AN ACT

relating to restrictions on the interchange of transplant immunosuppressant drugs.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 562.014, Occupations Code, is amended to read as follows:

Sec. 562.014. [~~APPLICATION TO~~] NARROW THERAPEUTIC INDEX DRUGS. (a) Except as provided by this section, drug selection as authorized by this subchapter does not apply to the refill of a prescription for a narrow therapeutic index drug. The board, in consultation with the Texas Medical [~~State~~] Board [~~of Medical Examiners~~], shall by rule establish a list of narrow therapeutic index drugs to which this subsection applies. A prescription for a narrow therapeutic index drug may 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 [~~physician~~]. If a pharmacist does not have the same drug product by the same manufacturer in stock to refill the prescription, the pharmacist may dispense a drug product that is generically equivalent if the pharmacist, before dispensing the generically equivalent drug product, notifies:

(1) the patient, at the time the prescription is dispensed, that a substitution of the prescribed drug product has been made; and

(2) the prescribing practitioner [~~physician~~] of the drug product substitution by telephone, facsimile, or mail, at the earliest reasonable time, but not later than 72 hours after dispensing the prescription.

(b) The board and the Texas Medical Board shall establish a joint 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. The committee must consist of an equal number of members from each board. The committee members shall select a member of the committee to serve as presiding officer for a one year term. The presiding officer may not represent the same board as the presiding officer's predecessor.

(c) The joint committee shall 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. 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, the committee shall recommend to the board that the drug not be placed on the list. The committee shall consider for inclusion in the list of narrow therapeutic index drugs the following drugs:

(1) Prograf;

(2) Cellcept;

(3) Neoral;

(4) Rapamune; and

(5) Sandimmune.

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

SECTION 2. Subchapter A, Chapter 562, Occupations Code, is amended by adding Sections 562.0141 and 562.0142 to read as follows:

Sec. 562.0141. TRANSPLANT IMMUNOSUPPRESSANT DRUG PRODUCT SELECTION PROHIBITED. (a) In this section:

(1) "Immunosuppressant drug" means any drug prescribed for immunosuppressant therapy following a transplant.

(2) "Interchange" means the substitution of one version of the same immunosuppressant drug, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed immunosuppressant drug, or a different immunosuppressant drug for the immunosuppressant drug originally prescribed.

(b) A pharmacist may not interchange 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) To comply with Subsection (b), a pharmacist shall notify a prescribing practitioner orally or electronically to secure permission to interchange an immunosuppressant drug or formulation of an immunosuppressant drug, brand or generic. The practitioner's authorization or denial of authorization must be documented by the pharmacist and by the practitioner.

(d) If a pharmacist 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, the pharmacist may dispense a drug product that is generically equivalent if the pharmacist, before dispensing the generally equivalent drug product:

(1) notifies and receives consent from the patient, at the time the prescription is dispensed, to substitute the prescribed drug product; and

(2) notifies the prescribing practitioner of the drug product substitution orally or electronically at the earliest reasonable time, but not later than 24 hours after dispensing the prescription.

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

Sec. 562.0142. ADOPTION OF RULES. (a) If, not later than October 1, 2007, a drug manufacturer requests that the joint committee under Section 562.014 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, the joint committee shall make a recommendation to the board to enable the board to adopt a rule and issue findings not later than July 1, 2008.

(b) If, not later than October 1, 2007, no drug manufacturer requests that the joint 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, Section 562.0141 expires October 1, 2007.

(c) If all drug manufacturers that request, before October 1, 2007, the joint 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 joint committee makes a recommendation to include the drug on that list, Section 562.0141 expires effective on the date of the manufacturers' withdrawal of those requests.

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

(e) If the joint 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, Section 562.0141 expires on July 1, 2008.

(f) If the joint 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, Section 562.0141 takes effect July 1, 2008.

(g) If the joint 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, the time limits established by Subsections (e) and (f) are tolled until the litigation is resolved or the attorney general renders an opinion.

(h) For purposes of this section, notice of the following must be published in the Texas Register not later than the third business day after the date of occurrence:

(1) a request by a drug manufacturer for inclusion of a drug on the list of narrow therapeutic index drugs;

(2) withdrawal of a request described by Subdivision (1);

(3) litigation described by Subsection (g);

(4) resolution of litigation described by Subsection (g); and

(5) a request for an attorney general's opinion described by Subsection (g).

SECTION 3. Section 562.009, Occupations Code, is amended by adding Subsection (e) to read as follows:

(e) If the prescription is for an immunosuppressant drug, as defined by Section 562.0141(a)(1), the pharmacist must comply with the provisions of Section 562.0141. This subsection expires if Section 562.0141 expires under the requirements of Section 562.0142.

SECTION 4. The Texas State Board of Pharmacy and Texas Medical Board shall establish the joint committee required by Subsection (b), Section 562.014, Occupations Code, as added by this Act, not later than the 90th day after the effective date of this

Act or September 1, 2007, whichever date occurs first.

SECTION 5. This Act takes effect immediately if it receives a vote of two-thirds of all members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2007.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 625 passed the Senate on April 12, 2007, by the following vote: Yeas 31, Nays 0; and that the Senate concurred in House amendments on May 15, 2007, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 625 passed the House, with amendments, on May 10, 2007, by the following vote: Yeas 124, Nays 16, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor