

BILL ANALYSIS

Senate Research Center

C.S.S.B. 1081
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

In recent years, pharmaceutical manufacturers have brought to market prescription agents with an aesthetic purpose or use. These products are approved by the United States Food and Drug Administration (FDA) and prescribed by a qualified physician or licensed prescribing practitioner for both safety and efficacy reasons. In Texas, the only place to purchase these agents is through a licensed pharmacy.

There is an expanding market of counterfeit and unregulated products within which they are sold as cosmetics. These products are compared as equivalent agents; however, they do not have the same regulatory oversight and scrutiny as drugs approved through the FDA. Often, this inequity results in a prescription for the FDA-approved product not to be filled. Similar products marketed for the same purpose do not require a prescribing practitioner in order to purchase them and are commonly chosen by the patient.

Current law encourages this type of diversion due to the inability of prescribing practitioners to dispense FDA-approved drugs from their offices. Lack of dispensing authority in this emerging area of the pharmaceutical industry has created an opportunity for compromised consumer safety as many patients turn to non-prescription alternatives, available through the Internet or department stores, that often warrant results achievable only through prescription-grade agents.

C.S.S.B. 1081 amends current law relating to the dispensing of pharmaceuticals with an aesthetic purpose by physicians and therapeutic optometrists.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas Medical Board in SECTION 1 (Section 116.004, Occupations Code) of this bill.

Rulemaking authority is expressly granted to the Texas Optometry Board in SECTION 1 (Section 116.004, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle A, Title 3, Occupations Code, by adding Chapter 116, as follows:

CHAPTER 116. DISPENSING OF PHARMACEUTICALS WITH AN AESTHETIC PURPOSE

Sec. 116.001. DEFINITIONS. Defines, in this chapter, "pharmaceutical with an aesthetic purpose," "physician," and "therapeutic optometrist."

Sec. 116.002. DISPENSING PERMITTED; FEE AUTHORIZED. (a) Authorizes a physician or therapeutic optometrist to dispense to that physician's or therapeutic optometrist's patients a pharmaceutical with an aesthetic purpose in excess of the patient's immediate needs without obtaining a license under Chapter 558 (License to Practice Pharmacy). Authorizes the physician or therapeutic optometrist to charge a fee for dispensing the pharmaceutical.

(b) Prohibits a physician from dispensing to that physician's patients a pharmaceutical with an aesthetic purpose in excess of the patient's immediate needs if the pharmaceutical is prescribed for a use other than the enhancement of the patient's physical appearance.

Sec. 116.003. NOTICE; LABELING; RECORDKEEPING. (a) Requires a physician or therapeutic optometrist, before dispensing a pharmaceutical with an aesthetic purpose to a patient to inform the patient that the prescription for the pharmaceutical may be filled at a pharmacy or dispensed in the physician's or therapeutic optometrist's office.

(b) Requires that each state and federal labeling and recordkeeping requirement applicable to the pharmaceutical with an aesthetic purpose be followed and documented. Requires that a record maintained under this section be accessible as provided under state and federal law.

Sec. 116.004. RULES; FEES. Requires the Texas Medical Board (TMB) to adopt rules for physicians, and requires the Texas Optometry Board (TOB) to adopt rules for therapeutic optometrists, with the advice of the Texas State Board of Pharmacy, to govern the packaging, labeling, and dispensing of pharmaceuticals with an aesthetic purpose under this chapter. Requires TMB and TOB to adopt reasonable fees as necessary to implement this chapter. Prohibits a fee adopted under this section from exceeding a fee adopted under Section 554.006 (Fees) for authorizing a pharmacist to dispense pharmaceuticals.

Sec. 116.005. PHARMACEUTICAL WITH AN AESTHETIC PURPOSE GROUP. Provides that the pharmaceutical with an aesthetic purpose group consists of bimatoprost and eflornithine.

SECTION 2. Amends Section 157.002(f), Occupations Code, to provide that Subsections (b) (authorizing a physician to delegate to certain persons the act of administering or providing dangerous drugs in the physician's office) and (c) (authorizing a physician to delegate certain persons the act of administering or providing dangerous drugs through a licensed facility) do not authorize a physician or a person acting under the supervision of a physician to keep a pharmacy, advertised or otherwise, for the retail sale of dangerous drugs, other than as authorized under Chapter 116 and Section 158.003 (Dispensing of Dangerous Drugs in Certain Rural Areas), without complying with the applicable laws relating to the dangerous drugs.

SECTION 3. Amends Section 563.051(d), Occupations Code, to provide that this section does not authorize a physician or a person acting under the supervision of a physician to keep a pharmacy, advertised or otherwise, for the retail sale of dangerous drugs, other than as authorized under Chapter 116 and Section 158.003, without complying with the applicable laws relating to the dangerous drugs.

SECTION 4. Requires TMB and TOB to adopt rules for the implementation of Chapter 116, Occupations Code, as added by this Act, not later than March 1, 2012.

SECTION 5. (a) Effective date, except as provided by Subsection (b) of this section: upon passage or September 1, 2011.

(b) Effective date, Section 116.002 and 116.003, Occupations Code, as added by this Act: March 1, 2012.