

## **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 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 sixteen 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 pharmaceutical industry appointed by the pharmaceutical research manufacturers of America.

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 nonvoting board member.
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.

**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. (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 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, 2009) Prior authorization program.**

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- 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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  - 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.

**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 web site 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 web site:
  - 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 web site.
  - 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.** 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.

**50-24.6-10. Adoption of rules.** The department shall adopt rules to implement this chapter.