BILL ANALYSIS

H.B. 2185
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

Nearly 20 percent of prescriptions nationwide are written for "off-label uses," referring to prescriptions that are legally prescribed for purposes, patient populations, or dosages different from what the FDA originally approved. After medications receive approval from the FDA, they are often found to have additional beneficial uses, but the FDA approval process for new uses of a medication is long and expensive. Unfortunately, the FDA's "gag rule" prohibits doctors and drug manufacturers from sharing information with patients about a medication's off-label uses. Due to a fear of prosecution and various disciplinary actions, patients often do not receive the information about a medication's off-label uses, many of which could save lives. H.B. 2185 seeks to address this issue by providing for the promotion of off-label uses of certain drugs, biological products, and devices and providing protections for those who legally do so.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

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

H.B. 2185 amends the Health and Safety Code to authorize a pharmaceutical manufacturer or the manufacturer's representative to promote, in the manufacturer's advertising or marketing materials or directly to a physician, health care provider, or third-party payer, a medically truthful and accurate off-label use of a drug, biological product, or device. A physician or health care provider may communicate or otherwise promote to a patient an off-label use of a drug, biological product, or device consistent with the off-label use promoted for that drug, product, or device, as applicable, by a pharmaceutical manufacturer. For purposes of the bill's provisions, "health care provider" means a person other than a physician who is licensed, certified, or otherwise authorized by state law to dispense or prescribe a prescription drug in the ordinary course of business or practice of a profession.

H.B. 2185 prohibits a pharmaceutical manufacturer or the manufacturer's representative from being prosecuted or subjected to disciplinary action for promoting an off-label use of a drug, biological product, or device and prohibits the state regulatory authority of a physician or health care provider from revoking or refusing to renew the license or certificate of or otherwise impose a disciplinary action against a physician or health care provider who communicates or otherwise promotes an off-label use of a drug, biological product, or device.

H.B. 2185 establishes that its provisions do not require a health benefit plan to provide health benefit coverage for an off-label use of a drug, biological product, or device. The bill prohibits the state or a local governmental entity from using public money to enforce or to cooperate with the federal government in enforcing certain provisions of the Federal Food, Drug, and Cosmetic Act against a pharmaceutical manufacturer or their representative for promoting an off-label use in a manner authorized by the bill. The bill also defines "off-label use," "physician," and "third-party payer."

EFFECTIVE DATE

September 1, 2021.