By: Janek S.B. No. 1186

A BILL TO BE ENTITLED

1	AN ACT
2	relating to operation of the Medicaid vendor drug program,
3	including the adoption of a preferred drug list and the negotiation
4	of supplemental drug rebates.
5	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
6	SECTION 1. Subchapter B, Chapter 32, Human Resources Code,
7	is amended by adding Sections 32.0462-32.0467 to read as follows:
8	Sec. 32.0462. PHARMACY BENEFIT MANAGER FOR VENDOR DRUG
9	PROGRAM. (a) In this section, "pharmacy benefit manager" has the
10	meaning assigned by Section 1, Article 21.07-6, Insurance Code.
11	(b) The Health and Human Services Commission shall contract
12	with a pharmacy benefit manager or other entity that has experience
13	in the development of preferred drug lists or in negotiating
14	supplemental rebates with pharmaceutical manufacturers to
15	administer all or part of the vendor drug program.
16	Sec. 32.0463. SUPPLEMENTAL MEDICAL ASSISTANCE REBATES. (a)
17	In this section:
18	(1) "Labeler" means a person that:
19	(A) has a labeler code from the United States
20	Food and Drug Administration under 21 C.F.R. Section 207.20; and
21	(B) receives prescription drugs from a
22	manufacturer or wholesaler and repackages those drugs for later
23	retail sale.
24	(2) "Manufacturer" means a manufacturer of

- 1 prescription drugs as defined by 42 U.S.C. Section 1396r-8(k)(5),
- 2 as amended, including a subsidiary or affiliate of a manufacturer.
- 3 (3) "Wholesaler" means a person licensed under
- 4 Subchapter I, Chapter 431, Health and Safety Code.
- 5 <u>(b) The Health and Human Services Commission shall</u>
- 6 negotiate with manufacturers and labelers to obtain supplemental
- 7 medical assistance rebates for prescription drugs sold in this
- 8 state.
- 9 (c) A manufacturer or labeler that sells prescription drugs
- 10 <u>in this state may voluntarily negotiate with the Health and Human</u>
- 11 Services Commission and enter into an agreement to provide
- 12 supplemental medical assistance rebates for prescription drugs
- 13 provided under the vendor drug program in excess of the rebates
- 14 required by 42 U.S.C. Section 1396r-8, as amended.
- (d) In negotiating terms for a supplemental medical
- 16 <u>assistance rebate amount, the Health and Human Services Commission</u>
- 17 shall consider:
- 18 (1) rebates calculated under the medical assistance
- 19 rebate program in accordance with 42 U.S.C. Section 1396r-8, as
- amended; and
- 21 (2) any other available information on prescription
- 22 drug <u>prices or rebates.</u>
- Sec. 32.0464. CONFIDENTIALITY OF REBATES, PRICING, AND
- 24 NEGOTIATIONS. Information obtained or maintained by the Health and
- 25 <u>Human Services Commission regarding supplemental medical</u>
- 26 assistance rebate negotiations or a supplemental medical
- 27 <u>assistance rebate agreement, including trade</u> secrets, rebate

- 1 amount, rebate percentage, and manufacturer or labeler pricing, is
- 2 confidential and not subject to disclosure under Chapter 552,
- 3 Government Code.
- 4 Sec. 32.0465. PREFERRED DRUG LIST FOR VENDOR DRUG PROGRAM.
- 5 (a) The Health and Human Services Commission shall adopt a
- 6 preferred drug list for the vendor drug program. In making a
- 7 <u>decision regarding the placement of a drug on the preferred drug</u>
- 8 list, the commission shall consider:
- 9 (1) the recommendations of the Medical Assistance
- 10 Pharmaceutical and Therapeutics Committee established under
- 11 Section 32.0467;
- 12 (2) the clinical efficacy of the drug; and
- 13 (3) the price of competing drugs after deducting any
- 14 federal and state rebate amounts.
- 15 (b) The commission shall provide for distribution of
- 16 current copies of the preferred drug list to all appropriate
- 17 providers of medical assistance in this state.
- (c) In this subsection, "labeler" and "manufacturer" have
- 19 the meanings assigned by Section 32.0463. The commission shall
- 20 ensure that:
- 21 (1) a manufacturer or labeler that reaches an
- 22 agreement with the commission on supplemental medical assistance
- 23 <u>rebates under Section 32.0463 has an opportunity to provide written</u>
- 24 evidence supporting inclusion of a drug on the preferred drug list;
- 25 and
- 26 (2) any drug that has been approved or has had any of
- 27 its particular uses approved by the United States Food and Drug

