BILL ANALYSIS

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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

In 2003, the legislature directed the Texas Health and Human Services Commission (HHSC) to implement a preferred drug list (PDL) for prescription drugs prescribed to enrollees in Medicaid or the Children's Health Insurance Program (CHIP). A Pharmaceutical and Therapeutics (P&T) Committee composed of practicing physicians and pharmacists advises HHSC on which drugs to designate as "preferred" or "non-preferred."

To be classified as preferred, state law specifies that a drug must not only be clinically effective, but also that the manufacturer provide a supplemental rebate. Without the rebate, even clinically efficacious and safe drugs cannot be classified as preferred. State law requires the physician or prescriber to obtain prior approval before the prescription for a non-preferred drug can be filled (with exceptions in an emergency). In some cases, the manufacturer may only give a rebate for certain strengths or formulations of its product (such as tablet form). If a physician needs a different dose or a different method of delivery, such as liquid formulation, prior approval must still be obtained even if the drug is otherwise safe and effective. When there is not a choice of dosage strength or delivery among preferred drugs, pediatricians and family physicians caring for children are most burdened since children often need lower doses and/or liquid agents to successfully take the medication.

Current statute does not require HHSC to disclose the factors that determine whether a drug is classified as preferred or non-preferred. Thus, physicians and prescribers do not know whether a drug was excluded from the preferred list solely because no rebate was provided or because of clinical issues.

Finally, the Medicaid PDL prior approval process is outdated. Currently, a physician or prescriber can only request approval through phone or fax. No electronic or Internet-based mechanism is available. While implementation of the PDL has resulted in considerable savings to the state, it also has increased physicians' and providers' administrative costs. Physicians' second most cited reason, after payment rates, for not participating in Medicaid is the program's administrative costs. Streamlining the Medicaid PDL would help minimize those expenses and help the state recruit more physicians into the program.

This legislation amends the Medicaid PDL to provide greater transparency regarding what factors the state and the P&T committee used in classifying a drug as preferred or non-preferred; ensure that for each preferred drug class, there will be multiple strengths and dosages available and multiple delivery methods; and require HHSC to offer electronic methods, in addition to phone and fax, to obtain prior approval.

As proposed, S.B. 1536 amends current law relating to preferred drug lists, including confidentiality, supplemental rebate, prior authorization, and publication requirements.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to the Health and Human Services Commission is modified in SECTION 4 (Section 531.074, Government Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Sections 531.071(a) and (c), as follows:

(a) Provides that notwithstanding any other state law, financial information obtained or maintained by the Health and Human Services Commission (HHSC) 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 (Public Information).

(c) Provides that notwithstanding Subsection (a), the following information is not confidential: general information about the aggregate costs of different classes of drugs; the fact that a supplemental rebate agreement was or was not reached between HHSC and a manufacturer or labeler for a particular drug; and 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, provided that the amount of the rebate or other confidential financial information described in this section is not disclosed, rather than is not confidential under Subsection (a). Makes a nonsubstantive change.

SECTION 2. Amends Section 531.072, Government Code, by amending Subsection (b) and adding Subsections (b-1), (b-2), and (g), as follows:

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

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

(2) a program benefit agreement as described in Section 531.070 has been reached by HHSC and a labeler or manufacturer.

(b-1) Requires that a placement of a drug on the preferred drug list include all strengths and dosages.

(b-2) Requires that each drug class include multiple methods of delivery of the drug, including liquid, tablet, capsule, and orally disintegrating tablet.

(g) Authorizes a generic manufacturer or labeler, beginning one year after the last review of the drug or its drug class, to make an application or request to have its drug reconsidered for preferred drug placement based upon satisfaction of the cost-effectiveness exception described by Subsection (b)(1).

SECTION 3. Amends Section 531.073, Government Code, by adding Subsection (g) to require HHSC to ensure that prior authorization claims submission may occur through multiple telecommunication modes, including electronic point-of-sale submission, telephonic submission, fax submission, and electronic communications via the Internet.

SECTION 4. Amends Sections 531.074(i) and (m), as follows:

(i) Requires HHSC to adopt rules governing the operation of the Pharmaceutical and Therapeutics Committee (committee), including rules prohibiting the committee from discussing confidential financial information described by Section 531.071 in a public meeting, and 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 HHSC to provide such information. Requires that confidential financial information described in Section 531.071 be omitted from the summary and that the written summary be posted to the Internet. Deletes existing text requiring the committee to comply with the rules adopted under this subsection. Makes nonsubstantive changes.

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

(1) 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 (h) (relating to considerations made when the committee develops recommendations for the preferred drug lists);

(2) 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

(3) for all recommendations of the committee against placement of a drug on the preferred drug list, a statement of which of the criteria listed in Subsection (h) were not satisfied and, if the clinical efficacy or safety criterion was not satisfied, a summary of the information relied upon by the committee supporting such conclusion. Makes nonsubstantive changes.

SECTION 5. Amends Subchapter B, Chapter 531, Government Code, by adding Section 531.0741, as follows:

Sec. 531.0741. PUBLICATION OF INFORMATION RELATING TO COMMISSION DECISION-MAKING. Requires HHSC to publish on the Internet its decisions on preferred drug list placement including:

(1) a list of drugs reviewed and HHSC's 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 HHSC and a manufacturer or labeler for a particular drug and, 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 and, if a recommendation was rejected for safety or clinical efficacy reasons, information supporting such a decision.

SECTION 6. Effective date: September 1, 2009.