By: McReynolds H.B. No. 3962

A BILL TO BE ENTITLED

AN ACT

relating to the regulation of controlled substances.

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

SECTION 1. Section 481.002, Health and Safety Code, is amended by adding Subdivision (2-a) and amending Subdivision (22) to read as follows:

(2-a) "Board" means the Texas State Board of Pharmacy.

(22) "Immediate precursor" means a substance designated [~~the director finds to be and~~] by rule under this chapter [~~designates~~] as being:

(A) a principal compound commonly used or produced primarily for use in the manufacture of a controlled substance;

(B) a substance that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance; and

(C) a substance the control of which is necessary to prevent, curtail, or limit the manufacture of a controlled substance.

SECTION 2. Section 481.003(a), Health and Safety Code, is amended to read as follows:

(a) The director may adopt rules to administer and enforce this chapter, except that the board may adopt rules relating to the issuance of prescriptions and information submitted in connection

with those prescriptions. The department and the board by rule shall adopt a memorandum of understanding outlining the responsibilities of each agency in regulating controlled substances under this chapter.

SECTION 3. Section 481.034(h), Health and Safety Code, is amended to read as follows:

(h) Not later than the 10th day after the date on which the commissioner designates, deletes, or reschedules a substance under Subsection (a), the commissioner shall give written notice of that action to the director, the board, and [~~to~~] each state licensing agency having jurisdiction over practitioners.

SECTION 4. Section 481.064(c), Health and Safety Code, is amended to read as follows:

(c) The director shall deposit the collected fees to the credit of the [~~operator's and chauffeur's license account in the~~] general revenue fund. The fees may be used only by the department and the board in the administration or enforcement of this subchapter.

SECTION 5. Section 481.074, Health and Safety Code, is amended by amending Subsections (b), (c), (d), (f), (k), (p), and (q), and reenacting and amending Subsection (o), as amended by Chapters 349 (S.B. 1188) and 1345 (S.B. 410), Acts of the 79th Legislature, Regular Session, 2005, to read as follows:

(b) Except in an emergency as defined by rule of the board [~~director~~] or as provided by Subsection (o) [~~or Section 481.075(j) or (m)~~], a person may not dispense or administer a controlled substance listed in Schedule II without the written prescription of

a practitioner [~~on an official prescription form that meets the requirements of and is completed by the practitioner in accordance with Section 481.075~~]. In an emergency, a person may dispense or administer a controlled substance listed in Schedule II on the oral or telephonically communicated prescription of a practitioner. The person who administers or dispenses the substance shall:

(1) if the person is a prescribing practitioner or a pharmacist, promptly comply with Subsection (c); or

(2) if the person is not a prescribing practitioner or a pharmacist, promptly write the oral or telephonically communicated prescription and include in the written record of the prescription the name, address, [~~department registration number,~~] and Federal Drug Enforcement Administration number of the prescribing practitioner[~~, all information required to be provided by a practitioner under Section 481.075(e)(1), and all information required to be provided by a dispensing pharmacist under Section 481.075(e)(2)~~].

(c) Not later than the seventh day after the date a prescribing practitioner authorizes an emergency oral or telephonically communicated prescription, the prescribing practitioner shall cause a written prescription[~~, completed in the manner required by Section 481.075,~~] to be delivered in person or mailed to the dispensing pharmacist at the pharmacy where the prescription was dispensed. The envelope of a prescription delivered by mail must be postmarked not later than the seventh day after the date the prescription was authorized. [~~On receipt of the prescription, the dispensing pharmacy shall file the transcription~~

~~of the telephonically communicated prescription and the pharmacy copy and shall send information to the director as required by Section 481.075.~~]

(d) Except as specified in Subsections (e) and (f), the board [~~director~~], by rule and in consultation with the Texas Medical Board and the department [~~Texas State Board of Pharmacy~~], shall establish the period after the date on which the prescription is issued that a person may fill a prescription for a controlled substance listed in Schedule II. A person may not refill a prescription for a substance listed in Schedule II.

