BILL ANALYSIS

Senate Research Center

H.B. 2163
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Health & Human Services
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Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The U.S. Department of Justice (DOJ) recently charged Forest Laboratories with defrauding the government of millions of dollars by illegally marketing Celexa and Lexapro for unapproved uses in children and teenagers. The DOJ complaint cited that concealed drug studies showed that the drugs were not effective in children and might cause suicidal tendencies; these drugs are on the list provided to the Health and Human Services Commission (HHSC) for fiscal year 2007. In fiscal year 2007, the Texas's Medicaid program spent $219 million on psychotropic medications for children ages 0 to 18; $500,000 of which was spent for babies. The Medicaid Vendor Drug program administers and monitors Medicaid drugs and reimbursement for drugs.

Off-label use of a drug is use for a problem or age group that was not approved by the FDA. Drugs are commonly used for off-label use, particularly in children. However, there are inherent risks in giving a drug to a population for which it was not approved.

Risks associated with antipsychotic drugs include: diabetes, weight gain, movement disorders (tremors), suicidal thoughts, heart problems, cholesterol problems, and in the elderly, stroke. At least one of these drugs has been associated with blood disorders as well. Of the five newer antipsychotic drugs, only Abilify and Risperdal are approved for children.

The Health and Human Services Commission Office of Inspector General (OIG) found that 47 percent of children on Medicaid who are taking antipsychotics did not have a diagnosis supporting that use.

The federal government and the State of Texas have sued several drug companies over the off-label marketing of antipsychotic drugs.

H.B. 2163 relates to a study regarding the provision of certain medications through the Medicaid vendor drug program to children younger than 16 years of age.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter B, Chapter 531, Government Code, by adding Section 531.0731, as follows:

> Sec. 531.0731. STUDY REGARDING THE PROVISION OF CERTAIN MEDICATION TO CHILDREN. (a) Requires the Health and Human Services Commission (HHSC) to conduct a study to determine the appropriateness and safety of providing antipsychotic or neuroleptic medication through the Medicaid vendor drug program to children younger than 16 years of age.
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> (b) Requires that the study conducted under Subsection (a) consider the following factors relevant to the appropriateness and safety of providing the medications to children: the physical and psychological medical diagnosis of a child's condition; whether the United States Food and Drug Administration has approved a medication for use by a child of a certain age; whether a child has

successfully taken a medication previously; access to quality medical care for a child receiving benefits under the program; the standard of care in the medical profession regarding the provision of such medications to a child; and any other factor HHSC considers relevant.

(c) Requires the executive commissioner of HHSC, not later than November 10, 2010, to submit a report containing the results of the study conducted under Subsection (a) to the governor, the lieutenant governor, the speaker of the house of representatives, and the chairs of the Senate Committee on Health and Human Services and the House Committee on Public Health.

SECTION 2. Effective date: September 1, 2009.