- 1 Administration under a priority review classification will be
- 2 reviewed by the Medical Assistance Pharmaceutical and Therapeutics
- 3 Committee at the next regularly scheduled meeting of the committee.
- 4 On receiving notice from a manufacturer or labeler of the
- 5 availability of a new product, the commission, to the extent
- 6 possible, shall schedule a review for the product at the next
- 7 <u>regularly scheduled meeting of the committee.</u>
- 8 (d) A recipient of drug benefits under the vendor drug
- 9 program may use the Medicaid fair hearing process to appeal a
- 10 preferred drug list decision made by the commission.
- 11 Sec. 32.0466. PRIOR AUTHORIZATION UNDER THE VENDOR DRUG
- 12 PROGRAM. (a) The Health and Human Services Commission, in its
- 13 rules and standards governing the vendor drug program, shall
- 14 require prior authorization for the reimbursement of a drug that is
- 15 not included in the preferred drug list adopted under Section
- 16 32.0465, except for antiretroviral drugs and any drug exempted from
- 17 prior authorization requirements by federal law and except as
- 18 provided by Subdivision (4). The commission shall establish
- 19 procedures for the prior authorization requirement to ensure that:
- 20 (1) there will be a response to a request for prior
- 21 <u>authorization</u> by telephone or other telecommunications device
- 22 <u>within 24 hours after receipt of a request for prior authorization</u>
- 23 from the prescribing physician;
- 24 (2) a 72-hour supply of the drug prescribed will be
- 25 provided in an emergency or if the commission does not provide a
- 26 response within the time required by Subdivision (1);
- 27 (3) prior authorization is sought by the prescribing

- 1 physician and not by the pharmacy; and
- 2 (4) a recipient of medical assistance who is being
- 3 treated with a mental health-related drug at the time the
- 4 commission adopts a preferred drug list under Section 32.0465 that
- 5 does not include the drug continues to receive the medication after
- 6 the adoption of the list without obtaining prior authorization
- 7 under this <u>section</u>.
- 8 (b) The Medical Assistance Pharmaceutical and Therapeutics
- 9 Committee may make recommendations for the commission's
- 10 consideration regarding a prior authorization requirement for any
- 11 drug covered by the vendor drug program.
- 12 Sec. 32.0467. MEDICAL ASSISTANCE PHARMACEUTICAL AND
- 13 THERAPEUTICS COMMITTEE. (a) The Medical Assistance Pharmaceutical
- 14 and Therapeutics Committee is established for the purposes of
- developing recommendations for a preferred drug list for the vendor
- 16 drug program.
- 17 (b) The committee consists of the following members
- 18 appointed by the governor:
- 19 (1) five physicians licensed under Subtitle B, Title
- 20 3, Occupations Code;
- 21 (2) five pharmacists licensed under Subtitle J, Title
- 22 <u>3, Occupations Code; and</u>
- 23 <u>(3) one public member.</u>
- 24 (c) In making appointments to the committee under
- 25 Subsection (b), the governor shall ensure that the committee
- 26 includes physicians or pharmacists participating in the medical
- 27 assistance program who:

- 1 (1) provide services to all segments of the program's
- 2 diverse population; and
- 3 (2) have experience in either developing or practicing
- 4 under a preferred drug list.
- 5 (d) A member of the committee is appointed for a two-year
- 6 term and may serve more than one term.
- 7 <u>(e) The committee shall elect a presiding officer and an</u>
- 8 assistant presiding officer from its membership, and each officer
- 9 shall serve a one-year term.
- 10 (f) The committee shall meet at least quarterly at the call
- 11 of the presiding officer.
- 12 (g) A member of the committee may not receive compensation
- 13 for serving on the committee but is entitled to reimbursement for
- 14 reasonable and necessary travel expenses incurred by the member
- while conducting the business of the committee, as provided by the
- 16 General Appropriations Act.
- 17 (h) In developing its recommendations for the preferred
- 18 drug list, the committee shall consider the clinical efficacy,
- 19 safety, and cost-effectiveness of a product.
- 20 (i) The Health and Human Services Commission shall adopt
- 21 rules governing the operation of the committee, including rules
- governing the procedures used by the committee for providing notice
- 23 of a meeting. The committee shall comply with the rules adopted
- 24 under this subsection.
- 25 (j) To the extent feasible, the committee shall review all
- 26 drug classes included in the preferred drug list adopted under
- 27 Section 32.0465 at least once every 12 months and may recommend

- 1 inclusions to and exclusions from the list to ensure that the list
- 2 provides for cost-effective medically appropriate drug therapies
- 3 for recipients of medical assistance.
- 4 (k) The committee shall conduct a closed meeting to consider
- 5 or discuss the negotiations of a supplemental medical assistance
- 6 rebate agreement under Section 32.0463 or any other information
- 7 relating to supplemental medical assistance rebates, including
- 8 trade secrets, rebate amount, rebate percentage, and manufacturer
- 9 or labeler pricing.
- 10 (1) The Health and Human Services Commission shall provide
- administrative support and resources as necessary for the committee
- to perform its duties under this section and Section 32.0466.
- (m) Chapter 2110, Government Code, does not apply to the
- 14 committee.
- 15 SECTION 2. If before implementing any provision of this Act
- 16 a state agency determines that a waiver or other authorization from
- 17 a federal agency is necessary for implementation, the state agency
- 18 shall request the waiver or authorization and may delay
- 19 implementing that provision until the waiver or authorization is
- 20 granted.
- 21 SECTION 3. Not later than November 1, 2003, the governor
- 22 shall appoint members to the Medical Assistance Pharmaceutical and
- 23 Therapeutics Committee established under Section 32.0467, Human
- 24 Resources Code, as added by this Act.
- 25 SECTION 4. Not later than January 1, 2004, the Health and
- 26 Human Services Commission shall implement Section 32.0463, Human
- 27 Resources Code, as added by this Act.

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- 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.
- 7 (b) Not later than March 1, 2004, the Health and Human 8 Services Commission shall adopt the preferred drug list as required 9 by Section 32.0465, Human Resources Code, as added by this Act.
- 10 SECTION 6. This Act takes effect September 1, 2003.