CHAPTER 7

(HB 103)

AN ACT relating to the Medicaid outpatient pharmacy program and declaring an emergency.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

SECTION 1. A NEW SECTION OF KRS 205.510 TO 205.645 IS CREATED TO READ AS FOLLOWS:

(1) The Pharmacy and Therapeutics Advisory Committee is established and attached to the Department for Medicaid Services for administrative purposes.

(2) The committee shall have fourteen (14) members, as follows:

(a) Twelve (12) voting members who shall be physicians currently participating in the Medicaid program who may legally prescribe a broad range of scheduled and nonscheduled drugs, as categorized by the U.S. Drug Enforcement Administration, or pharmacists who dispense prescriptions to Medicaid recipients, as follows:

1. Three (3) licensed, practicing family practice physicians;

2. Two (2) licensed, practicing physicians who are pediatricians;

3. One (1) licensed, practicing physician who is an obstetrician/gynecologist or gynecologist;

4. One (1) licensed, practicing internal medicine physician who is a primary care provider;

5. One (1) licensed, practicing physician from any medical specialty;

6. One (1) licensed, practicing physician who is a psychiatrist; and

7. Three (3) licensed, practicing pharmacists; and

(b) Two (2) nonvoting members, as follows:

1. The medical director of the department; and

2. A representative of the department's pharmacy program, as designated by the commissioner.

(3) One (1) voting committee member shall be appointed, and may be reappointed, by the Governor from a list of three (3) nominees received from the President of the Senate, and one (1) voting committee member shall be appointed, and may be reappointed, by the Governor from a list of three (3) nominees received from the Speaker of the House of Representatives. The remaining ten (10) voting committee members shall be appointed, and may be reappointed, by the Governor from a list of nominees submitted by the department. Terms of the voting committee members shall be three (3) years with no members serving more than two (2) consecutive terms.

(4) The Pharmacy and Therapeutics Advisory Committee shall:

(a) Act in an advisory capacity to the Governor, the secretary of the Cabinet for Health Services, and the Medicaid commissioner on the development and administration of an outpatient drug formulary;

(b) Perform drug reviews and make recommendations to the secretary regarding specific drugs or drug classes to be placed on prior authorization or otherwise restricted, as determined through a process established by the cabinet;

(c) Provide for an appeals process to be utilized by a person or entity that disagrees with recommendations of the committee;

(d) Establish bylaws or rules for the conduct of committee meetings; and

(e) Function in accordance with the Kentucky Open Meetings Law and the Kentucky Open Records Law.

(5) Voting members of the committee shall elect a chair and vice chair by majority vote. A quorum shall consist of seven (7) voting members of the committee.

(6) The committee shall meet every other month for a total of at least six (6) times per year or upon the call of the chair, the secretary of the Cabinet for Health Services, or the Governor. The Department for Medicaid Services shall post the agenda on its web site no later than fourteen (14) days prior to the date of a regularly scheduled meeting and no later than seventy-two (72) hours prior to the date of a specially called meeting. Options, including any recommendations, by the department for drug review or drug review placement shall be posted on the department's web site no later than seven (7) days prior to the date of the next regularly scheduled meeting and as soon as practicable prior to the date of the next specially called meeting.

(7) Members of the committee shall receive no compensation for service, but shall receive necessary and actual travel expenses associated with attending meetings.

(8) Any recommendation of the committee to the secretary of the Cabinet for Health Services shall be posted to the web site of the Department for Medicaid Services within seven (7) days of the date of the meeting at which the recommendation was made.

(9) A recommendation of the committee shall be submitted to the secretary for a final determination. If the secretary does not accept the recommendation of the committee, the secretary shall present the basis for the final determination at the next scheduled meeting of the committee. The secretary shall act on the committee's recommendation within thirty (30) days of the date that the recommendation was posted on the web site.

(10) Any interested party may request and may be permitted to make a presentation to the board on any item under consideration by the board. The Cabinet for Health Services shall, by administrative regulation promulgated under KRS Chapter 13A, establish requirements for any presentation made to the board.

(11) The secretary's final determination shall be posted on the web site of the Department for Medicaid Services.

(12) Any appeal from a decision of the secretary shall be made in accordance with KRS Chapter 13B, except that the time for filing an appeal shall be within thirty (30) days of the date of the posting of the secretary's final determination on the web site of the Department for Medicaid Services.

(13) The Cabinet for Health Services shall promulgate an administrative regulation in accordance with KRS Chapter 13A to implement the provisions of this section.

Section 2. KRS 205.5631 is amended to read as follows:

(1)~~[As used in KRS 205.5631 to 205.5639, "available" means the calendar date when a new drug is first covered on a statewide basis through normal distribution channels for the Medical Assistance Program patients in the Commonwealth.~~

~~(2)]~~ As used in KRS 205.5631 to 205.5639, "commissioner" means the commissioner of the Department for Medicaid Services.

