SUBJECT: Allowing promotion of off-label uses of certain drugs, products, devices

COMMITTEE: Public Health — favorable, without amendment

VOTE: 8 ayes — Klick, Guerra, Allison, Campos, Jetton, Oliverson, Price, Smith

2 nays — Collier, Zwiener

1 absent — Coleman

WITNESSES: For — Naomi Lopez, Goldwater Institute; (*Registered, but did not testify*: Michelle Wittenburg, KK125 Ovarian Cancer Research Foundation and Texas Cancer Survivors Coalition; Thomas Parkinson)

Against — Cynthia O'Keeffe; (*Registered, but did not testify*: Bill Kelly, Mayor's Office, City of Houston)

On — (*Registered, but did not testify*: Kevin Veal, Department of State Health Services)

BACKGROUND: After medications receive approval from the U.S. Food and Drug Administration, they often are found to have additional beneficial uses. Concerns have been raised that due to a fear of prosecution and disciplinary actions, patients often do not receive information about a medication's off-label uses.

DIGEST: HB 2185 would allow a pharmaceutical manufacturer or its representative to promote a medically truthful and accurate off-label use of a drug, biological product, or device in the manufacturer's advertising or marketing materials or directly to a physician, health care provider, or third-party payer.

A pharmaceutical manufacturer or its representative could not be prosecuted or be 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 the bill.

A physician or health care provider could 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 by a pharmaceutical manufacturer.

The state regulatory authority of a physician or health care provider could not revoke or refuse to renew the license or certificate of or otherwise impose a disciplinary action against the physician or health care provider who communicated or promoted an off-label use of a drug, biological product, or device under the bill.

The bill would 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 would prohibit 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 its representative for promoting an off-label use under the bill.

The bill would take effect September 1, 2021, and would apply to a prosecution or disciplinary action initiated or pending on or after that date.