

Overview of DCH

- *Created in 1999, the Department of Community Health is the lead planning agency for all health issues in the state such as health care policy, purchasing and regulation.*
- The department is responsible for:
  - Insuring over 2 million people
  - Maximizing the state's health care purchasing power
  - Planning coverage for uninsured Georgians
  - Coordinating health planning for state agencies

Challenges

- Enrollment growth
- Utilization increases is a dominant cost driver
- Technological advances in medicine
- Budget
- Pharmacy expenditures in Medicaid doubled between 2000 and 2004
- Integrate approach to allocation of scarce health care resource dollars

GA's Medicaid Pharmacy Program

- Program statistics
  - $1.1 Billion annual expenditures
  - 21 Million prescriptions per year
  - $64.40 PMPM
  - $55.88 per Rx
- Program initiatives
  - Quantity level limits
  - Enhanced prior authorization (PA) program
  - Preferred Drug List (PDL) and Supplemental Rebates (SR)

Preferred Drug List & Supplemental Rebates

- Concept/Process
  - Conduct clinical reviews of therapeutic classes of drugs
  - Solicit rebates from manufacturers in exchange for "preferred" status
  - Weigh clinical evidence and cost to make PDL decision
  - Notification of GME's PDL decision and implementation
  - Two levels of appeal including GME Medical Director review

PDL Guiding Principles

- Seek clinical evidence
- Balance evidence with prevalence and cost of the drug
- Require PA for non-preferred products
  - Clinical rationale preventing use of the preferred products
- Minimize disruptions to current therapies

PDL Inclusion of Mental Health Drugs

- Recognize advances in therapy
  - Antidepressants
  - Antipsychotics
  - ADHD medications
- Grandfather current users of non-PDL drugs where appropriate
- Provide access to all mental health drugs through PA and appeal process

Annual Mental Health Drug Expenditures

Prior to PDL...

- ADHD
  - $32.8 Million
- Antidpressants (SSRI, SNRI, DARI)
  - $72.3 Million
- Atypical Antipsychotics
  - $179.4 Million

Avoid Silo Mentality

- In-patient hospitalizations for MH patients paid by Medicaid
  - $4,771.54 PUPM
- Physician office fees for MH patients
  - $133.25 PUPM
- Community Mental Health charges paid by Medicaid for MH patients
  - $307.82 PUPM

Pharmaceuticals are the most cost-effective tool to manage mental illness.

PDL: ADHD Medications*

- Preferred
  - Generics
  - Adderall XR
  - Concerta
  - Dexedrine
  - Focalin
  - Metadate ER/CD
  - Methylin/Methylin ER
  - Dextrostat
  - Cylert
- Nonpreferred**
  - Brands with generics available
  - Desoxyn
  - Strattera
  - Provigil

**PA for all patients >21 years*

***No Grandfathering except Strattera*

PDL: Antidepressants

- Preferred
  - Generics: fluoxetine, citalopram, buproprion, maprotoline, mirtazapine, nefazadone, trazadone
  - Lexapro
  - Paxil CR
  - Zoloft
  - Effexor XR
- Nonpreferred*
  - Brands with Generics available
  - Paxil/paroxetine
  - Pexeva
  - Cymbalta

**All current users grandfathered*

PDL: Atypical Antipsychotics

- Preferred
  - Risperdal
  - Seroquel
  - Geodon
- Non-Preferred*
  - Zyprexa
  - Abilify
  - ODT formulations
  - Symbyax
  - Injectables (no PA required)

**All current users grandfathered*

Atypical Antipsychotics

- Numerous conflicting studies
  - Superior safety over typical antipsychotics
  - Efficacy varies among atypicals
- "How do you choose an atypical?"
  - Previous patient success
  - Side effect profile and concomitant disease states
  - Family member success

"It's largely an experiment"

Results to Date

- Increase in preferred drug marketshare
- Decrease in net pharmacy expenditures
- Decreased IP hospitalization costs for MH patients
- Decreased IP hospital days for MH patients
- No increase in ER visits or office visits for MH patients
- Initial PA requests determination in <10 minutes
- Appeals
  - First Level Appeals: 1 business day
  - Second Level Appeals: 2 business days

Next Steps

- Continue monitoring ***total resource utilization*** for MH patients
- Identify "false savings"
- Informative utilization alerts to prescribers
  - Noncompliance/non-persistence
  - High dose
  - Multiple prescribers
  - Poly-atypical utilization
  - Narcotic utilization among MH patients

