By: King of Taylor H.B. No. 3719

A BILL TO BE ENTITLED

AN ACT

relating to preferred drug lists, including confidentiality, supplemental rebate, prior approval and publication requirements.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 531, Subtitle I, Title 4, Government Code is amended to read as follows:

Sec. 531.071. CONFIDENTIALITY OF INFORMATION REGARDING DRUG REBATES, PRICING, AND NEGOTIATIONS. (a) Notwithstanding any other state law, financial information obtained or maintained by the commission regarding prescription drug rebate negotiations or a supplemental medical assistance or other rebate agreement, including trade secrets, rebate amount, rebate percentage, and manufacturer or labeler pricing, is confidential and not subject to disclosure under Chapter 552.

(b) Information that is confidential under Subsection (a) includes information described by Subsection (a) that is obtained or maintained by the commission in connection with the Medicaid vendor drug program, the child health plan program, the kidney health care program, the children with special health care needs program, or another state program administered by the commission or a health and human services agency.

(c) Notwithstanding Subsection (a), the following information is not confidential:

(1) general information about the aggregate costs of

different classes of drugs; [~~is not confidential under Subsection (a).~~]

(2) the fact that a supplemental rebate agreement was or was not reached between the commission and a manufacturer or labeler for a particular drug; and

(3) the fact that a supplemental rebate agreement for a particular drug was or was not of a sufficient amount to make the drug cost-effective for preferred drug list placement, without disclosing the amount of the rebate or other confidential financial information described in this Section.

Sec. 531.072. PREFERRED DRUG LISTS. (a) In a manner that complies with applicable state and federal law, the commission shall adopt preferred drug lists for the Medicaid vendor drug program and for prescription drugs purchased through the child health plan program. The commission may adopt preferred drug lists for community mental health centers, state mental health hospitals, and any other state program administered by the commission or a state health and human services agency.

(b) The preferred drug lists may contain only drugs provided by a manufacturer or labeler that reaches an agreement with the commission on supplemental rebates under Section 531.070 unless one of the following exceptions is met:

(1) the commission determines that the drug provided by a generic manufacturer or labeler without a supplemental rebate is as or more cost-effective than a drug provided by a brand name manufacturer or labeler who has reached a supplemental rebate agreement with the commission in the same drug class;

(2) a public benefit agreement as described in Section 531.070 has been reached by the commission and a labeler or manufacturer;

(b-1) Placement of a drug on the preferred drug list shall include all strengths and dosages

(b-2) Each drug class shall include multiple methods of delivery of the drug, including liquid, tablet, capsule, and orally disintegrating tablets.

(c) In making a decision regarding the placement of a drug on each of the preferred drug lists, the commission shall consider:

(1) the recommendations of the Pharmaceutical and Therapeutics Committee established under Section 531.074;

(2) the clinical efficacy of the drug;

(3) the price of competing drugs after deducting any federal and state rebate amounts; and

(4) program benefit offerings solely or in conjunction with rebates and other pricing information.

(d) The commission shall provide for the distribution of current copies of the preferred drug lists by posting the list on the Internet. In addition, the commission shall mail copies of the lists to any health care provider on request of that provider.

(e) In this subsection, "labeler" and "manufacturer" have the meanings assigned by Section 531.070. The commission shall ensure that:

(1) a manufacturer or labeler may submit written evidence supporting the inclusion of a drug on the preferred drug lists before a supplemental agreement is reached with the

commission; and

(2) any drug that has been approved or has had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting of the committee. On receiving notice from a manufacturer or labeler of the availability of a new product, the commission, to the extent possible, shall schedule a review for the product at the next regularly scheduled meeting of the committee.

(f) A recipient of drug benefits under the Medicaid vendor drug program may appeal a denial of prior authorization under Section 531.073 of a covered drug or covered dosage through the Medicaid fair hearing process.

(g) Provided that one year has passed since the last review of the drug or its drug class, a generic manufacturer or labeler may make an application or request to have its drug reconsidered for preferred drug placement based upon satisfaction of the cost-effectiveness exception described in Section 531.072(b)(1).

