CHAPTER 50-24.6
MEDICAL ASSISTANCE DRUG USE REVIEW AND AUTHORIZATION

50-24.6-01. Definitions.

As used in this chapter, unless the context otherwise requires:

1. "Board" means the drug use review board.
2. "Compendium" means the American hospital formulary service drug information, United States pharmacopeia-drug information, the DRUGDEX information system, American medical association drug evaluations, or nonproprietary peer-reviewed medical literature.
3. "Department" means the department of health and human services.
4. "Drug use review" means a program as described in 42 U.S.C. 1396r-8(g)(2).
5. "Drug use review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, to be medically necessary, and not result in adverse medical outcomes.
6. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or the department's contractor that proposed medical use of a particular drug for a medical assistance program recipient meets predetermined criteria for coverage by the medical assistance program.

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 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 commissioner of the department or the commissioner's designee;
   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 commissioner of the department or the commissioner's designee;
   e. One individual who represents consumer interests, appointed by the governor;
   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 association for accessible medicines.
3. Appointed board members shall serve staggered three-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 commissioner of the department or the commissioner's designee 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 representatives are nonvoting board members.

4. Voting board members shall select a presiding officer and a vice presiding officer on an annual basis from the board's voting membership. One-half or more of nonvacant voting board member positions constitutes a quorum.
5. The board shall meet at least once every three months and may meet at other times at the discretion of the presiding officer. A board member is entitled to receive from the department or the department's vendor per diem compensation and reimbursement of expenses as determined by the department or the department's vendor, 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.
6. A board member appointed under subdivisions a through d of subsection 2 is not subject to the bona fide resident of the state requirement under section 44-03-04 if the board member is providing services to residents of the state receiving medical assistance through telemedicine or telepharmacy. The affected association shall continue to recruit in-state board members for that board member position and will replace the nonresident board member once the affected association has enough appointees for all of their board member positions.
7. A board member appointed under subdivision f or subdivision g of subsection 2 is not subject to the bona fide resident of the state requirement under section 44-03-04.

50-24.6-03. Duties of the board.

The board shall:

1. Cooperate with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs under the medical assistance program. This drug use review program must be based on a compendium and drug use review criteria and must comply with 42 U.S.C. 1396r-8(g)(3).
2. Advise and make recommendations regarding any rule proposed for adoption by the department to implement the provisions of state and federal law related to drug use review.
3. Receive and consider information regarding the drug use review process which is provided by the department and by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program.
4. Review and recommend to the department any drugs to be included on prior authorization status.
5. Review no less than once each year the status of the list of drugs that have been placed on prior authorization.
6. Review and approve the prior authorization program process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation.
7. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.

50-24.6-04. 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. The department shall work with the

medical assistance recipient's health care provider to assure treatment can be found for diagnoses with no compendia supported medications.

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. a. For individuals eighteen years of age and older, except for quantity limits that may be no less than the pharmaceutical manufacturer's package insert, brand name drugs with a generic equivalent drug for which the cost to the state postrebate is less than the brand name drugs, generic drugs with a brand name equivalent drug for which the cost to the state postrebate is less than the generic drug, or medications that are considered line extension drugs, the department may not prior authorize substantially all drugs in the following medication classes:
   (1) Antipsychotics;
   (2) Antidepressants;
   (3) Anticonvulsants;
   (4) Antiretrovirals, for the treatment of human immunodeficiency virus;
   (5) Antineoplastic agents; and
   (6) Immunosuppressants, for prophylaxis of organ transplant rejection.

   b. For individuals under eighteen years of age, except for quantity limits that may be no less than the pharmaceutical manufacturer's package insert, brand name drugs with a generic equivalent drug for which the cost to the state postrebate is less than the brand name drugs, generic drugs with a brand name equivalent drug for which the cost to the state postrebate is less than the generic drug, or medications that are considered line extension drugs, the department may not prior authorize substantially all drugs in the following medication classes:
   (1) Antipsychotics;
   (2) Antidepressants;
   (3) Anticonvulsants;
   (4) Antiretrovirals, for the treatment of human immunodeficiency virus;
   (5) Antineoplastic agents; and
   (6) Immunosuppressants, for prophylaxis of organ transplant rejection.

