

## **BILL ANALYSIS**

Senate Research Center  
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C.S.S.B. 195  
By: Schwertner  
Health & Human Services  
3/30/2015  
Committee Report (Substituted)

### **AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

The Texas Prescription Program (TPP), also known as "Prescription Access in Texas," collects prescription data on all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas. It was created in 1982 and placed at the Department of Public Safety of the State of Texas to monitor and prevent the diversion of prescription drugs. Access to the database is statutorily restricted. Pharmacists and practitioners may access TPP to inquire about patients and verify their prescription records. TPP also provides law enforcement and policymakers with useful information about prescription trends.

C.S.S.B. 195:

- Transfers TPP from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP).
- Authorizes TSBP to enter into an interoperability agreement with other states to share information via a central database (such as the National Association of Boards of Pharmacy Prescription Monitoring Program, InterConnect).
- Enables practitioners to auto-enroll in TPP upon renewal of their occupational license or registration.
- Removes a provision requiring law enforcement to show "proper need" for TPP access.
- Guarantees DPS secure and confidential access to TPP, and directs requests for TPP access by other law enforcement entities to DPS for review and processing.
- Removes DPS from the Interagency Prescription Monitoring Workgroup.
- Grants TPP access to medical examiners.
- Eliminates CSR and authorizes each of the Article VIII licensing agencies participating in TPP to increase the occupational license, permit, and registration fees imposed on their respective licensees by an amount sufficient to cover the cost of administering TPP.
- Allows practitioners to delegate database access to any HIPPA-compliant employee.

C.S.S.B. 195 amends current law relating to prescriptions for certain controlled substances, access to information about those prescriptions, and the duties of prescribers and other entities registered with the Federal Drug Enforcement Administration, authorizes fees, and amends provisions subject to a criminal penalty.

### **RULEMAKING AUTHORITY**

Rulemaking authority previously granted to the director of the Department of Public Safety of the State of Texas (director of DPS) is modified in SECTION 3 (Section 481.003, Health and Safety Code) of this bill.

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy (TSBP) in SECTION 3 (Section 481.003, Health and Safety Code), SECTION 13 (Section 481.0761, Health and Safety Code), SECTION 18 (Sections 481.128, Health and Safety Code), SECTION 23 (Section 554.006, Occupations Code), and SECTION 24 (Section 554.051, Occupations Code) of this bill.

Rulemaking authority previously granted to the director of DPS is transferred to TSBP in SECTION 6 (Section 481.067, Health and Safety Code), SECTION 9 (Section 481.074, Health

and Safety Code), SECTION 10 (Sections 481.075, Health and Safety Code), SECTION 12 (Section 481.076, Health and Safety Code), and SECTION 13 (Section 481.0761, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the Department of Public Safety of the State of Texas is transferred to TSBP in SECTION 8 (Section 481.073, Health and Safety Code) of this bill.

Rulemaking authority previously granted to the director of DPS is rescinded in SECTION 13 (Section 481.0761, Health and Safety Code) and SECTION 25 (Section 481.062, Health and Safety Code) of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Section 552.118, Government Code, as follows:

Sec. 552.118. EXCEPTION: CONFIDENTIALITY OF OFFICIAL PRESCRIPTION PROGRAM INFORMATION. Provides that information is excepted from the requirements of Section 552.021 (Availability of Public Information) if it is:

(1) information on or derived from an official prescription form or electronic prescription record filed with the Texas State Board of Pharmacy (TSBP), rather than the director of the Department of Public Safety of the State of Texas (DPS), under Section 481.075 (Official Prescription Program), Health and Safety Code; or

(2) other information collected under Section 481.075 of that code.

SECTION 2. Amends Section 481.002, Health and Safety Code, by amending Subdivisions (4) and (45) and adding Subdivision (55), to redefine "controlled premises" and "registrant" and to define "board" to mean the Texas State Board of Pharmacy.