(2)~~[(3)]~~ As used in ***Section 3 of this Act***~~[KRS 205.5631 to 205.5639]~~, "new drug" means ***a drug that is approved for marketing by the Federal Food and Drug Administration***~~[any entity that is marketed]~~ under a product licensing application, new drug application, or a supplement to a new drug application, and ***that is a new chemical or molecular entity, but shall not mean***~~[prescribed by a health care provider with prescribing authority for a medically accepted indication, except those drugs or classes of drugs identified in 42 U.S.C. sec. 1396r-8(d)(2), as amended, and that is any of]~~ the following:

(a) ***Drugs, classes of drugs, or medical uses identified in 42 U.S.C. sec. 1396r-8(d)(2), as amended***~~[Any new chemical or molecular entity]~~;

(b) ***Drugs that are considered to be less than effective by the Federal Food and Drug Administration or drugs that are considered to be identical, related, or similar to the less than effective drugs***~~[Any new dosage form of an existing chemical or molecular entity]~~; ***and***

(c) ***Drugs that are excluded from coverage by the Kentucky Medicaid program due to lack of compliance by the drug manufacturer with federal drug rebate requirements***~~[Any combination of an existing chemical or molecular entity created for a distinct therapeutic purpose; or~~

~~(d) Any new indication for an existing chemical or molecular entity approved by the Federal Food and Drug Administration]~~.

Section 3. KRS 205.5632 is amended to read as follows:

(1) ***Upon initial coverage by the Kentucky Medicaid program, a new drug shall be exempt from prior authorization unless:***

(a) There has been a review of the drug and recommendation regarding prior authorization by the Pharmacy and Therapeutics Advisory Committee as provided under Section 1 of this Act and a final determination regarding prior authorization by the secretary of the Cabinet for Health Services; or

(b) The drug is in a specific class of drugs for which the Pharmacy and Therapeutics Advisory Committee has recommended, and the secretary of health services has determined, that all new drugs shall require prior authorization upon initial availability, in which case the drug shall require prior authorization and shall be scheduled for review by the Pharmacy and Therapeutics Advisory Committee within seventy-five (75) days~~[No prior authorization shall be required for reimbursement of any claim involving any Medicaid-covered new drug that is available after July 15, 1998, for a period of at least twelve (12) months, during which time the Drug Management Review Advisory Board may review the product]~~.

(2) The ***Cabinet for Health***~~[Department for Medicaid]~~ Services shall promulgate ***an*** administrative ***regulation***~~[regulations]~~ in accordance with KRS Chapter 13A ***that describes the process by which drugs under this section shall be determined to require prior***

authorization[~~for the drug submission program. Prior to implementation of the administrative regulations, the Drug Management Review Advisory Board shall review the guidelines.~~

~~(3) The Department for Medicaid Services shall, within twenty-four (24) months of July 15, 1998, analyze drug class reviews of all current drugs requiring prior authorization, and shall continue requiring prior authorization by using drug class reviews, safety, utilization factors, and unusual or extreme cost drivers having inappropriate economic impact on the Department for Medicaid Services, until the review criteria are promulgated by administrative regulations according to KRS Chapter 13A, and pursuant to KRS 205.5634(2). At least fifty percent (50%) of class reviews shall be completed within twelve (12) months of July 15, 1998.~~

~~(4) (a) Federal Food and Drug Administration (FDA) approved prescription drugs that have been determined to be within the same pharmacological category, and that have comparable clinical application, efficacy, and safety, and that are of comparable cost to other FDA-approved prescription drugs that have been placed on the Kentucky Medicaid nonprior-authorized drug file shall be placed on the Kentucky Medicaid nonprior-authorized drug file. Any drug that is removed from prior authorization in accordance with the provisions of this section shall be returned to prior authorization status if the comparable drug that was nonprior-authorized subsequently becomes prior authorized. To assure the cost effective operation of the Medicaid pharmacy program, the department shall file, no later than October 1, 2000, administrative regulations in accordance with KRS Chapter 13A that describe the process that will be employed to describe drug comparability with regard to efficacy, safety, and cost.~~

~~(b) For purposes of this subsection, "pharmacological category" means a category of drugs that is characterized as having very similar properties and therapeutic effects upon living organisms~~].

Section 4. KRS 205.5634 is amended to read as follows:

(1) The Drug Management Review Advisory Board shall coordinate the use of utilization data to identify appropriate use of pharmaceuticals and determine any need for educational interventions. Prospective drug utilization review and retrospective drug utilization review measures shall be utilized to monitor the success of the interventions. Interventions shall be evaluated for a period of not less than six (6) months.

