

Introduced by

Senators Lee, Hogan, K. Roers

Representatives Dobervich, M. Ruby, Weisz

1 A BILL for an Act to amend and reenact sections 50-24.6-02 and 50-24.6-04 of the North
2 Dakota Century Code, relating to the drug use review board and medical assistance prior
3 authorization.

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

5 **SECTION 1. AMENDMENT.** Section 50-24.6-02 of the North Dakota Century Code is
6 amended and reenacted as follows:

7 **50-24.6-02. Drug use review board.**

- 8 1. The board is established within the department for the implementation of a drug use
9 review program.
- 10 2. The board consists of seventeen members. The pharmacy administrator of the
11 department and the medical consultant to the department are ex officio nonvoting
12 board members who shall provide administrative services to the board. A majority of
13 the appointed members must be physicians and pharmacists participating in the
14 medical assistance program. Four or more of the appointed members must have
15 experience with a drug use review process or have participated in programs in which
16 prior authorization is used. The appointed members of the board must be:
- 17 a. Four physicians licensed in this state and actively engaged in the practice of
18 medicine, one of whom is a psychiatrist, appointed by the North Dakota medical
19 association;
- 20 b. Two physicians licensed in this state and actively engaged in the practice of
21 medicine, appointed by the executive director of the department;
- 22 c. Four pharmacists licensed in this state and actively engaged in the practice of
23 pharmacy, appointed by the North Dakota pharmaceutical association;

- 1 d. Two pharmacists licensed in this state and actively engaged in the practice of
2 pharmacy, appointed by the executive director of the department;
- 3 e. One individual who represents consumer interests, appointed by the governor;
- 4 f. One pharmacist or physician representing the brand pharmaceutical industry
5 appointed by the pharmaceutical research and manufacturers of America; and
- 6 g. One pharmacist or physician representing the generic pharmaceutical industry
7 appointed by the ~~generic pharmaceutical~~ association for accessible medicines.
- 8 3. Appointed board members shall serve staggered three-year terms. An appointed
9 member may be reappointed for a period not to exceed three 3-year terms. A vacancy
10 on the board must be filled for the balance of the unexpired term from the appropriate
11 board category as provided under subsection 2. The executive director of the
12 department may replace an appointed member of the board who fails to attend three
13 consecutive meetings of the board without advance excuse or who fails to perform the
14 duties expected of a board member. The pharmaceutical industry representatives are
15 nonvoting board members.
- 16 4. Voting board members shall select a ~~chairman~~presiding officer and a vice
17 ~~chairman~~presiding officer on an annual basis from the board's voting membership.
18 One-half or more of nonvacant voting board member positions constitutes a quorum.
- 19 5. The board shall meet ~~in person~~ at least once every three months and may meet at
20 other times ~~by teleconference or electronically~~ at the discretion of the
21 ~~chairman~~presiding officer. A board member is entitled to receive from the department
22 or the department's vendor per diem compensation and reimbursement of expenses
23 as determined by the department or the department's vendor, except that no
24 compensation under this section may be paid to any board member who receives
25 compensation or salary as a state employee or official.
- 26 6. A board member appointed under subdivision f or subdivision g of subsection 2 is not
27 subject to the bona fide resident of the state requirement under section 44-03-04.

28 **SECTION 2. AMENDMENT.** Section 50-24.6-04 of the North Dakota Century Code is
29 amended and reenacted as follows:

1 **50-24.6-04. Prior authorization program.**

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

- 7 a. The drug not requiring prior authorization has not been effective, or with
8 reasonable certainty is not expected to be effective, in treating the recipient's
9 condition;
- 10 b. The drug not requiring prior authorization causes or is reasonably expected to
11 cause adverse or harmful reactions to the health of the recipient; or
- 12 c. The drug is prescribed for a medically accepted use supported by a compendium
13 or by approved product labeling unless there is a therapeutically equivalent drug
14 that is available without prior authorization.

