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Fifty-eighth
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED HOUSE BILL NO. 1430

Introduced by

Representatives Devlin, Price, Weisz

Senators Fischer, J. Lee

A BILL for an Act to establish a drug utilization review program and drug prior authorization program within the department of human services; and to declare an emergency.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Definitions.

1. "Board" means the drug utilization review board.
2. "Committee" means the pharmacy and therapeutics committee.
3. "Compendia" means the "American hospital formulary services drug information", "United States pharmacopeia - drug information", and clinical information submitted to the department by the pharmaceutical research company that developed the product and is registered with the federal food and drug administration as the product distributor.
4. "Department" means the department of human services.
5. "Drug utilization review" means both retrospective and prospective drug utilization review. The reviews are designed to ensure that drug utilization is medically appropriate, medically necessary, and not likely to have adverse medical results.
6. "Drug utilization review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, medically necessary, and not result in adverse medical outcomes.
7. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or its contractor that proposed medical use of a particular medicine for a patient meets predetermined criteria for coverage by the program.
8. "Prospective drug utilization review" means that part of the drug utilization review program that occurs before a drug is dispensed and that uses the drug utilization

review criteria to screen for potential drug therapy problems related to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

9. "Retrospective drug utilization review" means that part of the drug utilization review program that is an historical review of drug utilization data using drug utilization review criteria examine pharmacy claims data and other information to identify overutilization, underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse or misuse.

SECTION 2. Establishment of drug utilization review board.

1. The drug utilization review board is established within the department for the implementation of a retrospective and prospective drug utilization review program.
2. The board consists of eighteen members appointed by the executive director of the department as follows:
   a. Six physicians licensed in this state and actively engaged in the practice of medicine, four of whom are chosen from a list of nominees provided by the North Dakota medical association;
   b. Six pharmacists licensed in this state, actively engaged in the practice of pharmacy, four of whom are chosen from a list of nominees provided by the North Dakota pharmacy association;
   c. Two individuals who are residents of this state chosen to represent program beneficiaries in this state; and
   d. Two individuals representing the pharmaceutical industry chosen from a list of nominees provided by the pharmaceutical research and manufacturers of America;
   e. The pharmacy administrator of the department; and
   f. The medical consultant to the department.
3. Board members shall serve staggered three-year terms. Two physicians, two pharmacists, and one beneficiary representative must be initially appointed for two-year terms; and two physicians, two pharmacists, and one industry

representative must be initially appointed for one-year terms. A member may be reappointed for a period not to exceed three 3-year terms. Vacancies on the board must be filled for the balance of the unexpired term from the appropriate board category as provided under subsection 2.

4. Board members shall select a chairman and a vice chairman on an annual basis from the board membership.

5. The board shall meet at least once every two months and may meet at other times at the discretion of the chairman.

SECTION 3. Duties of the drug utilization review board. The duties of the board must be consistent with 42 U.S.C. 1396r-8(g)(3). In addition, the board shall:

1. Advise and make recommendations regarding rules adopted by the department implementing the provisions of state and federal law related to drug utilization review;

2. Oversee the implementation of a retrospective and prospective drug utilization review program for the medical assistance program, including responsibility for recommending criteria for selection of contractors and reviewing contracts between the medical assistance program and any other entity that will process and review drug claims and profiles for the drug utilization review program in accordance with this Act;

3. Develop and apply the drug utilization review criteria for the retrospective and prospective drug utilization review programs, provided that the drug utilization review criteria are consistent with the indications supported and rejected by the compendia and federal food and drug administration-approved labeling for the drug. The board also shall consider outside information provided by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program;

4. Establish a process to reassess on a periodic basis the drug utilization review criteria and, as necessary, modify the prospective and retrospective drug utilization review programs; and

5. Provide a period for public comment during each board meeting. Notice of proposed changes to the drug utilization review criteria and modification of the

prospective and retrospective drug utilization review programs must be furnished to the public thirty days before the consideration or recommendation of any proposed changes to the drug utilization review programs.

SECTION 4. Prospective and retrospective drug utilization review programs.

