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Sixty-first
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1385
with Senate Amendments

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Introduced by

Representatives Weisz, Nelson, Pollert

Senators Erbele, Nething

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

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

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

50-24.6-02. Drug use review board.

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

d. Two pharmacists licensed in this state and actively engaged in the practice of pharmacy, appointed by the executive director of the department;

e. One individual who represents consumer interests, appointed by the governor; ~~and~~

f. One pharmacist or physician representing the brand pharmaceutical industry appointed by the pharmaceutical research and manufacturers of America; and

g. One pharmacist or physician representing the generic pharmaceutical industry appointed by the generic pharmaceutical association.

3. Appointed board members shall serve staggered three-year terms. ~~Two physicians and two pharmacists must be initially appointed for two-year terms, and two physicians and two pharmacists must be initially appointed for one-year terms.~~ An appointed member may be reappointed for a period not to exceed three 3-year terms. A vacancy on the board must be filled for the balance of the unexpired term from the appropriate board category as provided under subsection 2. The executive director of the department may replace an appointed member of the board who fails to attend three consecutive meetings of the board without advance excuse or who fails to perform the duties expected of a board member. The pharmaceutical industry ~~representative is a~~ representatives are nonvoting board ~~member~~ members.

4. Voting board members shall select a chairman and a vice chairman on an annual basis from the board's voting membership.

5. The board shall meet in person at least once every three months and may meet at other times by teleconference or electronically at the discretion of the chairman. A board member is entitled to receive from the department per diem compensation and reimbursement of expenses as determined by the department, except that no compensation under this section may be paid to any board member who receives compensation or salary as a state employee or official.

SECTION 2. 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, 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~~, or brand name drugs with a 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~~ the following medication classes:
   a. Antipsychotics;
   b. Antidepressants;
   c. Anticonvulsants;

d. Antiretrovirals, for the treatment of human immunodeficiency virus;

e. Antineoplastic agents, for the treatment of cancer; and

f. Stimulant medication used for the treatment of attention deficit disorder and attention deficit hyperactivity disorder.

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, 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.~~