

**SENATE BILL NO. 2076  
with House Amendments**

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Introduced by

Human Services Committee

(At the request of the Department of Health and Human Services)

1 A BILL for an Act to amend and reenact section 50-24.6-04 of the North Dakota Century Code,  
2 relating to prior authorization and certification of medically necessary medication.

3 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

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

6 **50-24.6-04. Prior authorization program - Certification program.**

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

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

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

17 c. The drug is prescribed for a medically accepted use supported by a compendium  
18 or by approved product labeling unless there is a therapeutically equivalent drug  
19 that is available without prior authorization. The department shall work with the  
20 medical assistance recipient's health care provider to assure treatment can be  
21 found for diagnoses with no compendia supported medications.

- 1           2. For any drug placed on the prior authorization program, the department shall provide  
2           medical and clinical criteria, cost information, and utilization data to the drug use  
3           review board for review and consideration. The board may consider department data  
4           and information from other sources to make a decision about placement of the drug on  
5           prior authorization.
- 6           3. a. ~~For individuals eighteen years of age and older, except~~ Except for quantity limits  
7           that may be no less than the pharmaceutical manufacturer's package insert,  
8           brand name drugs with a generic equivalent drug for which the cost to the state  
9           postrebate is less than the brand name drugs, generic drugs with a brand name  
10          equivalent drug for which the cost to the state postrebate is less than the generic  
11          drug, or medications that are considered line extension drugs, the department  
12          may not prior authorize substantially all drugs in the following medication classes:  
13          (1) Antipsychotics;  
14          (2) Antidepressants;  
15          (3) Anticonvulsants;  
16          (4) Antiretrovirals, for the treatment of human immunodeficiency virus;  
17          (5) Antineoplastic agents; and  
18          (6) Immunosuppressants, for prophylaxis of organ transplant rejection.
- 19          b. ~~For individuals under eighteen years of age, except for quantity limits that may be~~  
20          ~~no less than the pharmaceutical manufacturer's package insert, brand name~~  
21          ~~drugs with a generic equivalent drug for which the cost to the state postrebate is~~  
22          ~~less than the brand name drugs, generic drugs with a brand name equivalent~~  
23          ~~drug for which the cost to the state postrebate is less than the generic drug, or~~  
24          ~~medications that are considered line extension drugs, the department may not~~  
25          ~~prior authorize substantially all drugs in the following medication classes:~~  
26          (1) Antipsychotics;  
27          (2) Antidepressants;  
28          (3) Anticonvulsants;  
29          (4) Antiretrovirals, for the treatment of human immunodeficiency virus;  
30          (5) Antineoplastic agents; and  
31          (6) Immunosuppressants, for prophylaxis of organ transplant rejection.

- 1           e. ~~The restrictions of subdivision b do not apply for individuals under eighteen years~~  
2           of age, who have five or more concurrent prescriptions for psychotropic  
3           medications.
- 4           d. ~~Prior authorization for individuals under eighteen years of age is required for five~~  
5           or more concurrent prescriptions for antipsychotics, antidepressants,  
6           anticonvulsants, benzodiazepines, mood stabilizers, sedative, hypnotics, or  
7           medications used for the treatment of attention deficit hyperactivity disorder. The  
8           department shall grant authorization to exceed the limits after a prescriber  
9           requesting authorization consults with a board certified child and adolescent  
10          psychiatrist approved by the department.
- 11          e. The restrictions of this subsection do not apply if prior authorization is required by  
12          the centers for Medicare and Medicaid services.
- 13          f.c. The restrictions of this subsection do not apply to a medication class in  
14          subdivision a if a manufacturer of a drug in that class excludes the department  
15          from supplemental rebate offers or value-based purchasing agreement offers due  
16          to the existence of the prior authorization exclusion in subdivision a.
- 17          d. As used in this subsection, "line extension drug" means a new formulation of a  
18          drug. The term does not include an abuse-deterrent formulation of a drug.
- 19          g.e. As used in this subsection, "substantially all" means that all drugs and unique  
20          dosage forms in the medication classes outlined in paragraphs 1 through 6 of  
21          subdivisions ~~subdivision~~ a and b are expected to be covered without prior  
22          authorization, ~~with the following exceptions~~ except:
- 23                  (1) Multisource brands of the identical molecular structure;
- 24                  (2) Extended release products when the immediate-release product is included;
- 25                  (3) Products that have the same active ingredient or moiety; and
- 26                  (4) Dosage forms that do not provide a unique route of administration.
- 27          4. The department may use contractors to collect and analyze the documentation  
28          required under this section and to facilitate the prior authorization program.
- 29          5. The department shall consult with the board in the course of adopting rules to  
30          implement the prior authorization program. The rules must:

- 1           a.   Establish policies and procedures necessary to implement the prior authorization  
2           program.
- 3           b.   Develop a process that allows prescribers to furnish documentation required to  
4           obtain approval for a drug without interfering with patient care activities.
- 5           c.   Allow the board to establish panels of physicians and pharmacists which provide  
6           expert guidance and recommendations to the board in considering specific drugs  
7           or therapeutic classes of drugs to be included in the prior authorization program.
- 8         6.   The department may negotiate additional rebates from drug manufacturers to  
9           supplement the rebates required by federal law governing the medical assistance  
10          program. Additionally, the department may join a multistate supplemental drug rebate  
11          pool, and if the department negotiates additional rebates outside this pool, any other  
12          manufacturer must be allowed to match those rebates.
- 13         7.   The department shall develop a certification program to verify the medical necessity of  
14          each medication in a regimen containing five or more concurrent prescriptions for  
15          antipsychotic, antidepressant, anticonvulsant, benzodiazepine, mood stabilizer,  
16          sedative hypnotic, or attention deficit hyperactivity disorder medications.
- 17           a.   The certification program shall require each prescriber of a medication in an  
18           impacted regimen to certify annually the medication prescribed is medically  
19           necessary for the patient.
- 20           b.   If a prescriber does not certify a medication as a medically necessary part of the  
21           patient's regimen, the department may deny payment of the medication until the  
22           medication is certified by the prescriber.
- 23           c.   The certification program shall apply to individuals under the age of twenty-two  
24           and may apply to other individuals at the discretion of the department.