HOUSE BILL NO. HB0304

Medicaid-drug utilization review program.

Sponsored by: Representative(s) Hinckley and Ross

A BILL

for

AN ACT relating to the Wyoming Medical Assistance and Services Act; creating a drug utilization review program as specified; establishing a drug utilization review board as specified; specifying duties; providing a process for prior authorization of drugs; providing for appeals; and providing for an effective date.

Be It Enacted by the Legislature of the State of Wyoming:

Section 1. W.S. 42-4-301 through 42-4-306 are created to read:

ARTICLE 3

DRUG UTILIZATION REVIEW PROGRAM

42-4-301. Definitions.

(a) As used in this article:

(i) "Board" means the drug utilization review board established under W.S. 42-4-302;

(ii) "Compendia" means the American hospital formulary services drug information, United States pharmacopeias-drug information, peer-reviewed medical literature, 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;

(iii) "DUR 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;

(iv) "Department" means the Wyoming department of health;

(v) "Drug utilization review" or "DUR" means both retrospective and prospective drug utilization review programs that are designed to ensure that drug utilization

is medically appropriate, medically necessary and not likely to have adverse medical results;

(vi) "Prior authorization" means a process requiring the professional authorized by law to prescribe medications 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;

(vii) "Prospective DUR" means that part of the drug utilization review program that occurs before a drug is dispensed and that uses the DUR criteria to screen for potential drug therapy problems related to therapeutic duplication, drug and disease contraindications, drug to drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions and clinical abuse or misuse;

(viii) "Recipient" means any person who is eligible for services under the Wyoming Medical Assistance and Services Act;

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

42-4-302. Establishment of drug utilization review board; membership; terms.

(a) The drug utilization review board is hereby established within the department of health.

(b) The board shall consist of eleven (11) members as appointed by the director of the department as follows:

(i) Four (4) physicians licensed in this state and actively engaged in the practice of medicine chosen from a list of nominees provided by the Wyoming medical society;

(ii) Five (5) pharmacists licensed in this state, actively engaged in the practice of pharmacy, and chosen from a list of nominees provided by the Wyoming pharmaceutical association;

(iii) One (1) person who is a resident of this state appointed to represent recipients under the Wyoming Medical Assistance and Services Act; and

(iv) One (1) person representing the research-based pharmaceutical industry chosen in consultation with representatives from the pharmaceutical research and manufacturers of America.

(c) Board members shall serve staggered three (3) year terms. Of the initial board, one (1) physician, one (1) pharmacist and the member appointed under paragraph (b)(iii) of this section shall each be appointed for two (2) year terms, and one (1) physician, two (2) pharmacists and the member appointed under paragraph (b)(iv) of this section shall each be appointed for one (1) year terms. The remaining members of the initial board shall be appointed for three (3) year terms. Thereafter, members may be reappointed for three (3) additional full terms. Vacancies

on the board shall be filled for the balance of the unexpired term from nominee lists provided in accordance with subsection (b) of this section, as appropriate.

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

(e) The board shall meet at least quarterly and may meet at other times at the discretion of the chairman. Board meetings shall in all respects comply with the provisions of W.S. 16-4-401 through 16-4-407 and shall be subject to the provisions of the Wyoming Administrative Procedure Act, as applicable. Documents relating to decisions taken by the board with respect to DUR criteria and prior authorization recommendations shall be public records and provided to all interested parties upon request.

42-4-303. Drug utilization review board; duties.

(a) The board shall:

(i) Oversee the implementation of a retrospective and prospective DUR program for the Wyoming Medical Assistance and Services Act;

(ii) Develop and apply the DUR criteria for the retrospective and prospective DUR programs, provided that the DUR criteria shall be consistent with the indications supported or rejected by the compendia and approved by the federal Food and Drug Administration labeling for the drug;

(iii) Consider outside information provided by interested parties, including professionals authorized by law to prescribe medications who treat significant numbers of recipients under the Wyoming Medical Assistance and Services Act;

(iv) Establish a process to reassess on a periodic basis the DUR criteria and, as necessary, modify the prospective and retrospective DUR programs; and

(v) Provide a period for public comment during each board meeting. Notice of proposed changes to the DUR criteria and modification of the prospective and retrospective DUR programs shall be furnished thirty (30)

days prior to the consideration or recommendation of any proposed changes to the DUR programs.

(b) Notwithstanding any other provision of law, the board may implement a prior authorization program to make recommendations to the department regarding outpatient prescription drugs under the Wyoming Medical Assistance and Services Act.

(c) Neither the board nor the department shall establish a preferred drug list or require supplemental rebates from pharmaceutical manufacturers unless specifically authorized by the legislature.

42-4-304. Prospective and retrospective drug utilization review programs.

(a) The board, in cooperation with the department, shall create and implement a prospective and retrospective DUR program for purchase or payment of outpatient prescription drugs under the Wyoming Medical Assistance and Services Act, using DUR criteria to ensure that drug utilization is medically appropriate, medically necessary and not likely to result in adverse medical outcomes.

(b) The prospective DUR program shall be based on DUR 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 DUR review, a pharmacist shall not alter the prescribed outpatient drug therapy without a new prescription order by the prescribing physician and approval by the patient. The prospective DUR review shall screen for:

(i) Therapeutic duplication;

(ii) Drug and disease contraindications;

(iii) Drug to drug interactions;

(iv) Incorrect drug dosage or duration of drug treatment;

(v) Drug allergy interactions; and

(vi) Clinical abuse or misuse.

