PROPOSED AMENDMENT TO SENTATE BILL NO. 2076

A BILL for an Act to amend and reenact section 50-24.6-04 of the North Dakota Century Code, relating to prior authorization and certification program.

50-24.6-04. Prior authorization program – Certification 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~~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.~~c. The restrictions of this subsection do not apply to a medication class in subdivision a if a manufacturer of a drug in that class excludes the department from supplemental rebate offers or value-based purchasing agreement offers due to the existence of the prior authorization exclusion in subdivision a.

d. 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.~~e. 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~~subdivision a ~~and b~~ are expected to be covered without prior authorization, ~~with the following exceptions~~except:

(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.

7. The department shall develop a certification program to verify the medical necessity of medication regimens that contain 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.

   a. The certification program will require that each prescriber of a medication within an impacted regimen certify yearly that the medication they prescribed is medically necessary for that patient.

b. If a prescriber does not certify that a medication is a medically necessary part of their patient's regimen, the department may deny payment of the medication until it is certified by the prescriber.

c. The certification program will apply to:

(1) Individuals under the age of twenty-two.

(2) Other individuals at the discretion of the department.