

By: Menendez

H.B. No. 2016

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 shall 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

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 (b) The Health and Human Services Commission shall  
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 in this state may voluntarily negotiate with the Health and Human  
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.

15 (d) In negotiating terms for a supplemental medical  
16 assistance rebate amount, the Health and Human Services Commission  
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  
20 amended; and

21 (2) any other available information on prescription  
22 drug prices or rebates.

23 Sec. 32.0464. CONFIDENTIALITY OF REBATES, PRICING, AND  
24 NEGOTIATIONS. Information obtained or maintained by the Health and  
25 Human Services Commission regarding supplemental medical  
26 assistance rebate negotiations or a supplemental medical  
27 assistance rebate agreement, including trade 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 decision regarding the placement of a drug on the preferred drug  
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.

18 (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 rebates under Section 32.0463 has an opportunity to provide written  
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 regularly scheduled meeting of the committee.

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 authorization by telephone or other telecommunications device  
22 within 24 hours after receipt of a request for prior authorization  
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 section.

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  
15 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 3, Occupations Code; and

23 (3) one public member.

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           (e) The committee shall elect a presiding officer and an  
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  
15 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  
22 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 (l) The Health and Human Services Commission shall provide  
11 administrative support and resources as necessary for the committee  
12 to perform its duties under this section and Section 32.0466.

13 (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.

1           SECTION 5. (a) Not later than January 1, 2004, the Medical  
2 Assistance Pharmaceutical and Therapeutics Committee established  
3 under Section 32.0467, Human Resources Code, as added by this Act,  
4 shall submit recommendations for the preferred drug list the  
5 committee is required to develop under that section to the Health  
6 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.