BILL ANALYSIS

C.S.H.B. 3237
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

The current practice of the Texas Immunization Branch is to award 100% of the business, for a monovalent vaccine, to a single manufacturer, based on the lowest CDC pricing. The unintended result of this practice is a potential weakening of immunization practices and disruption of the vaccine production and supply chain in the state. Today, four of twelve available vaccines **[Hepatitis A, Hepatitis B, DTaP and Tdap]** are available from two manufacturers.

Vaccines carry far more risk for supply disruption compared to pharmaceuticals because they involve working with complex biological products and biotechnology processes that are not always predictable. Over the past five years, there have been shortages in 9 out of 12 vaccines recommended for children. Shortages lead to rationing, as well as temporary and confusing revisions to recommendations, such as with influenza vaccine and certain sole-source vaccines. In 2001 a major tetanus vaccine manufacturer left the market, and the US experienced a severe shortage of all tetanus containing vaccines. It took over a year for the remaining vaccine manufactures to increase production and for the tetanus vaccine shortage to end. Keeping more vaccine manufacturers engaged in a state minimizes the potential for vaccine shortages.

CSHB 3237 would provide Texas with additional protections for its vaccine supply by allowing providers to choose between either manufacture of those vaccines that are manufactured by more than one manufacturer when the price difference is 10 percent or less.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0102 to read as follows:

Sec. 161.0102. VACCINES FOR CHILDREN PROGRAM. (a) In this section: (1) "Vaccines for children program" means the program operated by the Department of State Health Services (department) under authority of 42 U.S.C. Section 1396s. (2) "Equivalent vaccines" means two or more vaccines that: (A) protect a recipient of a vaccine against the same disease or diseases; (B) require the administration of the same number of doses; and (C) are interchangeable according to the federal Advisory Committee on Immunization Practices.

(b) Except as provided by Subsection (c), where two or more manufacturers produce equivalent vaccines, the department shall procure an equal supply of the vaccine from each manufacturer.

(c) An equivalent vaccine must be: (1) approved by the United States Food and Drug Administration; (2) recommended by the federal Advisory Committee on Immunization Practices; and (3) made available to the department by the Centers for Disease Control and Prevention of the United States Public Health Service.

(d) The department shall procure an equal supply of each equivalent vaccine under Subsection (b) only if the cost to the department of providing each equivalent vaccine is not more than 110 percent of the lowest priced equivalent vaccine.

EFFECTIVE DATE

September 1, 2007.

COMPARISON OF ORIGINAL TO SUBSTITUTE

As drafted H.B.3237 required the department to allow certain providers to choose between particular vaccines, which are available to more than one manufacturer, prior to the state purchasing the vaccines when the price between the vaccines is less than ten percent. The C.S.H.B 3237 has the department purchase equal amounts of certain qualifying vaccines when the price difference between the vaccines is less than ten percent. The substitute bill excludes vaccines meeting the following requirements; must be approved by the United States Food and Drug Administration, recommended by the Federal Advisory Committee on Immunization Practices, and made available under contract with the Centers for Disease Control. The substitute clarifies that equivalent vaccines protect against the same disease, are administered with the same number of doses, and are considered interchangeable by the Federal Advisory Committee on Immunization Practices.