BILL ANALYSIS

C.S.H.B. 3719
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

In 2003, the legislature directed the Health and Human Services Commission (HHSC) to implement a preferred drug list for prescription drugs prescribed to enrollees in Medicaid or the child health plan program. A pharmaceutical and therapeutics committee composed of practicing physicians and pharmacists advises HHSC on which drugs to designate as preferred or nonpreferred.

To be classified as preferred, state law requires a drug to be clinically effective and requires the manufacturer to provide a supplemental rebate. This means that without the manufacturer rebate, even clinically effective and safe drugs cannot be classified as preferred. According to state law, nonpreferred drugs require the physician or prescriber to obtain prior approval before the prescription can be filled, except in the case of an emergency. In some cases, a manufacturer may only give a rebate for certain strengths or formulations of a product, meaning that if a physician needs a different dose or a different method of delivery, prior approval must be obtained even if the drug is otherwise safe and effective. When there is not a choice of dosage strength or delivery method among preferred drugs, the burden mostly impacts pediatricians and family physicians caring for children, since children often need lower doses or liquid formulations to successfully take a medication.

Current statute does not require HHSC to disclose the factors that determine whether a drug is classified as preferred or nonpreferred. This means physicians do not know whether a drug was excluded from the preferred list because no rebate was provided or because of clinical issues.

The Medicaid preferred drug list prior approval process is outdated. Currently, a physician or prescriber is only able to request approval by phone or fax, as there is no electronic or Internet-based mechanism available.

While implementation of the preferred drug list has resulted in considerable savings to the state, it has also resulted in increased administrative costs for physicians and providers. Second to payment rates, physicians' most frequently cited reason for not participating in Medicaid is the program's administrative costs. Streamlining the Medicaid preferred drug list would help minimize those expenses and help the state recruit more physicians into the program.

C.S.H.B. 3719 specifies drugs authorized to be contained in the preferred drug lists and considerations to be made in creating the lists, requires HHSC to ensure that requests for prior authorization may be submitted through multiple telecommunications methods, sets forth requirements for the Pharmaceutical and Therapeutics Committee, and requires certain information to be published to the HHSC Internet website.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the Health and Human Services Commission in SECTION 4 of this bill.

ANALYSIS

C.S.H.B. 3719 amends the Government Code to add an exception to provisions establishing the confidentiality of general information about the aggregate costs of different classes of drugs under a drug rebate agreement or supplemental rebate agreement administered by the Health and Human Services Commission (HHSC) for a drug name or information that could reveal a drug name. The bill clarifies that information about whether HHSC and a manufacturer or labeler reached or did not reach a supplemental rebate agreement for a particular drug is not confidential.

C.S.H.B. 3719 authorizes the preferred drug lists for the Medicaid vendor drug program and the children's health insurance program to contain a drug provided by a manufacturer or labeler that has not reached a supplemental rebate agreement with HHSC if the commission determines that inclusion of the drug on the preferred drug lists will have no negative cost impact to the state, or a drug provided by a manufacturer or labeler that has reached an agreement with HHSC to provide program benefits in lieu of supplemental rebates. The bill requires consideration to be given to including all strengths and dosage forms of a drug on the preferred drug lists. The bill requires HHSC, in addition to other prescribed considerations, to consider the inclusion of multiple methods of delivery within each drug class, including liquid, tablet, capsule, and orally disintegrating tablets.

C.S.H.B. 3719 requires HHSC to ensure that requests for prior authorization may be submitted by telephone, facsimile, or electronic communications through the Internet. The bill requires HHSC to provide an automated process that may be used to assess a Medicaid recipient's medical and drug claim history to determine whether the recipient's medical condition satisfies the applicable criteria for dispensing a drug without an additional prior authorization request.

C.S.H.B. 3719 requires the Pharmaceutical and Therapeutics Committee to meet in public and to permit public comment before voting on any changes in the preferred drug lists. The bill requires minutes of each meeting to be made available to the public not later than the 10th business day after the date the minutes are approved. The bill authorizes the committee to meet in executive session to discuss confidential information. The bill requires HHSC by rule to require the committee or the committee's designee to present a summary of any clinical efficacy and safety information or analyses regarding a drug under consideration for a preferred drug list that is provided to the committee by a private entity that has contracted with HHSC to provide the information. The bill requires the committee or the committee's designee to provide the summary in electronic form before the public meeting at which consideration of the drug occurs and requires confidential information to be omitted from the summary. The bill requires the summary to be posted to HHSC's Internet website.

