STATE OF OKLAHOMA

1st Session of the 50th Legislature (2005)

COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 1290 By: Cox

COMMITTEE SUBSTITUTE

An Act relating to public health and safety; amending 63 O.S. 2001, Section 5030.1, which relates to Medicaid Drug Utilization Review Board; making certain records subject to the Open Records Act; providing criteria for certain decisions; requiring certain reports; amending 63 O.S. 2001, Section 5030.5, as amended by Section 2, Chapter 411, O.S.L. 2002 (63 O.S. Supp. 2004, Section 5030.5), which relates to prior authorizations; providing for consideration of certain information; providing for public notice; providing for opportunity for certain presentation; and declaring an emergency.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 63 O.S. 2001, Section 5030.1, is amended to read as follows:

Section 5030.1 A. There is hereby created within the Oklahoma Health Care Authority the Medicaid Drug Utilization Review Board, which shall be responsible for the development, implementation and assessment of retrospective and prospective drug utilization programs under the direction of the Authority.

B. The Medicaid Drug Utilization Review Board shall consist of ten (10) members appointed by the administrator of the Authority as follows:

1. Four physicians, licensed and actively engaged in the practice of medicine or osteopathic medicine in this state, of which:

a. three shall be physicians chosen from a list of not less than six names submitted by the Oklahoma State Medical Association, and

b. one shall be a physician chosen from a list of not less than two names submitted by the Oklahoma Osteopathic Association;

2. Four licensed pharmacists actively engaged in the practice of pharmacy, chosen from a list of not less than six names submitted by the Oklahoma Pharmaceutical Association;

3. One person representing the lay community, who shall not be a physician or a pharmacist, but shall be a health care professional with recognized knowledge and expertise in at least one of the following:

a. clinically appropriate prescribing of covered outpatient drugs,

b. clinically appropriate dispensing and monitoring of covered outpatient drugs,

c. drug use review, evaluation and intervention, and

d. medical quality assurance; and

4. One person representing the pharmaceutical industry who is a resident of the State of Oklahoma, chosen from a list of not less than two names submitted by the Pharmaceutical Research and Manufacturers of America.

C. Members shall serve terms of three (3) years, except that one physician, one pharmacist and the lay representative shall each be initially appointed for two-year terms in order to stagger the terms. In making the appointments, the administrator shall provide, to the extent possible, for geographic balance in the representation on the Medicaid Drug Utilization Review Board. Members may be reappointed for a period not to exceed three three-year terms and one partial term. Vacancies on the Medicaid Drug Utilization Review Board shall be filled for the balance of the unexpired term from new

lists submitted by the entity originally submitting the list for the position vacated.

D. The Medicaid Drug Utilization Review Board shall elect from among its members a chair and a vice-chair who shall serve one-year terms, provided they may succeed themselves.

E. The proceedings of all meetings of the Medicaid Drug Utilization Review Board shall comply with the provisions of the Oklahoma Open Meeting Act and shall be subject to the provisions of the Administrative Procedures Act. Records of the Board shall be subject to the Open Records Act.

F. 1. The Medicaid Drug Utilization Review Board may advise and make recommendations to the Authority regarding existing, proposed and emergency rules governing retrospective and prospective drug utilization programs.

2. Recommendations of the Board regarding any limitations to be imposed on any drug or its use for a specific indication shall be based exclusively on sound clinical evidence found in labeling, drug compendia and peer-reviewed clinical literature pertaining to use of the drug in the relevant population. The clinical basis for decisions on the formulary or list of preferred drugs shall be in a written report that shall be made available to the public before consideration of the recommendation by the Oklahoma Health Care Authority. If the recommendation of the Board is contrary to the clinical evidence found in labeling, drug compendia or peer-reviewed literature, the recommendation of the Board shall be justified in the written report.

3. The Oklahoma Health Care Authority Board shall promulgate rules pursuant to the provisions of the Administrative Procedures Act for implementation of the provisions of this section.

SECTION 2. AMENDATORY 63 O.S. 2001, Section 5030.5, as amended by Section 2, Chapter 411, O.S.L. 2002 (63 O.S. Supp. 2004, Section 5030.5), is amended to read as follows:

Section 5030.5 A. Any drug prior authorization program approved or implemented by the Medicaid Drug Utilization Review Board shall meet the following conditions:

1. The Medicaid Drug Utilization Review Board shall make note of and consider information provided by interested parties, including, but not limited to, physicians, pharmacists, patients, and pharmaceutical manufacturers, related to the placement of a drug or drugs on prior authorization;

2. Any drug or drug class placed on prior authorization shall be reconsidered no later than twelve (12) months after such placement;

3. The program shall provide either telephone or fax approval or denial within twenty-four (24) hours after receipt of the prior authorization request; and

4. In an emergency situation, including a situation in which an answer to a prior authorization request is unavailable, a seventy-two-hour supply shall be dispensed, or, at the discretion of the Medicaid Drug Utilization Review Board, a greater amount that will assure a minimum effective duration of therapy for an acute intervention.

