By: Delisi, Menendez, Harper-Brown H.B. No. 1804

Substitute the following for H.B. No. 1804:

By: Deshotel C.S.H.B. No. 1804

A BILL TO BE ENTITLED

AN ACT

relating to operation of the Medicaid vendor drug program, including the adoption of a preferred drug list and the negotiation of supplemental drug rebates.

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

SECTION 1. Subchapter B, Chapter 32, Human Resources Code, is amended by adding Sections 32.0462-32.0467 to read as follows:

Sec. 32.0462. PHARMACY BENEFIT MANAGER FOR VENDOR DRUG PROGRAM. (a) In this section, "pharmacy benefit manager" has the meaning assigned by Section 1, Article 21.07-6, Insurance Code.

(b) The Health and Human Services Commission may contract with a pharmacy benefit manager or other entity that has experience in the development of preferred drug lists or in negotiating supplemental rebates with pharmaceutical manufacturers to administer all or part of the vendor drug program.

Sec. 32.0463. SUPPLEMENTAL MEDICAL ASSISTANCE REBATES. (a) In this section:

(1) "Labeler" means a person that:

(A) has a labeler code from the United States Food and Drug Administration under 21 C.F.R. Section 207.20; and

(B) receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

(2) "Manufacturer" means a manufacturer of

prescription drugs as defined by 42 U.S.C. Section 1396r-8(k)(5), as amended, including a subsidiary or affiliate of a manufacturer.

(3) "Wholesaler" means a person licensed under Subchapter I, Chapter 431, Health and Safety Code.

(b) The Health and Human Services Commission shall negotiate with manufacturers and labelers of brand name prescription drugs to obtain supplemental medical assistance rebates for prescription drugs sold in this state.

(c) A manufacturer or labeler that sells prescription drugs in this state may voluntarily negotiate with the commission and enter into an agreement to provide supplemental medical assistance rebates for prescription drugs provided under the vendor drug program in excess of the rebates required by 42 U.S.C. Section 1396r-8, as amended.

(d) In negotiating terms for a supplemental medical assistance rebate amount, the commission shall:

(1) consider:

(A) rebates calculated under the medical assistance rebate program in accordance with 42 U.S.C. Section 1396r-8, as amended; and

(B) any other available information on prescription drug prices or rebates; and

(2) ensure that the cost basis of a product is the product's average manufacturer price, as defined by 42 U.S.C. Section 1396r-8(k)(1), as amended.

(e) The commission or the commission's designated representative shall conduct a closed meeting to consider or

discuss the negotiations of a supplemental medical assistance rebate agreement under this section or any other information relating to supplemental medical assistance rebates, including trade secrets, rebate amount, rebate percentage, and manufacturer or labeler pricing. Information considered or discussed at a closed meeting under this subsection is confidential and not subject to disclosure under Chapter 552, Government Code.

Sec. 32.0464. CONFIDENTIALITY OF REBATES, PRICING, AND NEGOTIATIONS. Information obtained or maintained by the Health and Human Services Commission regarding supplemental medical assistance rebate negotiations or a supplemental medical assistance rebate agreement, including trade secrets, rebate amount, rebate percentage, and manufacturer or labeler pricing, is confidential and not subject to disclosure under Chapter 552, Government Code.

Sec. 32.0465. PREFERRED DRUG LIST FOR VENDOR DRUG PROGRAM. (a) The Health and Human Services Commission shall adopt a preferred drug list for the vendor drug program. In making a decision regarding the placement of a drug on the preferred drug list, the commission shall consider:

(1) evidence-based procedures;

(2) the recommendations of the Medical Assistance Pharmaceutical and Therapeutics Committee established under Section 32.0467;

(3) the clinical efficacy of the drug;

(4) the safety of the drug;

(5) the cost-effectiveness of the drug; and

(6) the cost of the drug, including consideration of any savings resulting from the state's ability to obtain a supplemental rebate for the drug under Section 32.0463.