(f) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question about whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner before partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record [~~the prescription on an official prescription form and must indicate~~] on the prescription [~~form~~] whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" is considered to have been filled in violation of this chapter. For each partial filling, the dispensing pharmacist shall record on the back of the [~~official~~] prescription [~~form~~] the date of the partial

filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Before any subsequent partial filling, the pharmacist must determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings may not exceed the total quantity prescribed. Schedule II prescriptions for patients in a long-term care facility or patients with a medical diagnosis documenting a terminal illness are valid for a period not to exceed 60 days following the issue date unless sooner terminated by discontinuance of the medication.

(k) A prescription for a controlled substance must show:

(1) the quantity of the substance prescribed:

(A) numerically, followed by the number written as a word, if the prescription is written; or

(B) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(2) the date of issue;

(3) the name, address, and date of birth or age of the patient or, if the controlled substance is prescribed for an animal, the species of the animal and the name and address of its owner;

(4) the name and strength of the controlled substance prescribed;

(5) the directions for use of the controlled substance;

(6) the intended use of the substance prescribed

unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(7) the legibly printed or stamped name, address, Federal Drug Enforcement Administration registration number, and telephone number of the practitioner at the practitioner's usual place of business; and

(8) if the prescription is handwritten, the signature of the prescribing practitioner[~~; and~~

[~~(9) if the prescribing practitioner is licensed in this state, the practitioner's department registration number~~].

(o) A pharmacist may dispense a Schedule II controlled substance pursuant to a facsimile copy of a [~~an official~~] prescription completed in the manner required by board rule [~~Section 481.075~~] and transmitted by the practitioner or the practitioner's agent to the pharmacy if:

(1) the prescription is written for:

(A) a Schedule II narcotic or nonnarcotic substance for a patient in a long-term care facility (LTCF), and the practitioner notes on the prescription "LTCF patient";

(B) a Schedule II narcotic product to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion; or

(C) a Schedule II narcotic substance for a patient with a medical diagnosis documenting a terminal illness or a patient enrolled in a hospice care program certified or paid for by Medicare under Title XVIII, Social Security Act (42 U.S.C.

Section 1395 et seq.), as amended, by Medicaid, or by a hospice program that is licensed under Chapter 142, and the practitioner or the practitioner's agent notes on the prescription "terminally ill" or "hospice patient"; and

(2) after transmitting the prescription, the prescribing practitioner or the practitioner's agent:

(A) writes across the face of the [~~official~~] prescription "VOID--sent by fax to (name and telephone number of receiving pharmacy)"; and

(B) files the [~~official~~] prescription in the patient's medical records instead of delivering it to the patient.

(p) On receipt of the prescription, the dispensing pharmacy shall file the facsimile copy of the prescription and shall send information relating to the prescription to the board [~~director~~] as required by board rule [~~Section 481.075~~].

(q) Each dispensing pharmacist shall send all information required by the board [~~director~~], including any information required to complete the Schedule III through V prescription forms, to the board [~~director~~] by electronic transfer or another form approved by the board [~~director~~] not later than the 15th day after the last day of the month in which the prescription is completely filled. The board shall submit any information received under this section to the director on request.

SECTION 6. Section 481.076, Health and Safety Code, is amended to read as follows:

Sec. 481.076. [~~OFFICIAL~~] PRESCRIPTION INFORMATION. (a) The board [~~director~~] may not permit any person to have access to

information submitted to the board [~~director~~] under Section 481.074(q) [~~or 481.075~~] except:

(1) an investigator for the Texas Medical Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, or the State Board of Veterinary Medical Examiners[~~, or the Texas State Board of Pharmacy~~];

(2) an authorized officer or member of the department engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state; [~~or~~]

(3) if the board [~~director~~] finds that proper need has been shown to the board, [~~director:~~

[~~(A)~~] a law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(4) [~~(B)~~] a pharmacist or practitioner who is a physician, dentist, veterinarian, podiatrist, or advanced practice nurse or physician assistant described by Section 481.002(39)(D) and is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner; or

(5) [~~(C)~~] a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity.