SECTION 3. Amends Section 481.003(a), Health and Safety Code, as follows:

(a) Authorizes the director of DPS (director) to adopt rules to administer and enforce this chapter, other than Sections 481.075, 481.076 (Official Prescription Information), and 481.0761 (Rules; Authority to Contract). Authorizes TSBP to adopt rules to administer Sections 481.075, 481.076, and 481.0761.

SECTION 4. Amends the heading to Section 481.061, Health and Safety Code, to read as follows:

Sec. 481.061. FEDERAL REGISTRATION REQUIRED.

SECTION 5. Amends Sections 481.061(a) and (b), Health and Safety Code, as follows:

(a) Prohibits a person who is not registered with the Federal Drug Enforcement Administration, rather than a person who is not a registrant, from manufacturing, distributing, prescribing, possessing, analyzing, or dispensing a controlled substance in this state, except as otherwise provided by this chapter.

(b) Authorizes a person who is registered with the Federal Drug Enforcement Administration, rather than a person who is registered by the director, to manufacture, distribute, analyze, dispense, or conduct research with a controlled substance to possess, manufacture, distribute, analyze, dispense, or conduct research with that substance to the extent authorized by the person's registration and in conformity with this chapter.

SECTION 6. Amends Section 481.067(a), Health and Safety Code, to require a person who is registered with the Federal Drug Enforcement Administration to manufacture, distribute, analyze, or dispense a controlled substance to keep records and maintain inventories in

compliance with recordkeeping and inventory requirements of federal law and with additional rules TSBP adopts, rather than rules the director adopts.

SECTION 7. Amends Section 481.068, Health and Safety Code, as follows:

Sec. 481.068. CONFIDENTIALITY. (a) Changes a reference to the director to TSBP.

(b) Prohibits a practitioner engaged in authorized medical practice or research, except as provided by Sections 481.074 and 481.075, from being required to furnish the name or identity of a patient or research subject to TSBP, the Department of State Health Services or any other agency, public official, or law enforcement officer, rather than to DPS, the director of the Texas Commission on Alcohol and Drug Abuse, or any other agency, public official, or law enforcement officer. Prohibits a practitioner from being compelled in a state or local civil, criminal, administrative, legislative, or other proceeding to furnish the name or identity of an individual that the practitioner is obligated to keep confidential.

(c) Changes a reference to the director to TSBP.

SECTION 8. Amends Section 481.073(a), Health and Safety Code, as follows:

(a) Authorizes only a practitioner defined by Section 481.002(39)(A) and an agent designated in writing by the practitioner in accordance with rules adopted by TSBP, rather than DPS, to communicate a prescription by telephone. Requires a pharmacy that receives a telephonically communicated prescription to promptly write the prescription and file and retain the prescription in the manner required by this subchapter. Requires a practitioner who designates an agent to communicate prescriptions to maintain the written designation of the agent in the practitioner's usual place of business and is required to make the designation available for inspection by investigators for the Texas State Board of Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, TSBP, and DPS. Requires a practitioner who designates a different agent to designate that agent in writing and maintain the designation in the same manner in which the practitioner initially designated an agent under this section.

SECTION 9. Amends Sections 481.074(b), (c), (d), (p), and (q), Health and Safety Code, as follows:

(b) and (c) Changes a reference to the director to TSBP.

(d) Changes a reference to the director to TSBP and changes a reference to the TSBP to DPS.

(p) Changes a reference to the director to TSBP.

(q) Requires each dispensing pharmacist to send all required information, rather than all information required by the director, including any information required to complete the Schedule III through V prescription forms, to TSBP by electronic transfer or another form approved by TSBP not later than the seventh day after the date the prescription is completely filled. Makes conforming changes.

SECTION 10. Amends Sections 481.075(c), (g), (i), (k), and (m), Health and Safety Code, as follows:

(c) Requires TSBP to issue official prescription forms to practitioners for a fee covering the actual cost of printing, processing, and mailing the forms, rather than forms at 100 a package. Changes references to the director to TSBP.

(g) Changes a reference to the director to TSBP.

