Session of 2011

SENATE BILL No. 117

By Committee on Ways and Means

2-7

AN ACT concerning the Kansas health policy authority's drug utilization program; amending K.S.A. 2010 Supp. 39-7,119, 39-7,121a and 77-421 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 2010 Supp. 39-7,119 is hereby amended to read as follows: 39-7,119. (a) There is hereby created the medicaid drug utilization review board which shall be responsible for the implementation of retrospective and prospective drug utilization programs under the Kansas medicaid program. *Every meeting of the medicaid drug utilization review board shall be subject to the provisions of the open meetings act.*

(b) Except as provided in subsection (i), the board shall consist of at least seven members appointed as follows:

(1) Two licensed physicians actively engaged in the practice of medicine, nominated by the Kansas medical society and appointed by the Kansas health policy authority from a list of four nominees;

(2) one licensed physician actively engaged in the practice of osteopathic medicine, nominated by the Kansas association of osteopathic medicine and appointed by the Kansas health policy authority from a list of four nominees;

(3) two licensed pharmacists actively engaged in the practice of pharmacy, nominated by the Kansas pharmacy association and appointed by the Kansas health policy authority from a list of four nominees;

(4) one person licensed as a pharmacist and actively engaged in academic pharmacy, appointed by the Kansas health policy authority from a list of four nominees provided by the university of Kansas;

(5) one licensed professional nurse actively engaged in long-term care nursing, nominated by the Kansas state nurses association and appointed by the Kansas health policy authority from a list of four nominees.

(c) The Kansas health policy authority may add two additional members so long as no class of professional representatives exceeds 51% of the membership.

(d) The physician and pharmacist members shall have expertise in the clinically appropriate prescribing and dispensing of outpatient drugs.

(e) The appointments to the board shall be for terms of three years. In making the appointments, the Kansas health policy authority shall provide for geographic balance in the representation on the board to the extent possible. Subject to the provisions of subsection (i), members may be reappointed.

(f) The board shall elect a chairperson from among board members who shall serve a one-year term. The chairperson may serve consecutive terms.

(g) The board, in accordance with K.S.A. 75-4319 and amendments thereto, may recess for a closed or executive meeting when it is considering matters relating to identifiable patients or providers.

(h) All actions of the medicaid drug utilization review board shall be upon the affirmative vote of five members of the board and the vote of each member present when action was taken shall be recorded by roll call vote.

(i) Upon the expiration of the term of office of any member of the medicaid drug utilization review board on or after the effective date of this act and in any case of a vacancy existing in the membership position of any member of the medicaid drug utilization review board on or after the effective date of this act, a successor shall be appointed by the Kansas health policy authority so that as the terms of members expire, or vacancies occur, members are appointed and the composition of the board is changed in accordance with the following and such appointment shall be made by the Kansas health policy authority in the following order of priority:

(1) One member shall be a licensed pharmacist who is actively performing or who has experience performing medicaid pharmacy services for a hospital and who is nominated by the Kansas hospital association and appointed by the Kansas health policy authority from a list of two or more nominees;

(2) one member shall be a licensed pharmacist who is actively performing or who has experience performing medicaid pharmacy services for a licensed adult care home and who is nominated by the state board of pharmacy and appointed by the Kansas health policy authority from a list of two or more nominees;

(3) one member shall be a licensed physician who is actively engaged in the general practice of allopathic medicine and who has practice experience with the state medicaid plan and who is nominated by the Kansas medical society and appointed by the Kansas health policy authority from a list of two or more nominees;

(4) one member shall be a licensed physician who is actively engaged in mental health practice providing care and treatment to persons with mental illness, who has practice experience with the state medicaid

plan and who is nominated by the Kansas psychiatric society and appointed by the Kansas health policy authority from a list of two or more nominees;

(5) one member shall be a licensed physician who is the medical director of a nursing facility, who has practice experience with the state medicaid plan and who is nominated by the Kansas medical society and appointed by the Kansas health policy authority from a list of two or more nominees;

(6) one member shall be a licensed physician who is actively engaged in the general practice of osteopathic medicine, who has practice experience with the state medicaid plan and who is nominated by the Kansas association of osteopathic medicine and who is appointed by the Kansas health policy authority from a list of two or more nominees;

(7) one member shall be a licensed pharmacist who is actively engaged in retail pharmacy, who has practice experience with the state medicaid plan and who is nominated by the state board of pharmacy and appointed by the Kansas health policy authority from a list of two or more nominees;

(8) one member shall be a licensed pharmacist who is actively engaged in or who has experience in research pharmacy and who is nominated jointly by the Kansas task force for the pharmaceutical research and manufacturers association and the university of Kansas and appointed by the Kansas health policy authority from a list of two or more jointly nominated persons; and

(9) one member shall be a licensed advanced registered nurse practitioner or physician assistant actively engaged in the practice of providing the health care and treatment services such person is licensed to perform, who has practice experience with the state medicaid plan and who is nominated jointly by the Kansas state nurses' association and the Kansas academy of physician assistants and appointed by the Kansas health policy authority from a list of two or more jointly nominated persons.