(b) This section does not prohibit the board [~~director~~] from creating, using, or disclosing statistical data about information

received by the board [~~director~~] under this section if the board [~~director~~] removes any information reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information.

(c) The board [~~director~~] by rule shall design and implement a system for submission of information to the board [~~director~~] by electronic or other means and for retrieval of information submitted to the board [~~director~~] under this section and Section [~~Sections~~] 481.074 [~~and 481.075~~]. The board [~~director~~] shall use automated information security techniques and devices to preclude improper access to the information. The board [~~director~~] shall submit the system design to the director [~~Texas State Board of Pharmacy~~] and the Texas Medical Board for review and approval or comment a reasonable time before implementation of the system and shall comply with the comments of those agencies unless it is unreasonable to do so.

(d) Information submitted to the board [~~director~~] under this section shall be released to the department upon request and may be used by the department or the board only for:

(1) the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(2) investigatory or evidentiary purposes in connection with the functions of an agency listed in Subsection (a)(1); or

(3) dissemination [~~by the director~~] to the public in the form of a statistical tabulation or report if all information

reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information has been removed.

(e) The board [~~director~~] shall remove from the information retrieval system, destroy, and make irretrievable the record of the identity of a patient submitted under this section to the board [~~director~~] not later than the end of the 12th calendar month after the month in which the identity is entered into the system. However, the board or the director may retain a patient identity that is necessary for use in a specific ongoing investigation conducted by the department in accordance with this section until the 30th day after the end of the month in which the necessity for retention of the identity ends.

(f) If the board or the director permits access to information under Subsection (a)(2) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the director shall notify and cooperate with that agency regarding the disposition of the matter before taking action against the person, unless the director determines that notification is reasonably likely to interfere with an administrative or criminal investigation or prosecution.

(g) If the board or the director permits access to information under Subsection (a)(3) [~~(a)(3)(A)~~] relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the board or the director shall notify that agency of the disclosure of the information not later than the 10th working day after the date the information is disclosed.

(h) If the board or the director withholds notification to an agency under Subsection (f), the board or the director shall notify the agency of the disclosure of the information and the reason for withholding notification when the director determines that notification is no longer likely to interfere with an administrative or criminal investigation or prosecution.

(i) Information submitted to the board or the director under Section 481.074(q) [~~481.075~~] is confidential and remains confidential regardless of whether the board or the director permits access to the information under this section.

SECTION 7. Sections 481.0761(a), (c), and (e), Health and Safety Code, are amended to read as follows:

(a) The board [~~director~~] shall consult with the director and the Texas Medical [~~State~~] Board [~~of Pharmacy~~] and by rule establish and revise as necessary a standardized database format that may be used by a pharmacy to transmit the information required by Sections 481.074 [~~481.074(q)~~] and 481.076 [~~481.075(i)~~] to the board [~~director~~] electronically or to deliver the information on storage media, including disks, tapes, and cassettes.

(c) The board [~~director~~] by rule may:

(1) permit more than one prescription to be administered or dispensed and recorded on one prescription form for a Schedule III through V controlled substance;

(2) [~~remove from or return to the official prescription program any aspect of a practitioner's or pharmacist's hospital practice, including administering or dispensing;~~

[~~(3)~~] waive or delay any requirement relating to the

time or manner of reporting;

(3) [~~(4)~~] establish compatibility protocols for electronic data transfer hardware, software, or format;

(4) [~~(5)~~] establish a procedure to control the release of information under Sections 481.074[~~, 481.075,~~] and 481.076; and

(5) [~~(6)~~] establish a minimum level of prescription activity below which a reporting activity may be modified or deleted.

(e) In adopting a rule relating to the electronic transfer of information under this subchapter, the board [~~director~~] shall consider the economic impact of the rule on practitioners and pharmacists and, to the extent permitted by law, act to minimize any negative economic impact, including the imposition of costs related to computer hardware or software or to the transfer of information. The board [~~director~~] may not adopt a rule relating to the electronic transfer of information under this subchapter that imposes a fee in addition to the fees authorized by Section 481.064.

