BILL ANALYSIS

C.S.H.B. 1804
By: Delisi
State Health Care Expenditures, Select
Committee Report (Substituted)

BACKGROUND AND PURPOSE

The use of pharmacy benefit managers (PBM's) allows states greater flexibility in serving larger populations with less money. PBM's bring with them the latest in cost management techniques critical when state budgets are stretched thin and it becomes essential to maximize limited resources. The Employee Retirement System and the Teacher Retirement System currently contract with a PBM, achieving savings in the management of their health care plans.

H.B. 1804 allows the Health and Human Services Commission (commission) to contract with a PBM. Also, the commission is required to create a Pharmacy and Therapeutic Committee to establish a preferred drug list (PDL) for the Medicaid Vendor Drug Program.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the Health and Human Services Commission in SECTION 1, Sec. 32.0467. Human Resources Code of this bill.

ANALYSIS

SECTION 1. Amends Subchapter B, Chapter 32, Human Resources Code, by adding Section 32.0462-32.0467 as follows:

Sec. 32.0462. PHARMACY BENEFIT MANAGER FOR VENDOR DRUG PROGRAM. States that "pharmacy benefit manager" has the meaning assigned by Section 1, Article 21.07-6, and Insurance Code.

Allows the Health and Human Services Commission (commission) to contract with a pharmacy benefit manager (PBM) or similar entity with experience in negotiations supplemental rebates with pharmaceutical manufacturers to administer all of part of the vendor drug program.

Sec. 32.0463. SUPPLEMENTAL MEDICAL ASSISTANCE REBATES. Defines "labeler" as a person that has a labeler code from the United States Food and Drug Administration under 21. C.F.R. Section 207.20 and receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

Defines "manufacturer" as 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.

Defines "wholesaler" as a person licensed under Subchapter I, Chapter 431, Health and Safety Code.

Requires the commission to negotiate with manufacturers and labelers of brand name drugs to obtain supplemental medical assistance rebates for prescription drugs sold in Texas.

Allows manufacturers or labelers selling prescription drugs in Texas to voluntarily negotiate with the commission to enter into agreements to provide supplemental medical assistance rebates for prescription drugs provided under the vendor drug program in excess of rebates required by 42 U.S.C. Section 1396r-

8, as amended.

The commission must consider the following when negotiating terms for a supplemental medical assistance rebate amount:

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

Any other available information on prescription drug prices or rebates.

The commission must 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.

Sec. 32.0464. CONFIDENTIALITY OF REBATES, PRICING, AND NEGOTIATIONS. Any information obtained or maintained by the 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 open records provisions under Chapter 552, Government Code.

Sec. 32.0465. PREFERRED DRUG LIST FOR VENDOR DRUG PROGRAM. Requires the commission to develop a preferred drug list, taking the following into consideration:

Evidenced based procedures;

The recommendations of the Medical Assistance Pharmaceutical and Therapeutics Committee established under Section 32.0467;

The clinical efficiency of the drug;

The safety of the drug;

The cost effectiveness of the drug; and

The cost of the drug including consideration of supplemental rebates.

The commission is required to provide for the electronic distribution of current copies of the preferred drug list to all appropriate providers and pharmacists in Texas. The commission shall make copies of the list available in writing upon request.

"Labeler" and "manufacturer" have the meanings assigned by Section 32.0463. Requires the commission to ensure that:

A manufacturer or labeler that reaches an agreement with the commission on supplemental medical assistance rebates under Section 32.0463 may provide written evidence supporting inclusion of a drug on the preferred drug list; and any drug approved or has had any of its particulars approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the Medical Assistance Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting of the committee. The commission, upon receiving notice from a manufacturer or labeler of the availability of a new product, to the extent possible, will schedule a review for the product a the next regularly schedule meeting of the committee.

Sec. 32.0466. PRIOR AUTHORIZATION UNDER THE VENDOR DRUG PROGRAM. Defines nonpreferred drug.

Requires the commission, under its rules and standards governing the vendor drug program, must require prior authorization for the reimbursement of a nonpreferred drug except for any drug exempted from prior authorization requirements by federal law and expect as provided by Subdivision (4). The commission must follow these procedures:

Requests for prior authorization must be accepted by the appropriate entity 24 hours a day;

There will be a response to a req tuest for prior authorization by telephone or other telecommunications device within 18 hours after receipt of a request for prior authorization from the prescribing physician; a 72-hour supply of the drug prescribed will be provided in an emergency of if the commission does not provide a response within the time required by Subdivision (1); Prior authorization is sought by the prescribing physician and not the pharmacy;

Chronically-ill recipients of medical assistance who are treated with a drug at the time the commission adopts a preferred drug list under Section 32.0465 that does not include the drug continues to receive the medication after the adoption of the list without obtaining prior authorization; and Patients who receive prior authorization for a particular drug do not have to obtain subsequent prior authorizations for that same drug.

Recipients can appeal a denial of prior authorization through the Medicaid fair hearing process.