Sec. 2. K.S.A. 2010 Supp. 39-7,121a is hereby amended to read as follows: 39-7,121a. (a) The Kansas health policy authority may establish an advisory committee pursuant to K.S.A. 75-5313, and amendments thereto, to advise the Kansas health policy authority in the development of a preferred formulary listing of covered drugs by the state medicaid program.

(b) The Kansas health policy authority shall evaluate drugs and drug classes for inclusion in the state medicaid preferred drug formulary based on safety, effectiveness and clinical outcomes of such treatments. In addition, the Kansas health policy authority shall evaluate drugs and drug classes to determine whether inclusion of such drugs or drug classes in a

starter dose program would be clinically efficacious and cost effective. If the factors of safety, effectiveness and clinical outcomes among drugs being considered in the same class indicate no therapeutic advantage, then the Kansas health policy authority shall consider the cost effectiveness and the net economic impact of such drugs in making recommendations for inclusion in the state medicaid preferred drug formulary. Drugs which do not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcomes over other drugs in the same class which have been selected for the preferred drug formulary may be excluded from the preferred drug formulary and may be subject to prior authorization in accordance with state and federal law, except, prior to July 1, 2003, where a prescriber has personally written "dispense as written" or "D.A.W.", or has signed the prescriber's name on the "dispense as written" signature line in accordance with K.S.A. 65-1637, and amendments thereto.

(c) The Kansas health policy authority shall consider the net economic impact of drugs selected or excluded from the preferred formulary and may gather information on the costs of specific drugs, rebates or discounts pursuant to 42 U.S.C. § 1396r-8, dispensing costs, dosing requirements and utilization of other drugs or other medicaid health care services.

(d) The Kansas health policy authority may accept all services, including, but not limited to, disease state management, associated with the delivery of pharmacy benefits under the state medicaid program having a determinable cost effect in addition to the medicaid prescription drug rebates required pursuant to 42 U.S.C. ~~section~~ *§* 1396r-8.

(e) The state medicaid preferred drug formulary shall be submitted to the medicaid drug utilization review board for review and policy recommendations.

(f) All meetings of any advisory committee established pursuant to subsection (a), including the preferred drug list committee, and all meetings of the Kansas health policy authority pursuant to subsection (b) which involve the evaluation of drugs and drug classes shall be subject to the provisions of the open meetings act.

(g) In addition to the provisions of subsection (f), all meetings of any advisory committee established pursuant to subsection (a), including the preferred drug list committee, shall include in its procedure for its meetings the following:

(1) Nonmembers of the committee and other interested parties shall be recognized by the comittee chairperson only during designated public comments periods.

(2) Pharmaceutical manufactureres or other interested parties shall submit their formulary submission in a standardized format to the Kansas

health policy designee at least three to four weeks prior to the date of the meeting of the advisory committee established pursuant to subsection (a), including the preferred drug list committee. The Kansas health policy authority and any advisory committee established pursuant to subsection (a), including preferred drug list committee, shall notify all pharmaceutical manufacturers or other interested parties known to the agency and the advisory committee of such meeting date at least six weeks in advance of such meeting date.

(3) Prior to any final action by either the Kansas health policy committee or any advisory committee established pursuant to subsection (a), including the preferred drug list committee, on a decision pertaining to a drug or drug class, there shall be a designated public comment period of at least 15 minutes for each drug in the therapeutic drug class under discussion for the purpose of providing key points outlining the evidence-based value of any drug under consideration.

Sec. 3. K.S.A. 2010 Supp. 77-421 is hereby amended to read as follows: 77-421. (a) (1) Except as provided by subsection (a)(2), subsection (a)(3) or subsection (a)(4), prior to the adoption of any permanent rule and regulation or any temporary rule and regulation which is required to be adopted as a temporary rule and regulation in order to comply with the requirements of the statute authorizing the same and after any such rule and regulation has been approved by the secretary of administration and the attorney general, the adopting state agency shall give at least 60 days' notice of its intended action in the Kansas register and to the secretary of state and to the joint committee on administrative rules and regulations established by K.S.A. 77-436, and amendments thereto. The notice shall be provided to the secretary of state and to the chairperson, vice chairperson, ranking minority member of the joint committee and legislative research department and shall be published in the Kansas register. A complete copy of all proposed rules and regulations and the complete economic impact statement required by K.S.A. 77-416, and amendments thereto, shall accompany the notice sent to the secretary of state. The notice shall contain:

(A) A summary of the substance of the proposed rules and regulations;

(B) a summary of the economic impact statement indicating the estimated economic impact on governmental agencies or units, persons subject to the proposed rules and regulations and the general public;

(C) a summary of the environmental benefit statement, if applicable, indicating the need for the proposed rules and regulations;

(D) the address where a complete copy of the proposed rules and regulations, the complete economic impact statement, the environmental benefit statement, if applicable, required by K.S.A. 77-416, and

amendments thereto, may be obtained;

(E) the time and place of the public hearing to be held; the manner in which interested parties may present their views; and

(F) a specific statement that the period of 60 days' notice constitutes a public comment period for the purpose of receiving written public comments on the proposed rules and regulations and the address where such comments may be submitted to the state agency. Publication of such notice in the Kansas register shall constitute notice to all parties affected by the rules and regulations.