(i) Requires each dispensing pharmacist to send all required information, rather than information required by the director, including any information required to complete an official prescription form or electronic prescription record, to TSBP by electronic transfer or another form approved by TSBP not later than the seventh day after the date the prescription is completely filled. Changes references to the director to TSBP.

(k) Requires a practitioner, not later than the 30th day after the date the practitioner's Federal Drug Enforcement Administration number or license to practice has been denied, suspended, canceled, surrendered, or revoked, to return to TSBP all official prescription forms in the practitioner's possession that have not been used for prescriptions. Deletes existing text requiring a practitioner, not later than the 30th day after the date the practitioner's DPS registration number has been denied, suspended, canceled, surrendered, or revoked, to return to DPS all official prescription forms in the practitioner's possession that have not been used for prescriptions.

(m) Authorizes a pharmacy in this state to fill a prescription for a controlled substance listed in Schedule II issued by a practitioner in another state if the prescription is filled in compliance with a written plan providing the manner in which the pharmacy may fill a Schedule II prescription issued by a practitioner in another state that is approved by TSBP, rather than the director in consultation with TSBP. Changes a reference to the director to TSBP.

SECTION 11. Amends the heading to Section 481.076, Health and Safety Code, to read as follows:

Sec. 481.076. OFFICIAL PRESCRIPTION INFORMATION; DUTIES OF TEXAS STATE BOARD OF PHARMACY.

SECTION 12. Amends Section 481.076, Health and Safety Code, by amending Subsections (a), (a-1), (a-2), (b), (c), (d), (e), (g), and (i) and adding Subsections (a-3), (a-4), (a-5), (j), and (k), as follows:

(a) Prohibits TSBP from permitting any person to have access to information submitted to TSBP under Section 481.074(q) or 481.075 except:

(1) an investigator for TSBP, the Texas Medical Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, the Texas Board of Nursing, or the Texas Optometry Board;

(2) an authorized officer or member of DPS or authorized employee of TSBP engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(3) DPS on behalf of 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) a medical examiner conducting an investigation;

(5) a pharmacist or a pharmacy technician, as defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist or a practitioner who is a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse or is a physician assistant described by Section 481.002(39)(D) (defining "practitioner") or an employee or other agent of a practitioner acting at the direction of a practitioner and is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner, provided that the person accessing the information is authorized to do so under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted under that Act;

(6) Redesignates Paragraph (C) as Subdivision (6) and makes a nonsubstantive change.

(7) one or more states or an association of states with which TSBP has an interoperability agreement, as provided by Subsection (j).

Redesignates Paragraph (B) as Subdivision (5). Deletes existing Paragraph (A) designation. Deletes existing text prohibiting the director from permitting any person to have access to information submitted to the director under Section 481.074(q) or 481.075 except certain persons if the director finds that proper need has been shown to the director.

(a-1) Authorizes a person authorized to receive information under Subsection (a)(4), (5), or (6), rather than Subsection (a)(3)(B) or (C), to access that information through a health information exchange, subject to proper security measures to ensure against disclosure to unauthorized persons.

(a-2) Authorizes a person authorized to receive information under Subsection (a)(5), rather than Subsection (a)(3)(B), to include that information in any form in the medical or pharmacy record of the patient who is the subject of the information. Provides that any information included in a patient's medical or pharmacy record under this subsection is subject to any applicable state or federal confidentiality or privacy laws.

(a-3) Requires TSBP to ensure that DPS has unrestricted access at all times to information received by TSBP under this section.

(a-4) Authorizes a law enforcement or prosecutorial official described by Subsection (a)(3) to obtain information received by TSBP under this section only if the official submits a request to DPS. Requires DPS to review and process each request under this subsection. Requires DPS, if DPS shows that the official has shown proper need for the information, to access the information on behalf of the official and submit the relevant information to the official.

(a-5) Provides that records relating to the access of information by DPS or by DPS on behalf of a law enforcement agency are confidential, including any information concerning the identities of the investigating agents or agencies. Prohibits TSBP from tracking or monitoring DPS's access to information.

(b) Changes references to the director to TSBP.

