BILL ANALYSIS

Senate Research Center
87R6968 JG-D

S.B. 1820
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Health & Human Services
4/19/2021
As Filed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Nearly 20 percent of prescriptions nationwide are written for "off-label uses." The term "off-label use" refers to prescriptions that are legally prescribed for purposes, patient populations, or dosages different from what the United States Food and Drug Administration (FDA) originally approved. After a medication receives approval from the FDA, medications are often found to have additional uses. However, the FDA's approval process for new uses of a medication is long and expensive.

The FDA's "gag rule" censors doctors and drug manufacturers, which prevents both parties from sharing information with patients about a medication's off-label uses. Out of fear of prosecution and various disciplinary actions, doctors and pharmaceutical companies are unable to provide patients with information about a medication's off-label uses, many of which could save lives.

S.B. 1820, also known as the "Truth in Medicine Act," seeks to allow accurate, truthful speech between pharmaceutical manufacturers, healthcare providers, and patients about drugs approved by the FDA for "off-label uses."

This bill:
Allows accurate, truthful speech between pharmaceutical manufacturers, health care providers, third-party payers, and patients about an off-label use for a certain substance.

- Protects pharmaceutical manufacturers, health care providers, and third-party payers from prosecution or disciplinary action for engaging in truthful conversations about off-label uses.

- Does not require a health benefit plan to provide coverage for off-label uses.

- Prohibits the use of state and local resources to enforce 21 U.S.C. Sections 331 and 335 against a pharmaceutical manufacturer for promoting an off-label use.

As proposed, S.B. 1820 amends current law relating to the promotion of off-label uses of certain drugs, biological products, and devices.

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 Subtitle A, Title 6, Health and Safety Code, by adding Chapter 444, as follows:

CHAPTER 444. OFF-LABEL USE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES

Sec. 444.001. DEFINITIONS. Defines "health care provider," "off-label use," and "physician."

Sec. 444.002. PROMOTION OF OFF-LABEL USE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES. (a) Authorizes a pharmaceutical manufacturer or a representative of a pharmaceutical manufacturer, notwithstanding any other law, to promote, in the manufacturer's advertising or marketing materials or directly to a physician or health care provider, a medically truthful and accurate off-label use of a drug, biological product, or device.

(b) Authorizes a physician or health care provider to 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 under Subsection (a).

Sec. 444.003. DISCIPLINARY ACTION PROHIBITED FOR PROMOTION OF OFF-LABEL USE. (a) Prohibits a pharmaceutical manufacturer or a representative of a pharmaceutical manufacturer from being prosecuted or being subject to disciplinary action, including a revocation of or refusal to renew a license or certification, for promoting an off-label use of a drug, biological product, or device under Section 444.002.

(b) 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 imposing 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 under Section 444.002.

Sec. 444.004. HEALTH BENEFIT PLAN COVERAGE FOR OFF-LABEL USE NOT REQUIRED. Provides that this chapter does not require a health benefit plan to provide health benefit coverage for an off-label use of a drug, biological product, or device.

Sec. 444.005. USE OF STATE MONEY FOR CERTAIN PURPOSES PROHIBITED. Prohibits this state or a local governmental entity from using public money to enforce or to cooperate with the federal government in enforcing 21 U.S.C. Sections 331 and 335 against a pharmaceutical manufacturer or a representative of a pharmaceutical manufacturer for promoting an off-label use under Section 444.002.

SECTION 2. Provides that Section 444.003, Health and Safety Code, as added by this Act, applies to a prosecution or disciplinary action initiated or pending on or after the effective date of this Act.

SECTION 3. Effective date: September 1, 2021.