H-0962.1

HOUSE BILL 1550

State of Washington 57th Legislature 2001 Regular Session

By Representative Pflug

Read first time 01/29/2001. 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; creating a new section; and declaring an emergency.

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 and as a health benefits payer under the state's medical assistance program, the legislature directs the department of social and health services' medical assistance administration to add a prior authorization component to its drug utilization review program to ensure that beneficiaries have access to medically necessary medicines in a clinically appropriate manner.

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) "Board" means the drug utilization review board established under section 3 of this act.

(2) "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)~~)) (3) "Committee" means the ((~~children's health services~~)) pharmacy and therapeutics committee created in section ((~~3~~)) 6 of this act.

((~~(3)~~)) (4) "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.

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

((~~(5)~~)) (7) "Department of health" means the Washington state department of health created pursuant to RCW 43.70.020.

((~~(6)~~)) (8) "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.

(9) "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 will not result in adverse medical outcomes.

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

((~~(7)~~)) (11) "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)~~)) (12) "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)~~)) (13) "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)~~)) (14) "Nursing home" means nursing home as defined in RCW 18.51.010.

((~~(11)~~)) (15) "Poverty" means the federal poverty level determined annually by the United States department of health and human services, or successor agency.

((~~(12)~~)) (16) "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 coverage by the program.

(17) "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.

(18) "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 overutilization, underutilization, 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.

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

NEW SECTION. **Sec. 3.** (1) The drug utilization review board is hereby established within the department of social and health services'

medical assistance administration for the implementation of a retrospective and prospective drug utilization review program.

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

(a) Four 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) Five 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;

(c) One person who is a resident of this state chosen to represent medical assistance beneficiaries in this state; and

(d) One person representing the pharmaceutical industry, chosen from a list of nominees provided by the pharmaceutical research and manufacturers of America.

(3) Board members shall serve staggered three-year terms. One physician, one pharmacist, and the beneficiary representative shall each be initially appointed for two-year terms, and one physician, two pharmacists, and the pharmaceutical industry representative shall each be initially appointed for one-year terms. Members may be reappointed for a period not to exceed three three-year terms. Vacancies on the board shall be filled for the balance of the unexpired term from nominee lists for the appropriate board category as under subsection (2) of this section.

(4) Board members shall select a chairperson and a vice-chairperson on an annual basis from the board membership.

(5) The board shall meet at least quarterly and may meet at other times at the discretion of the chairperson. Notice of any meeting of the board shall be published in the Washington state register thirty days before such meeting. Board meetings shall in all respects comply with the provisions of the open public meetings act, chapter 42.30 RCW, and shall be subject to the provisions of the administrative procedure act, chapter 34.05 RCW, as applicable.

NEW SECTION. **Sec. 4.** The board shall have the power and duty to:

(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 section;

(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 shall be consistent with the indications supported and/or rejected by the compendia and the food and drug administration's 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 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 shall be furnished thirty days prior to the consideration or recommendation of any proposed changes to the drug utilization review programs.

NEW SECTION. **Sec. 5.** (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 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 established by the board and 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.

(4) The retrospective drug utilization review program shall be based on drug utilization review criteria established by the board using 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) Overutilization or underutilization;

(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.

NEW SECTION. **Sec. 6.** (1) Notwithstanding any other provision of law, the department shall have the authority to implement a prior authorization program for outpatient prescription drugs under the medical assistance program only as provided in sections 3 through 8 of this act.

(2) The pharmacy and therapeutics committee is hereby established within the department of social and health services' medical assistance

administration for the purposes of implementing prior authorization for outpatient prescription drugs under the medical assistance program.

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

(a) Five 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) Four 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;

(c) One person who shall represent 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. Two physicians, one pharmacist, and the medical assistance beneficiary representative shall each be initially appointed for two-year terms, and one physician, one pharmacist, and the pharmaceutical industry representative shall each be initially appointed for one-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.

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

(6) The committee shall meet at least quarterly and may meet at other times at the discretion of the chairperson. 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, and shall be subject to the provisions of the administrative procedure act, chapter 34.05 RCW, as applicable.

NEW SECTION. **Sec. 7.** The committee shall have the power and duty to:

(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 medical assistance program;

(3) Establish the drug prior authorization review process in compliance with section 8 of this act;

(4) Make formal recommendations to the department regarding any outpatient prescription drug covered by the medical assistance program that is to be priorly authorized;

(5) Review on 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.

NEW SECTION. **Sec. 8.** (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, or, at the discretion of the committee, a supply greater than seventy-two hours that will assure a minimum effective duration of therapy for an acute intervention;

(c) 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) No drug may 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 outcomes;

(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 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 availability of use in treating program beneficiaries;

(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, and manufacturers or distributors of the drug;

(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 of prospective and retrospective drug utilization review data 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;

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

(g) 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.

(3) The committee shall develop a grievance mechanism for interested parties to hear appeals of 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 shall be entitled to an administrative hearing before the department under the provisions of the administrative procedure act.

(4) The committee shall review the prior authorization status of a drug every twelve months.

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

NEW SECTION. **Sec. 9.** Sections 3 through 8 of this act are each added to chapter 74.09 RCW.

NEW SECTION. **Sec. 10.** This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

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