Drugs treating HIV, AIDS, cancer, schizophrenia, bipolar disorder and hemophilia are exempted from the requirements of prior authorization.

Physicians are allowed to override the requirement for prior authorization if the prescribing physician communicates to the pharmacist that the drug is medically necessary if treatment with a preferred drug has been ineffective or if clinical conditions dictate it.

The commission shall monitor physicians use of overrides by drug name and physician name.

The commission may also restrict reimbursement for certain drugs to certain physicians.

If the physician obtains prior authorization or communicates medical necessity reimbursement may be provided notwithstanding any other provision of Section 32.0466.

Sec. 32.0467. MEDICAL ASSISTANCE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE. This committee is established to develop recommendation for a preferred drug list for the vendor drug program.
The committee shall be composed of:

Five physicians;
Four pharmacists;
One member who is an RN, ANP or PA; and
One member who is licensed in the practice of an allied health profession.

The governor, in making appointments, must ensure that physicians and pharmacists appointed to the committee:

Provide services to all segments of the program's diverse populations; and
Have experience in either developing or practicing under a preferred drug list.

Members will serve two-year terms and are eligible for not more than three consecutive terms. The committee must elect a presiding officer and an assistant presiding officer, with each officer serving a one-year term. The committee is required to meet at least quarterly at the call of the chair.

Members of the committee cannot receive compensation for service but may be entitled to certain reimbursements for expenses.

The committee must when developing recommendations for the preferred drug list consider:

Evidence based procedure;
Clinical efficacy;
Safety;
Cost-effectiveness of a product;
Availability of over-the-counter substitutes;
Any clinical information provided by a pharmaceutical manufacturer;
Any written testimony provided by a pharmaceutical manufacturer regarding a product's clinical efficacy; and
The cost of a product with consideration to supplemental rebates.

The commission must adopt rules governing the operation of the committee, including governing procedures used by the committee for providing notice of hearings.

As is feasible, the committee must review all drug classes included in the preferred drug list adopted under Section 32.0465 at least once every 12 months. The committee may also make recommendations for 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.

The committee must conduct closed meeting to consider or discuss negotiations of agreements under Section 32.0463 on any other information relating to information protected as confidential by this Act.

The commission is required to provide support services and resources as necessary.

Chapter 2110, Government Code, does not apply to this Act.

The committee is considered a part of the executive branch for purposes of Chapter 305, Government Code and its actions are considered administrative actions for purposes of Chapter 305, Government Code.

After each meeting, the committee shall produce a publicly available report.

SECITON 2. If a state agency believes that a waiver or authorization from the federal government for implementation, the state agency may request a waiver or authorization and delay implementation until the necessary waivers and authority are granted.

SECTION 3. Gubernatorial appointment must be made no later than November 1, 2003.

SECTION 4. Section 32.0463 must be implemented no later than January 1, 2004.

SECTION 5. Recommendations for the preferred drug list as compiled by the Medical Assistance Pharmaceutical and Therapeutics Committee must be submitted no later than January 1, 2004.

The preferred drug list must be adopted no later than March 1, 2004.

SECTION 6. Effective date: September 1, 2003.

EFFECTIVE DATE

This Act takes effect on September 1, 2003.

COMPARISON OF ORIGINAL TO SUBSTITUTE

The word “may” replaces the word “shall” at line 11, page 1.

The words “of brand name prescription” are inserted on lines 6-7 of page 2.

New language is added under Subdivision (2) line 23, page 2 that reads “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.”

The words “evidence-based procedures” are inserted at line 21, page 3.

The words “the safety of the drug;” are inserted at line 26, page 3.

The words “the cost-effectiveness of the drug; and” are inserted at line 27, page 3.

The words “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.” are inserted at lines 1-3, page 4.

A new subsection (b) is added at line 4, page 4.

The word “electronic” is inserted at line 13, page 4.

The words “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.” are inserted at lines 15-18, page 4.

A new subsection(a) is added at line 20, page 4.

The word “nonpreferred” is inserted on line 25, page 4.

Subdivision (c)(1) is added at line 3 page, 5.

Subdivision (c)(2) is added at line 6, page 5.

Subdivision (4) is struck and replaced with new language at line 13, page 5.

A new subdivision (5) is added at line 19, page 5.

The words “for prior authorization” are inserted at line 25, page 5.

A new subsection (e) is added at line 26, page 5.

A new subsection (f) is added at line 8, page 6.

A new subsection (g) is added at line 20, page 6.

A new subsection (h) is added at line 23, page 6.

A new subsection (i) is added at line 4, page 7.

Subdivision (2) at line 23, page 7 replaces original subdivision (2).

Subdivision (3) at line 25, page 7 replaces original subdivision (3).

A new subdivision (4) is added at line 1, page 8.

A new subdivision (5) is added at line 3, page 8.

The words “not more than three consecutive terms.” replace the words “more than one term” at line 14, page 8.

A new subsection (h) replaces the original subsection (h) at line 25, page 8.

A new subsection (n) is added at line 9, page 10.

A new subsection (o) is added at line 13, page 10.