(b) The commission shall establish categories of drugs for purposes of the preferred drug list, and each category must include at least two drugs. In establishing the drug categories, the commission shall review and use each of the therapeutic categories of drugs established by the United States Food and Drug Administration.

(c) On adoption of the preferred drug list and following any updates or other changes to the list, the commission shall provide for distribution of current copies of the preferred drug list in an electronic format to all pharmacists participating in the medical assistance program and other providers of medical assistance in this state. The commission shall also make copies of the preferred drug list and information regarding updates and other changes to the list available in writing, on request, to pharmacists and other providers participating in the medical assistance program.

Sec. 32.0466. PRIOR AUTHORIZATION UNDER VENDOR DRUG PROGRAM. (a) In this section, "nonpreferred drug" means a prescribed drug that is not included in the preferred drug list adopted under Section 32.0465.

(b) The Health and Human Services Commission, in its rules and standards governing the vendor drug program, shall establish a system under which reimbursement for a nonpreferred drug is not available unless the prescribing physician obtains prior authorization for prescribing the drug.

(c) The commission shall establish procedures for the prior authorization system to ensure that:

(1) a request for prior authorization can be made to the commission or the commission's designated representative 24 hours a day;

(2) there will be a response to a request for prior authorization by telephone or other telecommunications device within 18 hours after receipt of a request for prior authorization from the prescribing physician;

(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);

(4) a chronically ill recipient of medical assistance who at the time the commission adopts a preferred drug list under Section 32.0465 is being treated with a nonpreferred drug is allowed after the adoption of the list to continue to receive the medication as prescribed, including the number of refills permitted under the prescription; and

(5) a patient for whom a prescribing physician obtains prior authorization under this section for treatment with a nonpreferred drug is not required to obtain any further prior authorization for any future or new prescriptions of that drug.

(d) A recipient of drug benefits under the vendor drug program may use the Medicaid fair hearing process to appeal a denial of a request for prior authorization.

(e) Each prescribed drug for treatment of the following illnesses or conditions is exempt from the prior authorization

system:

(1) human immunodeficiency virus (HIV) infection;

(2) acquired immune deficiency syndrome (AIDS);

(3) cancer;

(4) schizophrenia;

(5) bipolar disorder; and

(6) hemophilia.

(f) Notwithstanding any other provision of this section but subject to Subsection (h), reimbursement may be provided for a nonpreferred drug that is prescribed without prior authorization if the prescribing physician communicates to the pharmacist that the drug is medically necessary in accordance with this subsection. A drug is considered medically necessary under this subsection if:

(1) treatment with each alternative drug available under the preferred drug list adopted under Section 32.0465 has been ineffective in treating the patient; or

(2) the patient suffers from a specific clinical condition that precludes use of each alternative drug available under the preferred drug list adopted under Section 32.0465.

(g) The commission shall monitor the degree to which drugs are prescribed under Subsection (f) by drug name and name of the prescribing physician.

(h) If considered necessary by the commission to prevent abuse or otherwise ensure proper operation of the vendor drug program, the commission may prohibit or limit the availability of reimbursement for a particular drug prescribed under Subsection (f). The commission's authority under this subsection includes the

authority to prohibit or limit the availability of reimbursement for a particular drug only when prescribed by a particular physician.

(i) Notwithstanding any other provision of this section, reimbursement may be provided for a new drug described by Section 32.0467(k) for which the commission has not yet made a decision regarding the drug's placement on the preferred drug list adopted under Section 32.0465 if the prescribing physician:

(1) obtains prior authorization under this section to prescribe the drug; or

(2) communicates to a pharmacist that the drug is medically necessary as provided by Subsection (f).

Sec. 32.0467. MEDICAL ASSISTANCE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE. (a) The Medical Assistance Pharmaceutical and Therapeutics Committee is established for the purpose of developing recommendations for a preferred drug list for the vendor drug program.

