H-1151.1

HOUSE BILL 1645

State of Washington 57th Legislature 2001 Regular Session

By Representatives Schual-Berke, Campbell, Edmonds, Alexander and Skinner

Read first time 01/31/2001. Referred to Committee on Health Care.

AN ACT Relating to the establishment of a drug utilization review program and a drug prior authorization program under the medical assistance program; amending RCW 74.09.010; adding new sections to chapter 74.09 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature recognizes that outpatient prescription drugs are an essential component of patient care. The legislature directs the department of social and health services' medical assistance administration to administer its prescription drug prior authorization and drug utilization programs in a manner that ensures that beneficiaries have access to medically necessary medicines, giving primary consideration to clinical efficacy and client care. Cost-effectiveness may also be considered where such consideration would not jeopardize beneficiary access to clinically efficacious prescription drugs.

Sec. 2. RCW 74.09.010 and 1990 c 296 s 6 are each amended to read as follows:

As used in this chapter:

(1) "Children's health program" means the health care services program provided to children under eighteen years of age and in households with incomes at or below the federal poverty level as annually defined by the federal department of health and human services as adjusted for family size, and who are not otherwise eligible for medical assistance or the limited casualty program for the medically needy.

(2) "Committee" means the ((~~children's health services~~)) drug utilization and education committee ((~~created in section 3 of this act~~)).

(3) "Compendia" means the "American Hospital Formulary Services Drug Information," "U.S. Pharmacopeia--Drug Information," peer-reviewed medical literature, and clinical information submitted to the state medicaid agency by the pharmaceutical research company that developed the product and is registered with the federal food and drug administration as the product distributor.

(4) "County" means the board of county commissioners, county council, county executive, or tribal jurisdiction, or its designee. A combination of two or more county authorities or tribal jurisdictions may enter into joint agreements to fulfill the requirements of RCW 74.09.415 through 74.09.435.

((~~(4)~~)) (5) "Department" means the department of social and health services.

((~~(5)~~)) (6) "Department of health" means the Washington state department of health created pursuant to RCW 43.70.020.

((~~(6)~~)) (7) "Drug utilization review" means both retrospective and prospective drug utilization review. Such programs are designed to ensure that drug utilization is: (a) Medically appropriate; (b) medically necessary; and (c) not likely to have adverse medical results.

(8) "Drug utilization review criteria" means standards recommended by the committee for use in determining whether use of a drug is likely to be medically appropriate, medically necessary, and will not result in adverse medical outcomes.

(9) "Internal management" means the administration of medical assistance, medical care services, the children's health program, and the limited casualty program.

((~~(7)~~)) (10) "Limited casualty program" means the medical care program provided to medically needy persons as defined under Title XIX

of the federal social security act, and to medically indigent persons who are without income or resources sufficient to secure necessary medical services.

((~~(8)~~)) (11) "Medical assistance" means the federal aid medical care program provided to categorically needy persons as defined under Title XIX of the federal social security act.

((~~(9)~~)) (12) "Medical care services" means the limited scope of care financed by state funds and provided to general assistance recipients, and recipients of alcohol and drug addiction services provided under chapter 74.50 RCW.

((~~(10)~~)) (13) "Nursing home" means nursing home as defined in RCW 18.51.010.

((~~(11)~~)) (14) "Poverty" means the federal poverty level determined annually by the United States department of health and human services, or successor agency.

((~~(12)~~)) (15) "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the state medicaid agency or its contractor that the proposed medical use of a particular medicine for a patient meets predetermined criteria for payment by the program.

(16) "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.

(17) "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 to examine pharmacy claims data and other information to identify overuse, underuse, appropriate use of branded and generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse or misuse.

(18) "Secretary" means the secretary of social and health services.

NEW SECTION. **Sec. 3.** A new section is added to chapter 74.09 RCW to read as follows:

(1) The drug utilization and education committee is hereby established within the department's medical assistance administration for the implementation of: (a) A retrospective and prospective drug utilization review program; and (b) a prior authorization program for outpatient prescription drugs under the medical assistance program.