(2)[~~ The Department for Medicaid Services shall promulgate administrative regulations in accordance with KRS Chapter 13A setting forth the procedures by which all products are placed in the prior authorization drug file.~~

~~(3) The commissioner may prior authorize any product that the commissioner determines may pose any significant safety issues or impose an inappropriate financial burden upon the Medicaid program. Placement of a drug on prior authorization by the commissioner shall initiate a review by the Drug Management Review Advisory Board.~~

~~(4) Drug reviews related to prior authorization decisions shall not take longer than ninety (90) days.~~

~~(5)~~] Implementation and performance of the duties of this section and KRS 205.5631, 205.5632, and 205.5636 and any drug review shall be performed by the staff of the Cabinet for Health Services, or its contractors.

Section 5. KRS 205.5638 is amended to read as follows:

(1) The Drug Management Review Advisory Board shall have at least the following duties and responsibilities:

(a) Review and make recommendations to the commissioner or designee on predetermined prospective drug use review standards submitted to the board by the Department for Medicaid Services or its contractor;

(b) Evaluate the use of the predetermined prospective drug use review standards and make recommendations to the commissioner or the commissioner's designee concerning modification or elimination of existing standards and the need for additional standards;

(c) Make recommendations to the commissioner or the commissioner's designee concerning guidelines governing written predetermined standards that pharmacies must use in conducting prospective drug use review if they do not use approved software;

(d) Oversee the retrospective drug use review contract and incorporate the results into predetermined retrospective drug use review standards;

(e) Review and make recommendations to the commissioner or the commissioner's designee on predetermined retrospective drug use standards submitted to the board by the Department for Medicaid Services;

(f) Make recommendations to the commissioner or the commissioner's designee concerning the modification or elimination of existing predetermined retrospective drug use review standards and the need for additional standards;

(g) Identify and develop educational topics on common drug therapy problems if needed to improve prescribing or dispensing practices of practitioners;

(h) Make recommendations to the commissioner or the commissioner's designee concerning which mix of interventions would most effectively lead to an improvement in the quality of drug therapy;

(i) Conduct periodic reevaluations to determine the effectiveness of educational effort and, if necessary, modify the interventions;

(j) ***Recommend*** ~~[Establish]~~ standards for the identification of suspected fraud and abuse;

(k) Prepare and submit to the commissioner an annual drug use review report that contains the following information:

1. A description of the nature and scope of the retrospective drug utilization program including the identity of the contractor, the frequency of screening of claims data and the criteria and standards used, along with new or revised copies of the clinical criteria, and in subsequent years, a list of revised criteria and deleted criteria;

2. A summary of nonpatient and provider specific educational activities including information on the use of each type of patient and provider specific intervention that indicates the guidelines for use and frequency of use by type of intervention and the effectiveness of each type of intervention on changes in prescribing or dispensing practices;

3. An evaluation of the adequacy of prospective drug use review database software; and

4. Details on policy guidelines adopted by the board pertaining to written criteria that pharmacies may use if they do not use a computer prospective drug utilization review database; ***and***

(l) ~~[Provide advice to the Department for Medicaid Services regarding outpatient drug coverage and the delivery of quality care in the most cost-effective manner possible, giving consideration to the therapeutic equivalence and the cost, including rebate, of drugs and within the context of disease management.]~~In advising the department, the board may consider the effectiveness of all interventions used to manage a particular disease over time, the stage and intensity of the disease, and the economic, clinical, and patient-prospective outcomes, including quality of life.~~[Rebate information shall be considered during executive sessions and shall assure that confidential rebate information is protected in accordance with federal and state law; and~~

~~(m) Recommend to the commissioner the criteria for publication pursuant to KRS Chapter 13A relating to the evaluation and consideration of new products with input from affected parties, including the pharmaceutical industry.]~~

(2) The board shall function in accordance with the Kentucky Open Meetings Law and the Kentucky Open Records Act. The board may designate subcommittees to address specific issues and to report findings to the board. In conducting its business, the board shall utilize distance communication technologies whenever possible.

(3) Clerical and administrative support shall be provided the board through the Cabinet for Health Services or by contract.

Section 6. The General Assembly confirms Executive Order 2001-1243, dated October 2, 2001, to the extent it is not otherwise confirmed or superseded by this Act.

Section 7. The initial voting member appointees to the Pharmacy and Therapeutics Advisory Committee shall serve terms as follows: four (4) shall serve a one (1) year term; four (4) shall serve a two (2) year term; and four (4) shall serve a three (3) year term. The members appointed to the committee prior to the effective date of this Act may continue to serve as members of the committee under the term schedule designated in this section. Vacancies arising after the effective date of this Act shall be filled as provided in Section 1 of this Act.

Section 8. Whereas the cost of the outpatient drug program is a major contributing factor to the Medicaid shortfall and is placing a significant strain on the budget of the Commonwealth, and the provisions of this Act will help alleviate this problem, an emergency is declared to exist, and this Act takes effect upon its passage and approval by the Governor or upon its otherwise becoming a law.

Approved February 21, 2002