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

(1) five physicians who are licensed under Subtitle B, Title 3, Occupations Code, and who represent a range of clinical specialties;

(2) two pharmacists who are licensed under Subtitle J, Title 3, Occupations Code, and who represent retail pharmacies;

(3) two pharmacists who are licensed under Subtitle J, Title 3, Occupations Code, and who represent academic pharmacies or clinical doctors of pharmacy;

(4) one member who is a registered nurse, advanced nurse practitioner, or physician assistant; and

(5) one member who is licensed in the practice of an allied health profession.

(c) In making appointments to the committee under Subsection (b), the governor shall ensure that the committee includes physicians or pharmacists participating in the medical assistance program who:

(1) provide services to the program's diverse population; and

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

(d) A member of the committee is appointed for a two-year term and may serve not more than three consecutive terms.

(e) The committee shall elect a physician member of the committee as presiding officer. The presiding officer shall serve a one-year term.

(f) The committee shall meet at least quarterly at the call of the presiding officer.

(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 list, the committee shall consider:

(1) evidence-based procedures;

(2) the clinical efficacy of a product;

(3) the safety of a product;

(4) the cost-effectiveness of a product;

(5) the availability of over-the-counter alternatives to a product;

(6) any clinical information provided by a pharmaceutical manufacturer;

(7) any written testimony provided by a pharmaceutical manufacturer regarding a product's clinical efficacy; and

(8) the cost of a product, including consideration of any savings resulting from the state's ability to obtain a supplemental rebate for the product under Section 32.0463.

(i) The Health and Human Services Commission shall adopt rules governing the operation of the committee, including rules governing the procedures used by the committee for providing notice of a meeting. The committee shall comply with the rules adopted under this subsection.

(j) To the extent feasible, the committee shall review all drug categories included in the preferred drug list adopted under Section 32.0465 at least once every 12 months and may recommend inclusions to and exclusions from the list to ensure that the list provides for cost-effective medically appropriate drug therapies for recipients of medical assistance.

(k) In this subsection, "labeler" and "manufacturer" have the meanings assigned by Section 32.0463. After receiving notice of the drug's availability from its manufacturer or labeler, the committee shall schedule a review at the next regularly scheduled

meeting of the committee for a new drug that has been approved or has had any of its particular uses approved by the United States Food and Drug Administration.

(l) The Health and Human Services Commission shall provide administrative support and resources as necessary for the committee to perform its duties under this section.

(m) Chapter 2110, Government Code, does not apply to the committee.

(n) The committee is considered part of the executive branch of state government, and any action undertaken by the committee is considered an administrative action for purposes of Chapter 305, Government Code.

(o) After each meeting, the committee shall prepare a report regarding the clinical basis for the committee's preferred drug list decision regarding each drug reviewed or considered by the committee at the meeting. The report must be made available to the public.

SECTION 2. If before implementing any provision of this Act a state agency determines that a waiver or other authorization from a federal agency is necessary for implementation, the state agency shall request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

SECTION 3. Not later than November 1, 2003, the governor shall appoint members to the Medical Assistance Pharmaceutical and Therapeutics Committee established under Section 32.0467, Human Resources Code, as added by this Act.

SECTION 4. Not later than January 1, 2004, the Health and Human Services Commission shall implement Section 32.0463, Human Resources Code, as added by this Act.

SECTION 5. (a) Not later than January 1, 2004, the Medical Assistance Pharmaceutical and Therapeutics Committee established under Section 32.0467, Human Resources Code, as added by this Act, shall submit recommendations for the preferred drug list the committee is required to develop under that section to the Health and Human Services Commission.

(b) Not later than March 1, 2004, the Health and Human Services Commission shall adopt the preferred drug list as required by Section 32.0465, Human Resources Code, as added by this Act.

SECTION 6. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2003.