

## **BILL ANALYSIS**

Senate Research Center  
82R7834 SLB-F

S.B. 1081  
By: Van de Putte  
Health & Human Services  
4/1/2011  
As Filed

### **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.

Currently, prescribing practitioners are only able to dispense prescription medications in two limited circumstances: a 72-hour emergency supply or under a rural location exemption. This bill creates a third exemption in Chapter 158 (Authority of Physician to Provide Certain Drugs and Supplies), Occupations Code, by allowing the dispensation of aesthetic pharmaceuticals by physicians.

As proposed, S.B. 1081 amends current law relating to the dispensation of pharmaceuticals with an aesthetic purpose by physicians.

### **RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the Texas Medical Board in SECTION 2 (Section 158.004, Occupations Code) of this bill.

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 4 of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. 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 Sections 158.003 (Dispensing of Dangerous Drugs in Certain Rural Areas) and 158.004, without complying with the applicable laws relating to the dangerous drugs.

SECTION 2. Amends Chapter 158, Occupations Code, by adding Sections 158.004 and 158.0045, as follows:

Sec. 158.004. DISPENSING OF PHARMACEUTICALS WITH AN AESTHETIC PURPOSE. (a) Defines "pharmaceutical with an aesthetic purpose."

(b) Authorizes a physician licensed under this subtitle to dispense to that physician'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 to charge a fee for dispensing the pharmaceutical.

(c) Requires a physician, 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 office.

(d) 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.

(e) Requires the Texas Medical Board, with the advice of the Texas State Board of Pharmacy, to adopt rules to govern the packaging, labeling, and dispensation of pharmaceuticals with an aesthetic purpose by a physician under this section and reasonable fees as necessary to implement this section. Prohibits a fee adopted under this subsection from exceeding a fee adopted under Section 554.006 (Fees) for authorizing a pharmacist to dispense pharmaceuticals.

Sec. 158.0045. PHARMACEUTICAL WITH AN AESTHETIC PURPOSE GROUP. Provides that the pharmaceutical with an aesthetic purpose group consists of:

- (1) bimatoprost;
- (2) eflornithine;
- (3) finasteride;
- (4) fluocinolone;
- (5) hydroquinone;
- (6) tretinoin;
- (7) minoxidil; and
- (8) tazarotene.

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 Sections 158.003 and 158.004, without complying with the applicable laws relating to the dangerous drugs.

SECTION 4. Requires the Texas State Board of Pharmacy to adopt rules for the implementation of Section 158.004, 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 158.004, Occupations Code, as added by this Act: March 1, 2012.