

ENROLLED SENATE
BILL NO. 625

By: Monson of the Senate

and

Stanley, Adkins, Gray and
Morgan of the House

An Act relating to public health and safety; amending Section 2, Chapter 161, O.S.L. 1995, as amended by Section 4, Chapter 221, O.S.L. 1996, and as renumbered by Section 7, Chapter 221, O.S.L. 1996 (63 O.S. Supp. 1998, Section 5030.1), which relates to the Medicaid Drug Utilization Review Board; expanding duties; clarifying references; defining terms; providing for powers and duties of the Board; requiring development of and recommendations regarding retrospective and prospective drug utilization review program; requiring specified guidelines for program operation; specifying conditions to be met by the Board; stating methods for formulating recommendations; providing latitude for the acceptance or rejection of specified recommendations; providing for codification; providing an effective date; and declaring an emergency.

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

SECTION 1. AMENDATORY Section 2, Chapter 161, O.S.L. 1995, as amended by Section 4, Chapter 221, O.S.L. 1996, and as renumbered by Section 7, Chapter 221, O.S.L. 1996 (63 O.S. Supp. 1998, 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 ~~(DUR)~~ 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 ~~DUR~~ 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 DUR 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 ~~Article I~~ of the Administrative Procedures Act.

F. The DUR 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. The Oklahoma Health Care Authority Board shall promulgate rules pursuant to the provisions of ~~Article I~~ of the Administrative Procedures Act for implementation of the provisions of this section.

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5030.2 of Title 63, unless there is created a duplication in numbering, reads as follows:

As used in Sections 1 through 5 of this act:

1. "Compendia" means the "American Hospital Formulary Services Drug Information", "U.S. Pharmacopoeia Drug Information", peer-reviewed medical literature, other information provided by individuals involved in health care, and information as needed by the Medicaid Drug Utilization Review Board;

2. "Criteria" means those explicit and predetermined elements that are used to assess or measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes;

3. "Authority" means the Oklahoma Health Care Authority;

4. "Drug-disease contraindication" means the possibility that the therapeutic effect of a drug would be adversely altered by the presence of another disease or condition;

5. "Drug interactions" means the possibility that two or more drugs taken by a patient may lead to clinically significant toxicity that is uncharacteristic of any one of the drugs present or that the taking of which leads to interference with the effectiveness of one or any of the drugs;

6. "Drug to drug interaction" means a clinically significant adverse medical effect that results from the use of two or more drugs together;

7. "Drug Utilization Review" or "DUR" means both retrospective and prospective drug utilization review designed to educate physicians and pharmacists and thereby ensure that prescriptions are appropriate, medically necessary and not likely to have adverse medical results;

8. "Overutilization" or "underutilization" means the use of a drug in such quantities that the desired therapeutic goal is not achieved;

9. "Prospective drug utilization review" means the part of a drug utilization review program that occurs before a drug is dispensed, and that is designed to screen, based on explicit and predetermined criteria and standards, for potential drug therapy problems, including, but not limited to:

- a. therapeutic duplication,
- b. drug-disease contraindications,
- c. incorrect drug dosage or duration of drug treatment,
- d. drug allergy interactions, and

- e. clinical abuse or misuse; and

10. "Retrospective drug utilization review" means the part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards on an ongoing basis with professional input. Retrospective drug utilization review includes the periodic examination of Medicaid drug pharmacy claims data and other information sources to identify the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care:

- a. among physicians, pharmacists, and patients, or
- b. associated with specific drugs.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5030.3 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The Medicaid Drug Utilization Review Board shall have the power and duty to:

1. Advise and make recommendations regarding rules promulgated by the Oklahoma Health Care Authority Board to implement the provisions of this act;

2. Oversee the development, implementation and assessment of a Medicaid retrospective and prospective drug utilization review program, including making recommendations regarding contractual agreements of the Oklahoma Health Care Authority with any entity involved in processing and reviewing Medicaid drug profiles for the drug utilization review program in accordance with the provisions of this act;

3. Develop and apply the criteria and standards to be used in retrospective and prospective drug utilization review. The criteria and standards shall be based on the compendia and federal Food and Drug Act approved labeling, and shall be developed with professional input;

4. Provide a period for public comment on each meeting agenda. As necessary, the Medicaid Drug Utilization Review Board may include a public hearing as part of a meeting agenda to solicit public comment regarding proposed changes in the prior authorization program and the retrospective and prospective drug utilization review processes. Notice of proposed changes to the prior authorization status of a drug or drugs shall be included in the monthly meeting agenda at least thirty (30) days prior to the consideration or recommendation of any proposed changes in prior authorization by the Medicaid Drug Utilization Review Board;

5. Establish provisions to timely reassess and, as necessary, revise the retrospective and prospective drug utilization review process;

6. Make recommendations regarding the prior authorization of prescription drugs pursuant to the provisions of Section 5 of this act; and

7. Provide members of the provider community with educational opportunities related to the clinical appropriateness of prescription drugs.

B. Any party aggrieved by a decision of the Oklahoma Health Care Authority Board or the Administrator of the Oklahoma Health Care Authority, pursuant to a recommendation of the Medicaid Drug Utilization Review Board, shall be entitled to an administrative hearing before the Oklahoma Health Care Authority Board pursuant to the provisions of the Administrative Procedures Act.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5030.4 of Title 63, unless there is created a duplication in numbering, reads as follows:

1. The Medicaid Drug Utilization Review Board shall develop and recommend to the Oklahoma Health Care Authority Board a retrospective and prospective drug utilization review program for medical outpatient drugs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

2. The retrospective and prospective drug utilization review program shall be operated under guidelines established by the Medicaid Drug Utilization Review Board as follows:

a. The retrospective drug utilization review program shall be based on guidelines established by the Medicaid Drug Utilization Review Board using the mechanized drug claims processing and information retrieval system to analyze claims data in order to:

- (1) identify patterns of fraud, abuse, gross overuse or underuse, and inappropriate or medically unnecessary care,
- (2) assess data on drug use against explicit predetermined standards that are based on the compendia and other sources for the purpose of monitoring:
 - (a) therapeutic appropriateness,
 - (b) overutilization or underutilization,
 - (c) appropriate use of generic drugs,
 - (d) therapeutic duplication,
 - (e) drug-disease contraindications
 - (f) drug-drug interactions,

- (g) incorrect drug dosage,
 - (h) duration of drug treatment, and
 - (i) clinical abuse or misuse, and
- (3) introduce remedial strategies in order to improve the quality of care and to conserve program funds or personal expenditures.
- b. (1) The prospective drug utilization review program shall be based on guidelines established by the Medicaid Drug Utilization Review Board and shall provide that, before a prescription is filled or delivered, a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from:
- (a) therapeutic duplication,
 - (b) drug-drug interactions,
 - (c) incorrect drug dosage or duration of drug treatment,
 - (d) drug-allergy interactions, and
 - (e) clinical abuse or misuse.
- (2) In conducting the prospective drug utilization review, a pharmacist may not alter the prescribed outpatient drug therapy without the consent of the prescribing physician or purchaser.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 5030.5 of Title 63, unless there is created a duplication in numbering, reads as follows:

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. 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 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; and

3. Review Oklahoma Medicaid specific data related to utilization criterion standards as provided in subdivision a of paragraph 2 of Section 4 of this act.

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.

SECTION 6. This act shall become effective July 1, 1999.

SECTION 7. 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.

Passed the Senate the 13th day of May, 1999.

President of the Senate

Passed the House of Representatives the 18th day of May, 1999.

Speaker of the House of
Representatives