Sec. 531.073. PRIOR AUTHORIZATION FOR CERTAIN PRESCRIPTION DRUGS. (a) The commission, in its rules and standards governing the Medicaid vendor drug program and the child health plan program, shall require prior authorization for the reimbursement of a drug that is not included in the appropriate preferred drug list adopted under Section 531.072, except for any drug exempted from prior authorization requirements by federal law. The commission may require prior authorization for the reimbursement of a drug

provided through any other state program administered by the commission or a state health and human services agency, including a community mental health center and a state mental health hospital if the commission adopts preferred drug lists under Section 531.072 that apply to those facilities and the drug is not included in the appropriate list. The commission shall require that the prior authorization be obtained by the prescribing physician or prescribing practitioner.

(a-1) Until the commission has completed a study evaluating the impact of a requirement of prior authorization on recipients of certain drugs, the commission shall delay requiring prior authorization for drugs that are used to treat patients with illnesses that:

(1) are life-threatening;

(2) are chronic; and

(3) require complex medical management strategies.

(a-2) Not later than the 30th day before the date on which prior authorization requirements are implemented, the commission shall post on the Internet for consumers and providers:

(1) a notification of the implementation date; and

(2) a detailed description of the procedures to be used in obtaining prior authorization.

(b) The commission shall establish procedures for the prior authorization requirement under the Medicaid vendor drug program to ensure that the requirements of 42 U.S.C. Section 1396r-8(d)(5) and its subsequent amendments are met. Specifically, the procedures must ensure that:

(1) a prior authorization requirement is not imposed for a drug before the drug has been considered at a meeting of the Pharmaceutical and Therapeutics Committee established under Section 531.074;

(2) there will be a response to a request for prior authorization by telephone or other telecommunications device within 24 hours after receipt of a request for prior authorization; and

(3) a 72-hour supply of the drug prescribed will be provided in an emergency or if the commission does not provide a response within the time required by Subdivision (2).

(c) The commission shall ensure that a prescription drug prescribed before implementation of a prior authorization requirement for that drug for a recipient under the child health plan program, the Medicaid program, or another state program administered by the commission or a health and human services agency or for a person who becomes eligible under the child health plan program, the Medicaid program, or another state program administered by the commission or a health and human services agency is not subject to any requirement for prior authorization under this section unless the recipient has exhausted all the prescription, including any authorized refills, or a period prescribed by the commission has expired, whichever occurs first.

(d) The commission shall implement procedures to ensure that a recipient under the child health plan program, the Medicaid program, or another state program administered by the commission or a person who becomes eligible under the child health plan program,

the Medicaid program, or another state program administered by the commission or a health and human services agency receives continuity of care in relation to certain prescriptions identified by the commission.

(e) The commission may by contract authorize a private entity to administer the prior authorization requirements imposed by this section on behalf of the commission.

(f) The commission shall ensure that the prior authorization requirements are implemented in a manner that minimizes the cost to the state and any administrative burden placed on providers.

(g) The commission shall ensure that prior approval claims submission occurs through multiple telecommunication modes, including electronic point-of-sale submission, telephonic submission, fax submission, and electronic communications via the Internet.

Sec. 531.074. PHARMACEUTICAL AND THERAPEUTICS COMMITTEE. (a) The Pharmaceutical and Therapeutics Committee is established for the purposes of developing recommendations for preferred drug lists adopted by the commission under Section 531.072.

(b) The committee consists of the following members appointed by the governor:

(1) six physicians licensed under Subtitle B, Title 3, Occupations Code, and participating in the Medicaid program, at least one of whom is a licensed physician who is actively engaged in mental health providing care and treatment to persons with severe mental illness and who has practice experience in the state

Medicaid plan; and

(2) five pharmacists licensed under Subtitle J, Title 3, Occupations Code, and participating in the Medicaid vendor drug program.