1. The board, in cooperation with the department, shall create and implement a prospective and retrospective drug utilization review program for outpatient prescription drugs under the medical assistance program using drug utilization review criteria to ensure that drug utilization is medically appropriate, medically necessary, and not likely to result in adverse medical outcomes.
2. The department may contract with an entity to process and review drug claims and profiles for the drug utilization review program provided that the department uses a competitive bidding process.
3. The prospective drug utilization review program must be based on drug utilization review criteria established by the board and must provide that, before a prescription is filled or delivered, a review must be conducted by a pharmacist at the point of sale to screen for potential drug therapy problems. In conducting the prospective drug utilization review, the prescribed outpatient drug therapy may not be altered without a new prescription order by the prescribing physician and approval by the patient. The prospective drug utilization review must screen for:
   a. Therapeutic duplication;
   b. Drug-disease contraindications;
   c. Drug-drug interactions;
   d. Incorrect drug dosage or duration of drug treatment;
   e. Drug-allergy interactions; and
   f. Clinical abuse or misuse.
4. The retrospective drug utilization review program must be based on drug utilization review criteria by the board using the department's mechanized drug claims processing and information retrieval system to analyze assistance claims to:
   a. Identify patterns of fraud, abuse, gross overuse or underuse, and inappropriate or medically unnecessary care;

b. Assess data on drug use by applying and reviewing criteria developed from the compendia or federal drug administration-approved labeling for the purpose of evaluating:
   (1) Therapeutic appropriateness;
   (2) Overutilization or underutilization;
   (3) Appropriate use of generic products;
   (4) Therapeutic duplication;
   (5) Drug-disease contraindications;
   (6) Drug-drug interactions;
   (7) Incorrect drug dosage or duration of drug treatment; and
   (8) Clinical abuse or misuse; and

c. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or beneficiary expenditures.

SECTION 5. Establishment of the pharmacy and therapeutics committee.

1. Notwithstanding any other law, the department may implement a prior authorization program for outpatient prescription drugs under the medical assistance program only as provided in this section.
2. The pharmacy and therapeutics committee is established within the department for the purposes of implementing prior authorization for outpatient prescription drugs under the medical assistance program. Members appointed to the committee may be appointed from among the board and may also serve as members of the board.
3. The committee consists of eight members appointed by the executive director of the department as follows:
   a. Three physicians of different medical specialities licensed in this state and actively engaged in the practice of medicine who may be chosen from among physician members of the board or from a list of nominees provided by the North Dakota medical association;
   b. Three pharmacists licensed in this state and actively engaged in the practice of pharmacy, who may be chosen from among the pharmacist members of

the board or from a list of nominees provided by North Dakota pharmacy association;

c. One person who represents medical assistance beneficiaries in this state; and

d. One person representing the pharmaceutical industry who is a resident of this state, chosen from a list of nominees provided by the pharmaceutical research and manufacturers of America.

4. Committee members shall serve staggered three-year terms. One physician, one pharmacist, and the consumer representative must be initially appointed for two-year terms; and one physician, one pharmacist, and the industry representative must be initially appointed for one-year terms. A member may be reappointed for a period not to exceed three 3-year terms. Vacancies on the board must be filled for the balance of the unexpired term from nominee lists for the appropriate board category as provided under subsection 3.

5. Committee members shall select a chairman and vice chairman on an annual basis from the committee membership.

6. The committee shall meet at least bimonthly and may meet at other times at the discretion of the chairman.

SECTION 6. Duties of the pharmacy and therapeutics committee. The committee shall:

1. Advise and make recommendations regarding rules to be adopted by the department regarding outpatient prescription drug prior authorization.

2. Oversee the implementation of a drug prior authorization program for the department's medical assistance program;

3. Establish the drug prior authorization review process in compliance with section 7 of this Act;

4. Make formal recommendations to the department regarding the outpatient prescription drug covered by the medical assistance program that is to be prior authorized;

5. Review on at least an annual basis whether drugs placed on prior authorization should remain on prior authorization; and

6. Modify the prior authorization review process, as necessary, to achieve the objectives of this Act.

SECTION 7. Drug prior authorization review process.