SECTION 8. Section 481.127(a), Health and Safety Code, is amended to read as follows:

(a) A person commits an offense if the person knowingly gives, permits, or obtains unauthorized access to information submitted to the board [~~director~~] under Section 481.074 [~~481.075~~].

SECTION 9. Section 481.128(a), Health and Safety Code, is amended to read as follows:

(a) A registrant or dispenser commits an offense if the registrant or dispenser knowingly:

(1) distributes, delivers, administers, or dispenses

a controlled substance in violation of Sections 481.070-481.074 [~~481.070-481.075~~];

(2) manufactures a controlled substance not authorized by the person's registration or distributes or dispenses a controlled substance not authorized by the person's registration to another registrant or other person;

(3) refuses or fails to make, keep, or furnish a record, report, notification, order form, statement, invoice, or information required by this chapter;

(4) prints, manufactures, possesses, or produces an official prescription form without the approval of the director;

(5) delivers or possesses a counterfeit official prescription form;

(6) refuses an entry into a premise for an inspection authorized by this chapter;

(7) [~~refuses or fails to return an official prescription form as required by Section 481.075(k);~~

[~~(8)~~] refuses or fails to make, keep, or furnish a record, report, notification, order form, statement, invoice, or information required by a rule adopted by the director; or

(8) [~~(9)~~] refuses or fails to maintain security required by this chapter or a rule adopted under this chapter.

SECTION 10. Section 552.118, Government Code, is amended to read as follows:

Sec. 552.118. EXCEPTION: [~~OFFICIAL~~] PRESCRIPTION INFORMATION [~~FORM~~]. Information is excepted from the requirements of Section 552.021 if it is:

(1) information on or derived from an official prescription form filed with the director of the Department of Public Safety under Section 481.075, Health and Safety Code, as that section existed before September 1, 2010; or

(2) other information collected under Section 481.074(q) or 481.075, Health and Safety Code, as that section existed before September 1, 2010 [~~of that code~~].

SECTION 11. Section 565.003(b), Occupations Code, is amended to read as follows:

(b) Unless compliance would violate the pharmacy or drug statutes or rules in the state in which the pharmacy is located the board may discipline an applicant for or the holder of a Class E pharmacy license if the board finds that the applicant or license holder has failed to comply with:

(1) Section 481.074 [~~or 481.075~~], Health and Safety Code;

(2) Texas substitution requirements regarding:

(A) the practitioner's directions concerning generic substitution;

(B) the patient's right to refuse generic substitution; or

(C) notification to the patient of the patient's right to refuse substitution;

(3) any board rule relating to providing drug information to the patient or the patient's agent in written form or by telephone; or

(4) any board rule adopted under Section 554.051(a)

and determined by the board to be applicable under Section 554.051(b).

SECTION 12. The following provisions are repealed:

(1) Section 481.002(47), Health and Safety Code;

(2) Section 481.075, Health and Safety Code;

(3) Sections 481.0761(b), (d), and (f), Health and Safety Code;

(4) Subchapter H, Chapter 481, Health and Safety Code;

(5) Section 157.059(c), Occupations Code; and

(6) Sections 7 and 8, Chapter 1391 (S.B. 1879), Acts of the 80th Legislature, Regular Session, 2007.

SECTION 13. (a) An advisory committee is created to advise the Texas State Board of Pharmacy on the implementation of this Act.

(b) The advisory committee is composed of:

(1) the executive director of the Texas State Board of Pharmacy or the executive director's designee;

(2) the public safety director of the Department of Public Safety or the director's designee;

(3) a physician appointed by the governor;

(4) a pharmacist appointed by the governor;

(5) a physician appointed by the lieutenant governor;

(6) a pharmacist appointed by the lieutenant governor;

(7) a physician appointed by the governor from a list of names submitted by the speaker of the house of representatives;

(8) a pharmacist appointed by the governor from a list of names submitted by the speaker of the house of representatives; and

(9) one member from each of the following boards:

(A) the Texas Medical Board;

(B) the Texas State Board of Pharmacy;

(C) the State Board of Dental Examiners; and

(D) the Texas Board of Nursing.