(2) The committee shall consist of eleven members as appointed by the secretary as follows:

(a) Three physicians licensed in this state and actively engaged in the practice of medicine chosen from a list of nominees provided by the Washington state medical association;

(b) One advanced registered nurse practitioner licensed in this state and actively engaged in the practice of nursing chosen from a list of nominees provided by the Washington state nurses association;

(c) Three pharmacists licensed in this state and actively engaged in the practice of pharmacy chosen from a list of nominees provided by the Washington state pharmacists association;

(d) Three health care consumer or advocate organization representatives chosen from nominees submitted by Washington state chartered nonprofit health organizations whose purpose it is to work with and for health care consumers and their families; and

(e) One person with background experience, education, or expertise in pharmacoeconomics.

(3) Committee members shall serve staggered three-year terms. Of the initial members, one physician, the advanced registered nurse practitioner, one pharmacist, and one consumer representative shall each be appointed for two-year terms, and one physician, two pharmacists, and the pharmacoeconomics representative shall each be appointed for one-year terms. The remaining committee members shall be appointed for three-year terms. Members may be reappointed for a period not to exceed three three-year terms. Vacancies on the committee shall be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as under subsection (2) of this section.

(4) Committee members shall select a chair and a vice-chair on an annual basis from the committee membership.

(5) The committee shall meet at least quarterly and may meet at other times at the discretion of the chair. The department shall provide staff support to the committee. Notice of any meeting of the committee shall be published in the Washington state register thirty

days before such meeting. Committee meetings shall in all respects comply with the provisions of the open public meetings act, chapter 42.30 RCW.

NEW SECTION. **Sec. 4.** A new section is added to chapter 74.09 RCW to read as follows:

The committee has the power and duty to:

(1) In regards to drug utilization review:

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

(b) Advise and make recommendations regarding the implementation of a retrospective and prospective drug utilization review program for the medical assistance program, including recommendations for 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 section;

(c) Advise and make recommendations regarding the drug utilization review criteria for the retrospective and prospective drug utilization review programs. Any recommended drug utilization review criteria must be consistent with the indications supported and/or rejected by the compendia and the food and drug administration's approved labeling for the drug. In developing its recommendations, the committee also shall consider outside information provided by interested parties, including prescribers who treat significant numbers of patients under the medical assistance program;

(d) Establish a process to review, on a periodic basis, the drug utilization review criteria and, as necessary, recommend modifications to the prospective and retrospective drug utilization review programs; and

(e) Provide a period for public comment during each committee meeting; and

(2) In regards to drug prior authorization:

(a) Advise and make recommendations regarding the rules to be adopted by the department regarding outpatient prescription drug prior authorization;

(b) Advise and make recommendations regarding the drug prior authorization review process established in section 6 of this act;

(c) Make formal recommendations to the department regarding any outpatient prescription drug covered by the medical assistance program that is to be subject to prior authorization;

(d) Review on an annual basis whether drugs placed on prior authorization should remain on prior authorization; and

(e) Make recommendations for modification of the prior authorization review process, as necessary, to achieve the objectives of this act.

NEW SECTION. **Sec. 5.** A new section is added to chapter 74.09 RCW to read as follows:

(1) The committee shall advise and make recommendations to the department in administration of its 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 shall use a competitive bidding process as required by the office of state procurement.

(3) The prospective drug utilization review program shall be based on drug utilization review criteria, after giving due consideration to criteria recommended by the committee. If the department rejects the criteria recommended by the committee, the department must specify the reasons for its finding that the committee's recommendation is inappropriate. Those reasons cannot be based exclusively upon cost considerations.

(4) The program shall provide that, before a prescription is filled or delivered, a review shall be conducted by a pharmacist at the point of sale to screen for potential drug therapy problems. In conducting the prospective drug utilization review, a pharmacist may not alter the prescribed outpatient drug therapy without a new prescription order by the prescribing physician and approval by the patient. The prospective drug utilization review shall 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.

(5) The retrospective drug utilization review program shall be based on drug utilization review criteria developed after giving due consideration to criteria recommended by the committee. If the department rejects the criteria recommended by the committee, the department must specify the reasons for its finding that the committee's recommendation is inappropriate. Those reasons cannot be based exclusively upon cost considerations.