(c) The retrospective DUR program shall be based on DUR criteria established by the board using the department's drug claims processing and information retrieval system to analyze claims under the Wyoming Medical Assistance and Services Act to:

(i) Identify patterns of fraud, abuse, gross overuse or underuse and inappropriate or medically unnecessary care;

(ii) Assess data on drug use by applying and reviewing criteria developed from the compendia or the federal Food and Drug Administration approved labeling for the purpose of evaluating:

(A) Therapeutic appropriateness of medications;

(B) Overutilization or underutilization of medications;

(C) Appropriate use of generic products;

(D) Therapeutic duplication of medications;

(E) Drug and disease contraindications;

(F) Drug to drug interactions;

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

(H) Clinical abuse or misuse; and

(iii) Propose remedial strategies to improve the quality of care and to promote effective use of state funds or beneficiary expenditures under the Wyoming Medical Assistance and Services Act.

42-4-305. Drug prior authorization review process.

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

(i) The program shall provide telephone, facsimile or other electronically transmitted approval or

denial within twenty-four (24) hours after receipt of the prior authorization request;

(ii) In an emergency situation, including a situation in which a response to a prior authorization request is unavailable, a seventy-two (72) hour supply of the prescribed drug shall be dispensed to an eligible recipient and paid for by the department under the Wyoming Medical Assistance and Services Act, or, at the discretion of the department, a supply greater than seventy-two (72) hours that will assure a minimum effect duration of therapy for an acute intervention;

(iii) Authorization shall be granted if the drug is prescribed for a medically accepted use supported by either the compendia, approved federal Food and Drug Administration product labeling or peer-reviewed literature unless there is a pharmaceutical equivalent generic drug as defined in 21 C.F.R. Part 320.1(c) that is available without prior authorization;

(iv) Provided that a drug is safe and effective for a medical condition, the department shall not limit or exclude coverage for a drug when prescribed for the medical

condition of a recipient if the drug previously has been approved by the department for the recipient's medical condition;

(v) The board shall consult with professionals authorized by law to prescribe medications to develop a streamlined process for the prescriber to furnish any documentation required including name, title, address and telephone number of the prescriber making the request, 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 to support a prior authorization request. The process shall flow directly from the patient care interaction and not a separate set of tasks required of the professional authorized by law to prescribe medications by the state.

(b) No drug may be recommended for the prior authorization list by the board and placed on the prior authorization list by the department unless the following conditions are met:

(i) The board analyzes the retrospective DUR data using the DUR 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;

(ii) The board considers the potential fiscal and patient care impact that could result from placement of the drug on the prior authorization list. Any consideration of the costs by the board shall reflect the total cost of treating the conditions for which the drug is prescribed, including nonpharmaceutical costs and costs incurred by the department for the Wyoming Medical Assistance and Services Act that may be affected by the drug's availability for use in treating program recipients. Costs to patients and to providers, including lost productivity, shall be considered;

(iii) The board provides thirty (30) days public notice prior to any meeting developing recommendations concerning whether the drug should be placed on the prior authorization list. All interested parties shall have the opportunity to present clinical data and other information in an oral presentation to the board. The board shall proactively seek comments from voluntary health organizations representing patients or specific disease areas. The board shall consider any information provided

by any interested party, including but not limited to physicians, pharmacists, recipients and manufacturers or distributors of the drug;

(iv) The board shall make a formal written recommendation to the department that the drug be placed on the prior authorization list which shall be supported by an analysis of prospective and retrospective DUR data demonstrating:

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

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

(C) The expected fiscal impact on the Wyoming Medical Assistance and Services Act. The analysis shall be available under W.S. 16-4-401 through 16-4-407.

(v) The department accepts the recommendation of the board and in a written decision determines whether the drug should be placed on the prior authorization list. The

department may consider any additional and clarifying information provided by any interested party in rendering its decision;

(vi) The department's decision is published for public comment for a period of no less than thirty (30) 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 professionals authorized by law to prescribe medications.

(c) Notwithstanding any other provision of this section, no drug shall be placed on the prior authorization list by the department which has been approved or had any of its particular uses approved by the federal Food and Drug Administration under a priority review classification.

(d) Any party aggrieved by a decision by the department to place a drug on the prior authorization list may appeal the decision in accordance with the Wyoming Administrative Procedure Act.

(e) The board shall review the prior authorization status of a drug on the prior authorization list every six

(6) months. The review shall include an analysis of total costs incurred and saved under the Wyoming Medical Assistance and Services Act, including the impact on patient care, impact on patients and providers, physician and hospital workload and administrative costs to the department.

(f) The board shall provide thirty (30) days public notice prior to any meeting determining whether changes should be made to the drug prior authorization review process.

42-4-306. No discrimination in drug substitution laws.

(a) Notwithstanding any other provision of law, no pharmacist shall substitute a generic drug product if a professional authorized by law to prescribe medications has written an order for a brand name drug, unless the recipient provides specific written consent to the substitution. Any pharmacist violating this subsection shall not be reimbursed by the department for the drug products dispensed in violation of this subsection.

(b) If a recipient of services under the Wyoming Medical Assistance and Services Act wishes to obtain the drug prescribed by the prescribing physician, the department may not discriminate against the recipient by requiring a higher co-payment than would be required if the patient consented to accept the drug preferred by the department.

Section 2. This act is effective July 1, 2003.

(END)