Discussion

GA Medicaid PDL Implementation of Mental Health Drugs

Class	Effective Date	Hard Edits	Notes
ADHD	5/1/04	7/1/04	Current Strattera users grandfathered
SSRI's	8/1/04	8/1/04	Current users grandfathered
Atypical Antipsychotics	9/1/04	9/1/04	Current users grandfathered
Atypical Antipsychotics (Orally disentigrating dosage formulations)	9/1/01	10/1/04	No grandfathering
New Generation and Misc Antidepressants*	11/1/04	12/1/04	Current users grandfathered

*** New Generation and Misc Antidepressants**

Preferred	Non-Preferred
Trazadone	Branded products with generics available
Buproprion/Buproprion SR	Cymbalta
Maprotoline	
Mirtazapine	
Wellbutrin XL	
Effexor/Effexor XR	
Nefazadone	

House Bill 1422 Senate Human Services Committee

Supplemental information forwarded by psychiatrist Cheryl Huber, MD on 02/27/2007
Information refers to MedCenter One Health System, Bismarck

For 1 Emergency Dept. visit-
Level 4 facility charge is approx. $300-400, plus MD (ER physician) $75-300 (this is not counting if a psychiatrist goes to the ED, then add approx. another $200), plus any medications or other supplies.

For an inpatient hospital stay, the facility charge is $650-800 per day, plus MD charge of approx. $130-230 per day, plus OT/RT charge (estimate at least $200 additional per day) plus our entry point is usually the ED, so add that as a 1 time charge. An average length of stay is 3-7 days.

The other possible consideration is the wait time to get into the State Hospital. Within the past couple months I had a patient who was committed to Jamestown SH, but they did not have an opening for at least 5 days.

Supplemental information forwarded by psychiatrist Andrew J. McLean, MD on 03/06/2007
Information refers to MeritCare Health System, Fargo

A psychiatric visit to the ER is a cost of $206.00 and reimbursed by Medicaid at $103.28.
or a more complex consultation and visit by Psychiatry in ER is at $284.00 and reimbursed at $149.03.

The daily cost of inpatient care is $1250 plus additional charges for lab, etc. can put it at $1400.

Medicaid reimburses 37.4 % of charges or $523.60

#12

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1422

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to amend and reenact section 50-24.6-04 of the North Dakota Century Code, relating to the prior authorization program; to provide for review by the drug utilization review board; to provide an effective date; and to provide an expiration date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 50-24.6-04 of the North Dakota Century Code is amended and reenacted as follows:

50-24.6-04. (Effective through July 31, ~~2007~~ 2009) Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:
   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;
   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or
   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.
2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.
3. Except for quantity limits that may be no less than the pharmaceutical manufacturer's package insert or AB-rated generic equivalent drug for which the cost to the state postrebate is less than the brand name drugs, in the aggregate, the department may not prior authorize or otherwise restrict single-source or brand name antipsychotic, antidepressant, or other medications used to treat mental illnesses, such as schizophrenia, depression, or bipolar disorder, and drugs prescribed for the treatment of:

a. Acquired immune deficiency syndrome or human immunodeficiency virus; and
b. Cancer.

4. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.
5. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:
   a. Establish policies and procedures necessary to implement the prior authorization program.
   b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.
   c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

(Effective after July 31, ~~2007~~ 2009) Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:
   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;
   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or
   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.
2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.
3. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.

4. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:
   a. Establish policies and procedures necessary to implement the prior authorization program.
   b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.
   c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

SECTION 2. DRUG UTILIZATION REVIEW BOARD REVIEW. During the 2007-2008 interim, the drug utilization review board shall review the drugs identified in subsection 3 of section 50-24.6-04 and make recommendations for managing the utilization of the identified drugs or of any other drugs for the conditions identified in subsection 3. By July 1, 2008, the drug utilization review board shall report its findings and recommendations for legislative changes to the legislative council, including any legislation necessary to make the suggested changes. The legislative council shall receive the board's report and report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixty-first legislative assembly."

Renumber accordingly

SECTION 2. DRUG UTILIZATION REVIEW BOARD REVIEW. During the 2007-2008 interim, the drug utilization review board shall review the **utilization, cost, and effectiveness of the** drugs identified in subsection 3 of section 50-24.6-04 and make recommendations for managing the utilization of the identified drugs or of any other drugs for the conditions identified drugs or of any other drugs for the conditions identified in subsection 3. **The** drug utilization review board shall **make semi-annual reports of its progress, and one final report due by October 1, 2008, of its** findings and recommendations for legislative changes to **a committee of the** legislative council, including any legislation necessary to make the suggested changes. The legislative council shall receive the board's report and report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixty-first legislative assembly."

Renumber accordingly.