(6) The retrospective drug utilization program shall use the department's mechanized drug claims processing and information retrieval system to analyze medical 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 using criteria developed from the compendia for the purpose of evaluating:

(i) Therapeutic appropriateness;

(ii) Overuse or underuse;

(iii) Appropriate use of branded and generic products;

(iv) Therapeutic duplication;

(v) Drug-disease contraindications;

(vi) Drug-drug interactions;

(vii) Incorrect drug dosage or duration of drug treatment; and

(viii) 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.

(7) The department shall provide advance notice of proposed changes to the drug utilization review criteria and modification of the prospective and retrospective drug utilization review programs thirty days before the planned implementation of such changes.

NEW SECTION. **Sec. 6.** A new section is added to chapter 74.09 RCW to read as follows:

(1) Any drug prior authorization program shall meet the following conditions:

(a) The program shall provide telephone, fax, or other electronically transmitted approval or denial within twenty-four hours after receipt of the 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 shall be dispensed and paid for by the medical assistance program;

(c) In an emergency situation, authorization shall be granted if the drug is prescribed for a medically accepted indication supported by the compendia unless there is a therapeutically equivalent generic drug that is available without prior authorization; and

(d) The program shall consult with prescribers to develop a streamlined process for the prescriber to furnish any documentation required to support a prior authorization request. To the extent possible, such process shall flow directly from the patient care interaction and not a separate set of tasks required of the prescriber by the state.

(2) The committee may review any drug to develop recommendations to the department regarding the appropriateness of placing the drug on prior authorization. Review by the committee is not a precondition to the department's placing a drug on prior authorization. In deciding whether to make a drug subject to prior authorization, the department shall give primary consideration to clinical efficacy and patient care. Cost-effectiveness may also be considered where such consideration would not jeopardize beneficiary access to clinically efficacious prescription drugs.

(3) In the review of any drug, the committee shall adhere to the following conditions:

(a) Any consideration of the cost of the drug by the committee shall reflect the total cost of treating the conditions for which the drug is prescribed, including nonpharmaceutical costs that may be affected by the drug's use in treating program beneficiaries;

(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) The committee considers available retrospective drug utilization review data to identify a drug whose use is likely not to be medically appropriate or medically necessary, or likely to result in adverse medical outcomes;

(d) The committee provides thirty days' public notice prior to any meeting developing recommendations concerning whether such a drug should be placed on prior authorization. Any interested party 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 party, including but not limited to physicians, pharmacists, beneficiaries or other health care consumers, and manufacturers or distributors of the drug; and

(e) The committee makes a formal written recommendation to the department that such a drug be placed on prior authorization which shall be supported by an analysis demonstrating: (i) The expected impact of such a decision on the clinical care likely to be received by beneficiaries for whom the drug is medically necessary; (ii) the expected impact on physicians whose patients require the drug; and (iii) the expected fiscal impact on the medical assistance program.

(4) The department must provide a written decision regarding its acceptance or rejection of a recommendation of the committee. If the department rejects the recommendation of the committee, the department must specify the reasons for its finding that the committee's recommendation is inappropriate. Those reasons cannot be based exclusively upon cost considerations. The department may consider any additional and clarifying information provided by any interested party rendering its decision.

(5) The department's decision shall be published for public comment for a period of no less than thirty days. The effective date of the decision shall not be prior to the close of the comment period and effective notice of the decision's finality is available to prescribers.

(6) The department shall develop a grievance mechanism to hear appeals by interested parties of the department's decision to place a drug on prior authorization. After participating in the grievance mechanism, any interested party aggrieved by the placement of a drug on prior authorization is entitled to an administrative hearing before the department under the provisions of the administrative procedure act, chapter 34.05 RCW.

(7) The committee shall review the prior authorization status of a drug when new and substantive data is provided to the department.

(8) The committee shall provide thirty days' public notice prior to any meeting to determine whether changes should be recommended to the drug prior authorization review process.

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