(c) Requires TSBP by rule to design and implement a system for submission of information to TSBP by electronic or other means and for retrieval of information submitted to TSBP under this section and Sections 481.074 and 481.075. Requires TSBP to use automated information security techniques and devices to preclude improper access to the information. Requires TSBP to submit the system design to the director, rather than TSBP, and the Texas Medical Board for review and comment, rather than approval or comment, a reasonable time before implementation of the system and is required to comply with the comments of those agencies unless it is unreasonable to do so. Makes conforming and nonsubstantive changes.

(d) and (e) Makes conforming changes.

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

(i) Changes references to the director to DPS.

(j) Authorizes TSBP to enter into an interoperability agreement with one or more states or an association of states authorizing TSBP to access prescription monitoring information maintained or collected by the other state or states or the association, including information maintained on a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect. Provides that, pursuant to an interoperability agreement, TSBP may authorize the prescription monitoring program of one or more states or an association of states to access information submitted to TSBP under Sections 481.074(q) and 481.075, including by submitting or sharing information through a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect.

(k) Entitles a person authorized to access information under Subsection (a)(4) who is registered with TSBP for electronic access to the information to directly access the information available from other states pursuant to an interoperability agreement described by Subsection (j).

SECTION 13. Amends Section 481.0761, Health and Safety Code, by amending Subsections (a), (c), (d), (e), and (f) and adding Subsection (g), as follows:

(a) Requires TSBP to by rule establish, rather than requires the director to consult with TSBP 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(q) and 481.075(i) to TSBP electronically or to deliver the information on storage media, including disks, tapes, and cassettes. Makes conforming changes.

(c) Authorizes TSBP, rather than the director, by rule to establish compatibility protocols for electronic data transfer hardware, software, or format, including any necessary modifications for participation in a database described by Section 481.076(j).

(d) Makes a conforming change.

(e) Deletes existing text prohibiting the director from adopting 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 (Registration Fees). Makes a conforming change.

(f) Makes conforming changes.

(g) Authorizes TSBP to adopt rules providing for a person authorized to access information under Section 481.076(a)(5) to be enrolled in electronic access to the information described by Section 481.076(a) at the time the person obtains or renews the person's applicable professional or occupational license or registration.

SECTION 14. Amends Section 481.077(c), Health and Safety Code, to provide that this section and Section 481.078 do not apply to a person to whom a registration has been issued by the Federal Drug Enforcement Agency, rather than issued under Section 481.063 (Registration Application; Issuance or Denial).

SECTION 15. Amends Section 481.080(d), Health and Safety Code, to provide that this section and Section 481.081 do not apply to a person to whom a registration has been issued by the Federal Drug Enforcement Agency, rather than under Section 481.063.

SECTION 16. Amends Section 481.124(b), Health and Safety Code, to provide that, for purposes of this section, an intent to unlawfully manufacture the controlled substance methamphetamine is presumed if the actor possesses or transports in one container, vehicle, or building, phenylacetic acid, or more than nine grams, three containers packaged for retail sale, or 300 tablets or capsules of a product containing ephedrine or pseudoephedrine, and at least three of the following items an item of equipment subject to regulation under Section 481.080 (Chemical Laboratory Apparatus Record-Keeping Requirements and Penalties), if the person is not a registrant, rather than if the person is not registered under Section 481.063.

SECTION 17. Amends Section 481.127(a), Health and Safety Code, to change a reference to the director to TSBP.

SECTION 18. Amends Sections 481.128(a) and (b), Health and Safety Code, as follows:

(a) Provides that a registrant or dispenser commits an offense if the registrant or dispenser knowingly manufactures a controlled substance not authorized by the person's Federal Drug Enforcement Administration registration or distributes or dispenses a controlled substance not authorized by the person's registration to another registrant or other person, 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 TSBP. Makes a conforming change.

(b) Provides that, if the registrant or dispenser knowingly refuses or fails to make, keep, or furnish a record, report, notification, order form, statement, invoice, or information or maintain security required by a rule adopted by the director or the board, the registrant or dispenser is liable to the state for a civil penalty of not more than \$5,000 for each act.