C.S.H.B. 3719 clarifies that the disclosure required for each specific drug relating to preferred drug list status is to be released immediately after the committee deliberations conclude and is to include each specific drug recommended against preferred drug status. The bill requires the disclosure to be posted on HHSC's Internet website not later than the 10th business day after the conclusion of deliberations, rather than requiring the disclosure to be made in writing with no specific deadline. The bill requires the public disclosure to include the general basis for the recommendation for each drug class and, for each recommendation, whether a supplemental rebate agreement or a program benefit agreement was reached.

C.S.H.B. 3719 requires HHSC to publish on HHSC's Internet website any decisions on preferred drug list placement, including: a list of drugs reviewed and HHSC's decision for or against placement on a preferred drug list of each drug reviewed; for each recommendation, whether a supplemental rebate agreement or a program benefit agreement was reached; and the rationale for any departure from a recommendation of the Pharmaceutical and Therapeutics Committee.

C.S.H.B. 3719 requires the executive commissioner of HHSC, not later than December 1, 2010,

to implement the bill's provisions relating to submission of request for prior authorization by telephone, facsimile, or electronic communications through the Internet and an automated process for assessing a Medicaid recipient's claim history to satisfy criteria for dispensing a drug without prior authorization. The bill requires a state agency that is affected by a provision of the bill to request a federal waiver or authorization if the agency determines that a waiver or authorization is necessary for the implementation of the provision, and it authorizes the agency to delay implementation until the federal waiver or authorization is obtained.

EFFECTIVE DATE

September 1, 2009.

COMPARISON OF ORIGINAL AND SUBSTITUTE

C.S.H.B. 3719 differs from the original by omitting a provision included in the original clarifying that 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 is confidential. The substitute adds an exception not included in the original to make confidential a drug name or information that could reveal a drug name in general information about the aggregate costs of certain drugs. The substitute differs from the original by omitting a provision included in the original excepting from confidentiality requirements 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 placement on the preferred drug list.

C.S.H.B. 3719 differs from the original by authorizing a drug provided by a manufacturer or labeler that has not reached a supplemental rebate agreement with HHSC to be placed on the preferred drug lists if the commission determines that the drug's inclusion will have no negative cost impact to the state, whereas the original bases the inclusion of such a drug on HHSC determination that the drug is as or more cost-effective than a drug provided by a brand name manufacturer or labeler who has reached a supplemental rebate agreement in the same drug class. The substitute omits a provision included in the original authorizing a generic manufacturer or labeler to make an application or request to have its drug reconsidered for preferred drug placement based on satisfaction of a determination of the drug's cost-effectiveness, provided that one year has passed since the last review of the drug or its drug class.

C.S.H.B. 3719 differs from the original by omitting point-of-sale submission from the methods for submitting prior authorization requests required to be used by HHSC. The substitute adds a provision not included in the original relating to an automated process for assessing a Medicaid recipient's claim history to satisfy criteria for dispensing a drug without prior authorization.

C.S.H.B. 3719 adds a provision not included in the original to require the Pharmaceutical and Therapeutics Committee or the committee's designee to provide the clinical efficacy and safety summary in electronic form before the public meeting at which consideration of the drug for inclusion on the preferred drug list occurs. The substitute adds a provision not included in the original to require immediate public disclosure of each drug recommended for or against preferred drug status on conclusion of the committee deliberations. The substitute adds a 10-day posting deadline not included in the original for posting the committee's recommendations on the HHSC website. The substitute differs from the original by omitting from the elements required to be included in the disclosure a statement on the criterion related to a drug's clinical efficacy, safety, and cost-effectiveness that was not satisfied by a drug recommended against inclusion on the preferred drug list and a summary of the information on which the committee relied for its decision. The substitute differs from the original by omitting provisions requiring the publication of information about supplemental rebate agreements reached for certain drugs and if such agreement was or was not of a sufficient amount to make the drug cost-effective for placement on the preferred drug list. The substitute omits a provision included in the original requiring the

disclosure of information supporting the rejection of a recommendation by the committee if the rejection was for safety or clinical efficacy reasons.

C.S.H.B. 3719 differs from the original by including a provision requiring the committee to meet in public for comment before voting on changes to the preferred drug list. The substitute adds provisions not included in the original providing for certain provisions to take effect December 1, 2010, and requiring request of a federal waiver if necessary.