(c) The executive director of the Texas State Board of Pharmacy or the executive director's designee is the presiding officer of the advisory committee. The committee shall meet at the call of the presiding officer or at the request of any three members other than the presiding officer.

(d) The advisory committee shall:

(1) develop recommendations regarding the implementation of an electronic controlled substance monitoring system that would be used for prescriptions of controlled substances listed in Schedule II through V as established under Subchapter B, Chapter 481, Health and Safety Code;

(2) develop recommendations as to which data should be provided to the Texas State Board of Pharmacy to support a controlled substance monitoring system recommended under Subdivision (1), including provider identification information;

(3) monitor and develop recommendations regarding the implementation and enforcement of a controlled substance monitoring system recommended under Subdivision (1);

(4) develop recommended procedures necessary for real-time point-of-service access for a practitioner authorized to prescribe or dispense controlled substances listed in Schedule II through V to enable the practitioner to obtain:

(A) the prescription history for a particular patient; or

(B) the practitioner's own dispensing or prescribing activity; and

(5) develop recommended procedures that should be followed by the Texas State Board of Pharmacy and the applicable licensing authority of this state, another state, or the United States when:

(A) the Texas State Board of Pharmacy shares information related to the diversion of controlled substances with a licensing authority for the purpose of licensing enforcement; or

(B) a licensing authority shares information related to diversion of controlled substances with the department for the purpose of criminal enforcement.

(e) The executive director or the executive director's designee of the Texas State Board of Pharmacy shall report the recommendations developed under Subsection (d) of this section to the governor, the lieutenant governor, speaker of the house of representatives, and appropriate committees of the senate and the house of representatives not later than July 1, 2011.

(f) This section expires and the advisory committee is abolished on September 1, 2011.

SECTION 14. (a) The Department of Public Safety, Texas Medical Board, Texas State Board of Pharmacy, State Board of Dental Examiners, and Texas Board of Nursing shall submit to the presiding officers of the Senate Committee on Health and Human Services and the House Committee on Public Health a report that details the

number and type of actions relating to the prosecution of violations of Chapter 481, Health and Safety Code, as amended by this Act.

(b) Each agency shall submit its initial report under Subsection (a) of this section not later than November 1, 2009. Each agency shall submit an update of its initial report not later than May 1 and November 1 of each year.

(c) This section expires November 1, 2013.

SECTION 15. (a) The Texas State Board of Pharmacy and the public safety director of the Department of Public Safety shall enter into the memorandum of understanding required by Section 481.003, Health and Safety Code, as amended by this Act, not later than January 1, 2010.

(b) The Texas State Board of Pharmacy shall adopt any rules required by Chapter 481, Health and Safety Code, as amended by this Act, not later than September 1, 2010.

(c) Not later than September 1, 2010, the Department of Public Safety shall transfer the records received under Sections 481.074, 481.076, and 481.0761, Health and Safety Code, to the Texas State Board of Pharmacy.

(d) A rule, form, policy, procedure, or decision adopted under Chapter 481, Health and Safety Code, as it existed before amendment by this Act, continues in effect as a rule, form, policy, procedure, or decision and remains in effect until amended or replaced.

(e) A reference in law or an administrative rule to the public safety director of the Department of Public Safety relating

to rulemaking authority given and duties transferred to the Texas State Board of Pharmacy by this Act is a reference to the Texas State Board of Pharmacy.

SECTION 16. The changes in law made by this Act in amending Sections 481.074, 481.076, and 481.127, Health and Safety Code, and in repealing Sections 481.002(47) and 481.075, Health and Safety Code, and Section 157.059(c), Occupations Code, take effect September 1, 2010.

SECTION 17. Except as otherwise provided by this Act, this Act takes effect September 1, 2009.