

**FIRST ENGROSSMENT
with Senate Amendments**

Fifty-eighth
Legislative Assembly
of North Dakota

ENGROSSED HOUSE BILL NO. 1430

Introduced by

Representatives Devlin, Price, Weisz

Senators Fischer, J. Lee

1 A BILL for an Act to establish a medical assistance drug use review program and drug prior
2 authorization program within the department of human services; to provide for a legislative
3 council study of medical assistance pharmacy benefit management; to provide an expiration
4 date; and to declare an emergency.

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

6 **SECTION 1. Definitions.** As used in this Act, unless the context otherwise requires:

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

21 **SECTION 2. Drug use review board.**

- 22 1. The board is established within the department for the implementation of a drug
23 use review program.

- 1 2. The board consists of fifteen members. The pharmacy administrator of the
2 department and the medical consultant to the department are ex officio nonvoting
3 board members who shall provide administrative services to the board. The
4 executive director of the department shall appoint the remaining thirteen board
5 members. A majority of the appointed members must be physicians and
6 pharmacists participating in the medical assistance program. Four or more of the
7 appointed members must have experience with a drug use review process or have
8 participated in programs in which prior authorization is used. The appointed
9 members of the board must be:
- 10 a. Six physicians licensed in this state and actively engaged in the practice of
11 medicine, one of whom is a psychiatrist, and four of whom are chosen from a
12 list of nominees provided by the North Dakota medical association;
- 13 b. Six pharmacists licensed in this state and actively engaged in the practice of
14 pharmacy, four of whom are chosen from a list of nominees provided by the
15 North Dakota pharmaceutical association; and
- 16 c. One pharmacist or physician representing the pharmaceutical industry who is
17 chosen from a list of nominees provided by the pharmaceutical research
18 manufacturers of America.
- 19 3. Appointed board members shall serve staggered three-year terms. Two
20 physicians and two pharmacists must be initially appointed for two-year terms, and
21 two physicians and two pharmacists must be initially appointed for one-year terms.
22 An appointed member may be reappointed for a period not to exceed three 3-year
23 terms. A vacancy on the board must be filled for the balance of the unexpired term
24 from the appropriate board category as provided under subsection 2. The
25 executive director of the department may replace an appointed member of the
26 board who fails to attend three consecutive meetings of the board without advance
27 excuse or who fails to perform the duties expected of a board member. The
28 pharmaceutical industry representative is a nonvoting board member.
- 29 4. Voting board members shall select a chairman and a vice chairman on an annual
30 basis from the board's voting membership.

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

7 **SECTION 3. Duties of the board.** The board shall:

- 8 1. Cooperate with the department to create and implement a prospective and
9 retrospective drug use review program for outpatient prescription drugs under the
10 medical assistance program. This drug use review program must be based on a
11 compendium and drug use review criteria and must comply with 42 U.S.C.
12 1396r-8(g)(3).
- 13 2. Advise and make recommendations regarding any rule proposed for adoption by
14 the department to implement the provisions of state and federal law related to drug
15 use review.
- 16 3. Receive and consider information regarding the drug use review process which is
17 provided by the department and by interested parties, including prescribers who
18 treat significant numbers of patients under the department's medical assistance
19 program.
- 20 4. Review and recommend to the department any drugs to be included on prior
21 authorization status.
- 22 5. Review no less than once each year the status of the list of drugs that have been
23 placed on prior authorization.
- 24 6. Review and approve the prior authorization program process used by the
25 department, including the process to accommodate the provision of a drug benefit
26 in an emergency situation.
- 27 7. Propose remedial strategies to improve the quality of care and to promote effective
28 use of medical assistance program funds or recipient expenditures.

29 **SECTION 4. Prior authorization program.**

- 30 1. The department shall develop and implement a prior authorization program that
31 meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug

- 1 products when a medical assistance recipient's health care provider prescribes a
2 drug that is identified as requiring prior authorization. Authorization must be
3 granted for provision of the drug if:
- 4 a. The drug not requiring prior authorization has not been effective, or with
5 reasonable certainty is not expected to be effective, in treating the recipient's
6 condition;
 - 7 b. The drug not requiring prior authorization causes or is reasonably expected to
8 cause adverse or harmful reactions to the health of the recipient; or
 - 9 c. The drug is prescribed for a medically accepted use supported by a
10 compendium or by approved product labeling unless there is a therapeutically
11 equivalent drug that is available without prior authorization.
- 12 2. For any drug placed on the prior authorization program, the department shall
13 provide medical and clinical criteria, cost information, and utilization data to the
14 drug use review board for review and consideration. The board may consider
15 department data and information from other sources to make a decision about
16 placement of the drug on prior authorization.
- 17 3. The department may use contractors to collect and analyze the documentation
18 required under this section and to facilitate the prior authorization program.
- 19 4. The department shall consult with the board in the course of adopting rules to
20 implement the prior authorization program. The rules must:
- 21 a. Establish policies and procedures necessary to implement the prior
22 authorization program.
 - 23 b. Develop a process that allows prescribers to furnish documentation required
24 to obtain approval for a drug without interfering with patient care activities.
 - 25 c. Allow the board to establish panels of physicians and pharmacists which
26 provide expert guidance and recommendations to the board in considering
27 specific drugs or therapeutic classes of drugs to be included in the prior
28 authorization program.

29 **SECTION 5. Public notice - Applicability.**

- 30 1. The department shall provide thirty days' notice of all meetings of the board. The
31 notice requirement is met if the department provides notice of the meeting on the

1 department's web site and provides, by written or electronic means, individual
2 notice to each person that has requested such notice. If the meeting agenda
3 includes board consideration of a change to the prior authorization program, the
4 department shall include in the notice a list of the affected drugs, and upon request
5 the board shall provide background information. Any interested party may attend a
6 meeting of the board and provide information or recommendations related to the
7 inclusion of a drug in a prior authorization program.

- 8 2. The department shall post on the department's web site:
- 9 a. The most current and applicable list of drugs requiring prior authorization,
10 together with any limits on coverage of these drugs.
 - 11 b. In downloadable format, forms necessary to complete prior authorization
12 requests.
 - 13 c. Decisions regarding changes to the prior authorization program list. The
14 department shall allow a period of no less than thirty days for public comment
15 following posting on the web site.
 - 16 d. Meeting notice.
- 17 3. The department may not discontinue the provision of prescription drug benefits
18 being provided to medical assistance recipients before the effective date of this Act
19 based solely on the subsequent placement of the drug on the prior authorization
20 program.

21 **SECTION 6. Grievances.** The department shall adopt rules for a grievance procedure
22 by which an interested person may appeal a department decision to place a drug on prior
23 authorization.

24 **SECTION 7. Appeals.** A medical assistance recipient who is aggrieved by the
25 placement of a drug on prior authorization may appeal as authorized under chapter 28-32.

26 **SECTION 8. Financial incentives prohibited.** The department may not offer or pay,
27 directly or indirectly, any material inducement, bonus, or other financial incentive to a
28 participating provider based on the denial or delay of medically necessary and appropriate
29 prescription drug therapy or based on a reduction in the proportion of recipients who receive
30 prescription drug therapy under the medical assistance program.

1 **SECTION 9. Maximum allowable costs and use of edits.** To promote efficiency and
2 savings in the department's service to eligible medical assistance program recipients, the
3 department shall create and implement the broadest possible list of drugs that can be paid at
4 the maximum allowable costs. To further promote efficiency and savings, the department shall
5 maximize use of edit programs that pertain to payment of medical assistance program
6 pharmaceutical claims. Upon request of a member of the legislative assembly, the department
7 shall provide to that member a summary of edit programs available to the medical assistance
8 program and a description of the department's progress in implementing the edit programs.

9 **SECTION 10. Adoption of rules.** The department shall adopt rules to implement
10 sections 1 through 9 of this Act.

11 **SECTION 11. MEDICAL ASSISTANCE PHARMACY BENEFIT MANAGEMENT -**
12 **LEGISLATIVE COUNCIL STUDY.** The legislative council shall consider studying, during the
13 2003-04 interim, the value of medical assistance program use of benefit purchasing pools,
14 preferred drug lists, and other pharmacy benefit management concepts, including the fiscal
15 impact of the appeals and grievance process on existing programs. If the study is conducted
16 by the legislative council, the legislative council shall report its findings and recommendations,
17 together with any legislation required to implement the recommendations, to the fifty-ninth
18 legislative assembly.

19 **SECTION 12. EXPIRATION DATE.** Section 6 of this Act is effective through June 30,
20 2005, and after that date is ineffective.

21 **SECTION 13. EMERGENCY.** This Act is declared to be an emergency measure.