(c) In making appointments to the committee under Subsection (b), the governor shall ensure that the committee includes physicians and pharmacists who:

(1) represent different specialties and provide services to all segments of the Medicaid program's diverse population;

(2) have experience in either developing or practicing under a preferred drug list; and

(3) do not have contractual relationships, ownership interests, or other conflicts of interest with a pharmaceutical manufacturer or labeler or with an entity engaged by the commission to assist in the development of the preferred drug lists or the administration of the prior authorization system.

(d) A member of the committee is appointed for a two-year term and may serve more than one term.

(e) The governor shall appoint a physician to be the presiding officer of the committee. The presiding officer serves at the pleasure of the governor.

(f) The committee shall meet at least monthly during the six-month period following establishment of the committee to enable the committee to develop recommendations for the initial preferred drug lists. After that period, the committee shall meet at least quarterly and at other times at the call of the presiding officer or

a majority of the committee members.

(g) A member of the committee may not receive compensation for serving on the committee but is entitled to reimbursement for reasonable and necessary travel expenses incurred by the member while conducting the business of the committee, as provided by the General Appropriations Act.

(h) In developing its recommendations for the preferred drug lists, the committee shall consider the clinical efficacy, safety, and cost-effectiveness and any program benefit associated with a product.

(i) The commission shall adopt rules governing the operation of the committee, including rules:

(1) governing the procedures used by the committee for providing notice of a meeting; [~~and~~]

(2) [~~rules~~] prohibiting the committee from discussing confidential financial information described by Section 531.071 in a public meeting; and [~~The committee shall comply with the rules adopted under this subsection.~~]

(3) requiring the committee or its delegate to present in oral and written form, at the public meeting, a summary of any clinical efficacy and safety information or analyses provided to the committee by a private entity that has contracted with the commission to provide such information. Confidential financial information described in Section 531.071 shall be omitted from the summary. The written summary shall be posted to the Internet.

(j) To the extent feasible, the committee shall review all drug classes included in the preferred drug lists adopted under

Section 531.072 at least once every 12 months and may recommend inclusions to and exclusions from the lists to ensure that the lists provide for cost-effective medically appropriate drug therapies for Medicaid recipients, children receiving health benefits coverage under the child health plan program, and any other affected individuals.

(k) The commission shall provide administrative support and resources as necessary for the committee to perform its duties.

(l) Chapter 2110 does not apply to the committee.

(m) The commission or the commission's agent shall publicly disclose each specific drug recommended for or against preferred drug list status for each drug class included in the preferred drug list for the Medicaid vendor drug program. The disclosure must be made in writing and posted to the Internet after the conclusion of committee deliberations that result in recommendations made to the executive commissioner regarding the placement of drugs on the preferred drug list. Such public disclosure shall include:

(A) the general basis for each recommendation for or against placement on the preferred drug list, including a statement of satisfaction of or failure to meet the criteria listed in Subsection 531.074(h);

(B) for all recommendations of the committee supporting placement of a drug on the preferred drug list, a statement that a supplemental rebate agreement was reached or, in the absence of a supplemental rebate agreement, a statement noting which exception described in Section 531.072(b) has been satisfied; and

(C) for all recommendations of the committee against placement of a drug on the preferred drug list, a statement of which of the criterion listed in Subsection 531.074(h) was not satisfied. If the clinical efficacy or safety criterion were not satisfied, a summary of the information relied upon by the committee supporting such conclusion must also be provided.

Sec. 531.075. Publication of Information Relating to Commission Decision-making. (a) The commission shall publish on the Internet its decisions on preferred drug list placement including:

(1) A list of drugs reviewed and its decision for or against placement on the preferred drug list for each drug;

(2) A statement that a supplemental rebate agreement was or was not reached between the commission and a manufacturer or labeler for a particular drug. If a supplemental rebate agreement was reached, a statement that such agreement was or was not of a sufficient amount to make the drug cost-effective for preferred drug list placement, without disclosing the amount of the rebate or other confidential information described in Section 531.071; and

(3) The rationale for any departure from the recommendations of the pharmaceutical and therapeutics committee. If a recommendation was rejected for safety or clinical efficacy reasons, information supporting such decision shall be disclosed.

SECTION 2. This Act takes effect September 1, 2009.