   c. The restrictions of subdivision b do not apply for individuals under eighteen years of age, who have five or more concurrent prescriptions for psychotropic medications.

   d. Prior authorization for individuals under eighteen years of age is required for five or more concurrent prescriptions for antipsychotics, antidepressants, anticonvulsants, benzodiazepines, mood stabilizers, sedative, hypnotics, or medications used for the treatment of attention deficit hyperactivity disorder. The department shall grant authorization to exceed the limits after a prescriber requesting authorization consults with a board certified child and adolescent psychiatrist approved by the department.

   e. The restrictions of this subsection do not apply if prior authorization is required by the centers for Medicare and Medicaid services.

   f. As used in this subsection, "line extension drug" means a new formulation of a drug. The term does not include an abuse-deterrent formulation of a drug.

   g. As used in this subsection, "substantially all" means that all drugs and unique dosage forms in the medication classes outlined in paragraphs 1 through 6 of subdivisions a and b are expected to be covered without prior authorization, with the following exceptions:
   (1) Multisource brands of the identical molecular structure;
   (2) Extended release products when the immediate-release product is included;
   (3) Products that have the same active ingredient or moiety; and
   (4) Dosage forms that do not provide a unique route of administration.

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.
6. The department may negotiate additional rebates from drug manufacturers to supplement the rebates required by federal law governing the medical assistance program. Additionally, the department may join a multistate supplemental drug rebate pool, and if the department negotiates additional rebates outside this pool, any other manufacturer must be allowed to match those rebates.

50-24.6-05. Public notice - Applicability.

1. The department shall provide thirty days' notice of all meetings of the board. The notice requirement is met if the department provides notice of the meeting on the department's website and provides, by written or electronic means, individual notice to each person that has requested such notice. If the meeting agenda includes board consideration of a change to the prior authorization program, the department shall include in the notice a list of the affected drugs, and upon request the board shall provide background information. Any interested party may attend a meeting of the board and provide information or recommendations related to the inclusion of a drug in a prior authorization program.
2. The department shall post on the department's website:
   a. The most current and applicable list of drugs requiring prior authorization, together with any limits on coverage of these drugs.
   b. In downloadable format, forms necessary to complete prior authorization requests.
   c. Decisions regarding changes to the prior authorization program list. The department shall allow a period of no less than thirty days for public comment following posting on the website.
   d. Meeting notice.
3. The department may not discontinue the provision of prescription drug benefits being provided to medical assistance recipients before April 14, 2003, based solely on the subsequent placement of the drug on the prior authorization program.

50-24.6-06. Grievances.

Expired under S.L. 2003, ch. 430, § 12.

50-24.6-07. Appeals.

A medical assistance recipient who is aggrieved by the placement of a drug on prior authorization may appeal as authorized under chapter 28-32.

50-24.6-08. Financial incentives prohibited.

The department may not offer or pay, directly or indirectly, any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy or based on a reduction in the proportion of recipients who receive prescription drug therapy under the medical assistance program.

50-24.6-09. Maximum allowable costs and use of edits.

1. To promote efficiency and savings in the department's service to eligible medical assistance program recipients, the department shall create and implement the broadest possible list of drugs that can be paid at the maximum allowable costs. To further promote efficiency and savings, the department shall maximize use of edit programs that pertain to payment of medical assistance program pharmaceutical claims. Upon request of a member of the legislative assembly, the department shall provide to that member a summary of edit programs available to the medical assistance program and a description of the department's progress in implementing the edit programs.
2. The department shall participate in current and future innovative rebate and other program options, including value-based purchasing programs, as feasible, reasonable, and cost-effective for the state.

50-24.6-10. Adoption of rules.

The department shall adopt rules to implement this chapter.