1. Any drug prior authorization program must meet the following conditions:
   a. The program must provide telephone, facsimile, or other electronically transmitted approval or denial within twenty-four hours after receipt of the completed prior authorization request.
   b. In an emergency situation, including a situation in which a response to a prior authorization request is unavailable, a seventy-two hour supply of the prescribed drug must be dispensed and paid for by the medical assistance program, or, at the discretion of the committee, a supply greater than seventy-two hours which will assure a minimum effective duration of therapy for an acute intervention.
   c. Authorization must be granted if the drug is prescribed for a medically accepted use supported by either the compendia or approved product labeling unless there is a therapeutically equivalent generic drug that is available without prior authorization. The department may contract with third parties to collect and analyze the documentation required by this subsection.
   d. To support the prior authorization request, the program must consult with prescribers to develop a streamlined process for the prescriber to furnish any documentation required, including the name, title, address, and telephone number of the prescriber making the request; the date of the request; the product name of the requested drug; a description of the circumstances and basis for the request; and whether the request is an emergency. The process must flow directly from the patient care interaction and not a separate set of tasks required of the prescriber by the department.
2. A drug may not be recommended for prior authorization by the committee and placed on prior authorization by the department unless the following conditions are met:
   a. The committee analyzes the retrospective drug utilization review data using the drug utilization review criteria to identify a drug whose use is likely not to

be medically appropriate or medically necessary, or likely to result in adverse medical outcome;

b. The committee considers the potential impact on patient care and the potential fiscal impact that may result from placement of such a drug on prior authorization;

c. Any consideration of the cost of the drug by the committee must reflect the total cost of treating the conditions for which the drug is prescribed, including nonpharmaceutical costs and costs incurred by other sectors of the state health care program that may be affected by the drug's availability for use in treating program beneficiaries;

d. The committee provides at least thirty days' advance public notice before any meeting developing recommendations concerning whether such a drug should be placed on prior authorization. Any interested person may request an opportunity to make an oral presentation to the committee related to the prior authorization of the drug. The committee shall also consider any information provided by any interested person, including physicians, pharmacists, beneficiaries, and manufacturers or distributors of the drug;

e. The committee makes a formal written recommendation to the department that the drug be placed on prior authorization which must be supported by an analysis of prospective and retrospective drug utilization review data demonstrating:

(1) The expected impact of the decision on the clinical care likely to be received by beneficiaries for whom the drug is medically necessary;

(2) The expected impact on physicians whose patients require the drug; and

(3) The expected fiscal impact on the medical assistance program;

f. The department accepts or rejects the recommendation of the committee and, in a written decision, determines whether the drug should be placed on prior authorization. The department may consider any additional and clarifying information provided by any interested party rendering its decision;

g. The department's decision must be published for public comment for a period of no less than thirty days. The effective date of the decision may not be before the close of the comment period and effective notice of the decision's finality is available to prescribers.

3. The committee shall develop a grievance mechanism for interested parties to appeal the department's decision to place a drug on prior authorization. After participating in the grievance mechanism developed by the committee, any interested party aggrieved by the placement of a drug on prior authorization is entitled to an administrative hearing before the department under chapter 28-32.

4. The committee shall review the prior authorization status of a drug not less than once each year.

5. The committee shall provide at least thirty days advance public notice prior to any meeting determining whether changes should be made to the drug prior authorization review process.

SECTION 8. Denial or delay of care. Notwithstanding any other provision of law, any individual whose health care has been denied or delayed more than twenty-four hours as a result of an administrative procedure implemented by the department or any of its contractors may bring an action in district court. The administrative procedures include prior authorization, formularies, preferred drug lists, step therapy, or treatment protocols. The court may provide equitable relief and specific remedies. If a department contractor has acted with disregard for the prescribing physician's judgment regarding medically necessary care for the individual, the court may provide for exemplary damages. If the court finds against the department, the court shall award reasonable attorney's fees and court costs, regardless of whether the court awards specific relief or damages to the plaintiff.

SECTION 9. Preferred drug list procedures. A pharmaceutical manufacturer may appeal to the district court a decision of the department or its contractor to exclude a specific drug from a preferred drug list or formulary on the grounds that the decision is arbitrary, unfair, or a violation of state law, or in the case of a single source drug, on the grounds that the exclusion is not consistent with 42 U.S.C. 1396r-8(d)(4).

SECTION 10. 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 a reduction in the proportion of beneficiaries who receive prescription drug therapy under the medical assistance program.

SECTION 11. Adoption of rules. The department may adopt rules to implement this Act.

SECTION 12. EMERGENCY. This Act is declared to be an emergency measure.