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

20 3. a. For individuals twenty-one years of age and older, except for quantity limits that
21 may be no less than the pharmaceutical manufacturer's package insert, brand
22 name drugs with a generic equivalent drug for which the cost to the state
23 postrebate is less than the brand name drugs, generic drugs with a brand name
24 equivalent drug for which the cost to the state postrebate is less than the generic
25 drug, or medications that are considered line extension drugs, the department
26 may not prior authorize substantially all drugs in the following medication classes:

- 27 (1) Antipsychotics;
- 28 (2) Antidepressants;
- 29 (3) Anticonvulsants;
- 30 (4) Antiretrovirals, for the treatment of human immunodeficiency virus;
- 31 (5) Antineoplastic agents, ~~for the treatment of cancer;~~ and

- 1 (6) ~~Stimulant medication used for the treatment of attention deficit disorder and~~
2 ~~attention deficit hyperactivity disorder, except an individual who prescribes~~
3 ~~this medication at a rate two times higher than the rate of the top ten~~
4 ~~prescribers excluding the top prescriber may be subject to prior~~
5 ~~authorization~~Immunosuppressants, for prophylaxis of organ transplant
6 ~~rejection.~~
- 7 b. For individuals under twenty-one years of age, except for quantity limits that may
8 be no less than the pharmaceutical manufacturer's package insert, brand name
9 drugs with a generic equivalent drug for which the cost to the state postrebate is
10 less than the brand name drugs, generic drugs with a brand name equivalent
11 drug for which the cost to the state postrebate is less than the generic drug, or
12 medications that are considered line extension drugs, the department may not
13 prior authorize substantially all drugs in the following medication classes:
- 14 (1) Antipsychotics;
15 (2) Antidepressants;
16 (3) Anticonvulsants;
17 (4) Antiretrovirals, for the treatment of human immunodeficiency virus;
18 (5) Antineoplastic agents, ~~for the treatment of cancer;~~ and
19 (6) ~~Stimulant medication used for the treatment of attention deficit hyperactivity~~
20 ~~disorder~~Immunosuppressants, for prophylaxis of organ transplant rejection.
- 21 c. The restrictions of subdivision b do not apply for individuals under twenty-one
22 years of age, who have five or more concurrent prescriptions for psychotropic
23 medications.
- 24 d. Prior authorization for individuals under twenty-one years of age is required for
25 five or more concurrent prescriptions for antipsychotics, antidepressants,
26 anticonvulsants, benzodiazepines, mood stabilizers, sedative, hypnotics, or
27 medications used for the treatment of attention deficit hyperactivity disorder. The
28 department shall grant authorization to exceed the limits after a prescriber
29 requesting authorization consults with a board certified pediatric psychiatrist
30 approved by the department.

- 1 e. The restrictions of this subsection do not apply if prior authorization is required by
2 the centers for Medicare and Medicaid services.
- 3 f. As used in this subsection, "line extension drug" means a new formulation of a
4 drug. The term does not include an abuse-deterrent formulation of a drug.
- 5 g. As used in this subsection, "substantially all" means that all drugs and unique
6 dosage forms in the medication classes outlined in paragraphs 1 through 6 of
7 subdivisions a and b are expected to be covered without prior authorization, with
8 the following exceptions:
- 9 (1) Multisource brands of the identical molecular structure;
10 (2) Extended release products when the immediate-release product is included;
11 (3) Products that have the same active ingredient or moiety; and
12 (4) Dosage forms that do not provide a unique route of administration.
- 13 4. The department may use contractors to collect and analyze the documentation
14 required under this section and to facilitate the prior authorization program.
- 15 5. The department shall consult with the board in the course of adopting rules to
16 implement the prior authorization program. The rules must:
- 17 a. Establish policies and procedures necessary to implement the prior authorization
18 program.
- 19 b. Develop a process that allows prescribers to furnish documentation required to
20 obtain approval for a drug without interfering with patient care activities.
- 21 c. Allow the board to establish panels of physicians and pharmacists which provide
22 expert guidance and recommendations to the board in considering specific drugs
23 or therapeutic classes of drugs to be included in the prior authorization program.
- 24 6. The department may negotiate additional rebates from drug manufacturers to
25 supplement the rebates required by federal law governing the medical assistance
26 program. Additionally, the department may join a multistate supplemental drug rebate
27 pool, and if the department negotiates additional rebates outside this pool, any other
28 manufacturer must be allowed to match those rebates.