(2) Prior to adopting any rule and regulation which establishes seasons and fixes bag, creel, possession, size or length limits for the taking or possession of wildlife and after such rule and regulation has been approved by the secretary of administration and the attorney general, the secretary of the department of wildlife and parks shall give at least 30 days' notice of its intended action in the Kansas register and to the secretary of state and to the joint committee on administrative rules and regulations created pursuant to K.S.A. 77-436, and amendments thereto. All other provisions of subsection (a)(1) shall apply to such rules and regulations, except that the statement required by subsection (a)(1)(E) shall state that the period of 30 days' notice constitutes a public comment period on such rules and regulations.

~~(3) Prior to adopting any rule and regulation which establishes any permanent prior authorization on a prescription-only drug pursuant to K.S.A. 39-7,120, and amendments thereto, or which concerns coverage or reimbursement for pharmaceuticals under the pharmacy program of the state medicaid plan, and after such rule and regulation has been approved by the secretary of administration and the attorney general, the Kansas health policy authority shall give at least 30 days' notice of its intended action in the Kansas register and to the secretary of state and to the joint committee on administrative rules and regulations created pursuant to K.S.A. 77-436, and amendments thereto. All other provisions of subsection (a)(1) shall apply to such rules and regulations, except that the statement required by subsection (a)(1)(E) shall state that the period of 30 days' notice constitutes a public comment period on such rules and regulations.~~

~~(4)~~ *(3)* Prior to adopting any rule and regulation pursuant to subsection (c), the state *agency* shall give at least 30 days' notice of its intended action in the Kansas register and to the secretary of state and to the joint committee on administrative rules and regulations created pursuant to K.S.A. 77-436, and amendments thereto. All other provisions of subsection (a)(1) shall apply to such rules and regulations, except that the statement required by subsection (a)(1)(E) shall state that the period of notice constitutes a public comment period on such rules and

regulations.

(b) (1) On the date of the hearing, all interested parties shall be given reasonable opportunity to present their views or arguments on adoption of the rule and regulation, either orally or in writing. At the time it adopts or amends a rule and regulation, the state agency shall prepare a concise statement of the principal reasons for adopting the rule and regulation or amendment thereto, including:

(A) The agency's reasons for not accepting substantial arguments made in testimony and comments; and

(B) the reasons for any substantial change between the text of the proposed adopted or amended rule and regulation contained in the published notice of the proposed adoption or amendment of the rule and regulation and the text of the rule and regulation as finally adopted.

(2) Whenever a state agency is required by any other statute to give notice and hold a hearing before adopting, amending, reviving or revoking a rule and regulation, the state agency, in lieu of following the requirements or statutory procedure set out in such other law, may give notice and hold hearings on proposed rules and regulations in the manner prescribed by this section.

(3) Notwithstanding the other provisions of this section, the Kansas parole board and the secretary of corrections, may give notice or an opportunity to be heard to any inmate in the custody of the secretary of corrections with regard to the adoption of any rule and regulation, but the secretary shall not be required to give such notice or opportunity.

(c) (1) The agency shall initiate new rulemaking proceedings under this act, if a state agency proposes to adopt a final rule and regulation that:

(A) Differs in subject matter or effect in any material respect from the rule and regulation as originally proposed; and

(B) is not a logical outgrowth of the rule and regulation as originally proposed.

(2) In accordance with subsection (a), the period for public comment required by K.S.A. 77-421, and amendments thereto, may be shortened to not less than 30 days.

(3) For the purposes of this provision, a rule and regulation is not the logical outgrowth of the rule and regulation as originally proposed if a person affected by the final rule and regulation was not put on notice that such person's interests were affected in the rulemaking.

(d) When, pursuant to this or any other statute, a state agency holds a hearing on the adoption of a proposed rule and regulation, the agency shall cause written minutes or other records, including a record maintained on sound recording tape or on any electronically accessed media or any combination of written or electronically accessed media

records of the hearing to be made. If the proposed rule and regulation is adopted and becomes effective, the state agency shall maintain, for not less than three years after its effective date, such minutes or other records, together with any recording, transcript or other record made of the hearing and a list of all persons who appeared at the hearing and who they represented, any written testimony presented at the hearing and any written comments submitted during the public comment period.

(e) No rule and regulation shall be adopted by a board, commission, authority or other similar body except at a meeting which is open to the public and notwithstanding any other provision of law to the contrary, no rule and regulation shall be adopted by a board, commission, authority or other similar body unless it receives approval by roll call vote of a majority of the total membership thereof.

Sec. 4. K.S.A. 2010 Supp. 39-7,119, 39-7,121a and 77-421 are hereby repealed.

Sec. 5. This act shall take effect and be in force from and after its publication in the statute book.