BILL ANALYSIS

Senate Research Center

S.B. 625
By: Janek
Health & Human Services
8/7/2007
Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Current law allows a pharmacist to substitute a generic drug for a brand-name prescription. However, certain immunosuppressant transplant surgeries require specific medication that work in different phases of the immune response, minimize side effects, and produce effective immunosupression to prevent rejection of a transplanted organ and maintain sufficient immunity to prevent infection. Certain generic forms of these medications may cause adverse effects prior to a transplant surgery because generic products do not always contain the same amount of an active ingredient or are formulated in a different manner than their brand-name counterpart. As a result, patients are placed at a health risk if the brand of prescription is changed without a doctor's notice.

S.B. 625 requires a pharmacist to obtain a prescribing doctor's signature before a substitution of a prescribed immunosuppressant medication can be made.

RULEMAKING AUTHORITY

Rulemaking authority previously granted to the Texas State Board of Pharmacy is modified in SECTION 1 (Section 562.014, Occupations Code) of this bill.

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 2 (Section 562.0142, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 562.014, Occupations Code, as follows:

Sec. 562.014. New heading: NARROW THERAPEUTIC INDEX DRUGS. (a) Creates this subsection from existing text. Requires the Texas State Board of Pharmacy (board) by rule, in consultation with the Texas Medical Board (medical board), rather than the Texas State Board of Medical Examiners, to establish a list of narrow therapeutic index drugs to which this subsection applies. Authorizes a prescription for a narrow therapeutic index drug to be refilled only by using the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless otherwise agreed to by the prescribing practitioner, rather than physician. Makes a conforming change.

(b) Requires the board and the medical board to establish a joint committee (committee) to recommend to the board a list of narrow therapeutic index drugs and the rules, if any, by which this section applies to those drugs. Sets forth provisions regarding the composition of the committee and the selection of the presiding officer of the committee.

(c) Requires the committee to make a recommendation to the board on whether to include a drug on the list of narrow therapeutic index drugs as required by Section 562.0142. Requires the committee to recommend to the board that the drug not be placed on the list in the event of a tie vote by the committee on whether to recommend that a drug listed in this subsection be included on the list of narrow therapeutic index drugs. Requires the committee to consider certain drugs for inclusion in the list of narrow therapeutic index drugs.

(d) Provides that Subsection (c) and this subsection expire December 31, 2008.

SECTION 2. Amends Subchapter A, Chapter 562, Occupations Code, by adding Sections 562.0141 and 562.0142, as follows:

Sec. 562.0141. TRANSPLANT IMMUNOSUPPRESSANT DRUG PRODUCT SELECTION PROHIBITED. (a) Defines "immunosuppressant drug" and "interchange."

(b) Prohibits a pharmacist from interchanging an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic, for the treatment of a patient following a transplant without prior consent to the interchange from the prescribing practitioner.

(c) Requires a pharmacist to notify a prescribing practitioner orally or electronically to secure permission to interchange an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic. Requires the practitioner's authorization or denial of authorization to be documented by the pharmacist and by the practitioner.

(d) Authorizes a pharmacist, if he or she does not have the same drug product by the same manufacturer in stock to refill the prescription, or if the practitioner is unavailable to give authorization, to dispense a drug product that is generically equivalent provided that the pharmacist takes certain actions regarding notification and consent before dispensing the generally equivalent drug product.

(e) Provides that this section is only effective subject to the conditions established by Section 562.0142.

Sec. 562.0142. ADOPTION OF RULES. (a) Requires the committee to make a recommendation to the board to enable the board to adopt a rule and issue findings not later than July 1, 2008, if, not later than October 1, 2007, a drug manufacturer requests that the committee conduct a hearing and make a recommendation to include a drug listed in Section 562.014(c) on the list of narrow therapeutic index drugs.

(b) Provides that Section 562.0141 expires October 1, 2007, if, not later than that date, no drug manufacturer requests that the committee conduct a hearing and make recommendations to the board to include a drug listed in Section 562.014(c) on the list of narrow therapeutic index drugs.

(c) Provides that Section 562.0141 expires effective on the date of the manufacturer's withdrawal requests if all drug manufacturers that request, before October 1, 2007, the committee to conduct a hearing and make a recommendation to the board to include a drug listed in Section 562.014(c) on the list of narrow therapeutic index drugs subsequently withdraw those requests before the date the committee makes a recommendation to include the drug on that list.

(d) Provides that if the committee receives a request under Subsection (a) the recommendation of the committee under this subsection is authorized to include the drugs listed in Section 562.014(c) or the committee is authorized to recommend that no drug should be added to the list of narrow therapeutic index drugs following the review by the committee.

(e) Provides that Section 562.0141 expires on July 1, 2008, if the committee receives a request under Subsection (a) and, not later than July 1, 2008, the board adopts a rule to include any drug listed in Section 562.014(c) on the list of narrow therapeutic index drugs or determines by rule that no drug should be added to the list of narrow therapeutic index drugs.

(f) Provides that Section 562.0141 takes effect July 1, 2008, if the committee receives a request under Subsection (a) and the board does not before July 1, 2008, adopt a rule to include any drug listed in Section 562.014(c) on the list of

narrow therapeutic index drugs or determine by rule that no drug should be added to the list of narrow therapeutic index drugs.

(g) Provides that the time limits established by Subsections (e) and (f) are tolled until litigation is resolved or the attorney general renders an opinion if the committee receives a request under Subsection (a) and litigation or a request for an attorney general's opinion regarding this section, Section 562.014, or Section 562.0141 is filed by a drug manufacturer between the effective date of this section and July 1, 2008.

(h) Requires notice of certain actions to be published in the Texas Register not later than the third business day after the date of occurrence.

SECTION 3. Amends Section 562.009, Occupations Code, by adding Subsection (e), to require a pharmacist to comply with the provisions of Section 562.0141 if the prescription is for an immunosuppressant drug. Provides that this subsection expires if Section 562.0141 expires under the requirements of Section 562.0142.

SECTION 4. Requires the board and the medical board to establish the committee not later than the 90th day after the effective date of this Act or September 1, 2007, whichever date occurs first.

SECTION 5. Effective date: upon passage or September 1, 2007.