B. In formulating its recommendations for placement of a drug or drug class on prior authorization to the Oklahoma Health Care Authority Board, the Medicaid Drug Utilization Review Board shall:

1. Consider the potential impact of any administrative delay on patient care and the potential fiscal impact of such prior authorization on pharmacy, physician, hospitalization and outpatient costs. <u>The Board shall consider any information provided by any interested party, including, but not limited to, physicians, pharmacists, drug manufacturers and distributors, and persons for whom the relevant drug is prescribed.</u> Any recommendation making a drug subject to placement on prior authorization shall be

accompanied by a statement of the cost and clinical efficacy of such placement;

2. Provide thirty (30) days' public notice prior to any meeting at which recommendations for prior authorization of a specific drug shall be considered. Such notice shall also be provided to any person requesting notification. The Board shall provide a period for public comment on each meeting agenda. Prior to making any recommendations, the Medicaid Drug Utilization Review Board shall solicit public comment regarding proposed changes in the prior authorization program in accordance with the provisions of the Oklahoma Open Meeting Act and the Administrative Procedures Act. Any person may request an opportunity to make an oral presentation to the Board relevant to the prior authorization of any drug. The request for an oral presentation shall not be denied or unreasonably limited by the Board; and

3. Review Oklahoma Medicaid specific data related to utilization criterion standards as provided in division (1) of subparagraph b of paragraph 2 of Section 5030.4 of this title.

C. The Oklahoma Health Care Authority Board may accept or reject the recommendations of the Medicaid Drug Utilization Review Board in whole or in part, and may amend or add to such recommendations.

D. The Oklahoma Health Care Authority shall immediately provide coverage under prior authorization for any new drug approved by the United States Food and Drug Administration if the drug falls within a drug class that the Authority has already placed under prior authorization.

E. 1. Prior to a vote by the Medicaid Drug Utilization Review Board to consider expansion of product-based prior authorization, the Oklahoma Health Care Authority shall:

a. develop a written estimate of savings expected to accrue from the proposed expansion, and

b. make the estimate of savings available, on request of interested persons, no later than the day following the first scheduled discussion of the estimate by the Board at a regularly scheduled meeting.

2. The written savings estimate based upon savings estimate assumptions specified by paragraph 3 of this subsection prepared by the Authority shall include as a minimum:

a. a summary of all paid prescription claims for patients with a product in the therapeutic category under consideration during the most recent month with complete data, plus a breakdown, as available, of these patients according to whether the patients are residents of a long-term care facility or are receiving Advantage Waiver program services,

b. current number of prescriptions, amount reimbursed and trend for each product within the category under consideration,

c. average active ingredient cost reimbursed per day of therapy for each product and strength within the category under consideration,

d. for each product and strength within the category under consideration, where applicable, the prevailing State Maximum Allowable Cost reimbursed per dosage unit,

e. the anticipated impact of any patent expiration of any product within the category under consideration scheduled to occur within two (2) years from the anticipated implementation date of the proposed prior authorization expansion, and

f. a detailed estimate of administrative costs involved in the prior authorization expansion including, but

not limited to, the anticipated increase in petition volume.

3. Savings estimate assumptions shall include, at a minimum:

a. the prescription conversion rate of products requiring prior authorization (Tier II) to products not requiring prior authorization (Tier I) and to other alternative products,

b. aggregated rebate amount for the proposed Tier I and Tier II products within the category under consideration,

c. market shift of Tier II products due to other causes including, but not limited to, patent expiration,

d. Tier I to Tier II prescription conversion rate, and

e. nature of medical benefits and complications typically seen with products in this class when therapy is switched from one product to another.

4. The Board shall consider prior authorization expansion in accordance with the following Board meeting sequence:

a. first meeting: publish the category or categories to be considered for prior authorization expansion in the future business section of the Medicaid Drug Utilization Review Board agenda,

b. second meeting: presentation and discussion of the written estimate of savings,

c. third meeting: make formal notice in the agenda of intent to vote on the proposed prior authorization expansion, and

d. fourth meeting: vote on prior authorization expansion.

SECTION 3. It being immediately necessary for the preservation of the public peace, health and safety, an emergency is hereby

declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

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