SECTION 19. Amends Section 481.129(a), Health and Safety Code, as follows:

(a) Provides that a person commits an offense if the person knowingly:

(1) distributes as a registrant or dispenser a controlled substance listed in Schedule I or II, unless the person distributes the controlled substance as authorized under the federal Controlled Substances Act (21 U.S.C. Section 801 et seq.), rather than the controlled substance under an order form as required by Section 481.069 (Order Forms);

(2) uses in the course of manufacturing, prescribing, or distributing a controlled substance a Federal Drug Enforcement Administration registration number that is fictitious, revoked, suspended, or issued to another person;

(3)-(6) Makes no change to these subdivisions.

SECTION 20. Amends Section 481.159(a), Health and Safety Code, to delete existing text requiring the court, if a district court orders the forfeiture of a controlled substance property or plant under Chapter 59 (Forfeiture of Contraband), Code of Criminal Procedure, or under this code, to also order a law enforcement agency to deliver the property or plant to a person authorized by the director to receive it for a purpose described by Section 481.065(a) (authorizing the director to authorize the possession, distribution, planting, and cultivation of controlled substances by a person engaged in research, training animals to detect controlled substances, or designing or calibrating devices to detect controlled substances).

SECTION 21. Amends Section 481.301, Health and Safety Code, as follows:

Sec. 481.301. IMPOSITION OF PENALTY. Deletes existing text authorizing DPS to impose an administrative penalty on a person who violates Section 481.066 (Voluntary Surrender, Cancellation, Suspension, Probation, or Revocation of Registration) or Section 481.069. Provides that DPS or TSBP, as applicable, may impose, rather than DPS may impose, an administrative penalty on a person who violates certain enumerated sections.

SECTION 22. Amends Section 481.352, Health and Safety Code, as follows:

Sec. 481.352. MEMBERS. Provides that the work group is composed of certain persons, including the executive director of TSBP or the executive director's designee, rather than the director, who serves as chair of the work group. Makes conforming changes.

SECTION 23. Amends Section 554.006, Occupations Code, as follows:

Sec. 554.006. FEES. (a) Creates this subsection from existing text. Requires TSBP by rule to establish reasonable and necessary fees so that the fees, in the aggregate, produce sufficient revenue to cover the cost of administering this subtitle.

(b) Requires TSBP by rule to establish reasonable and necessary fees so that the fees, in the aggregate, produce sufficient revenue to cover the cost of establishing and maintaining the program described by Sections 481.075, 481.076, and 481.0761, Health and Safety Code.

(c) Authorizes TSBP to assess the fee described by Subsection (b) on individuals or entities authorized to prescribe or dispense controlled substances under Chapter 481 (Texas Controlled Substances Act), Health and Safety Code, and to access the program described by Sections 481.075, 481.076, and 481.0761, Health and Safety Code.

(d) Requires each agency that licenses individuals or entities authorized to prescribe or dispense controlled substances under Chapter 481, Health and Safety Code, and to access the program described by Sections 481.075, 481.076, and 481.0761, Health and Safety Code, to increase the occupational license, permit, or registration fee of the license holders or use available excess revenue in an amount sufficient to operate that program as specified by TSBP.

(e) Requires that a fee collected by an agency under Subsection (d) be transferred to TSBP for the purpose of establishing and maintaining the program described by Sections 481.075, 481.076, and 481.0761, Health and Safety Code.

SECTION 24. Amends Section 554.051, Occupations Code, by adding Subsection (a-1), to authorize TSBP to adopt rules to administer Sections 481.075, 481.076, and 481.0761, Health and Safety Code.

SECTION 25. Repealer: Section 481.061(c) (providing that a separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, analyzes, dispenses, or possesses a controlled substance, except that the director may not require separate registration for a physician licensed under Subtitle B, Title 3, Occupations Code, or a practitioner engaged in research with a nonnarcotic controlled substance listed in Schedules II through V if the registrant is already registered under this subchapter in another capacity), Health and Safety Code.

Repealer: Section 481.061(d) (requiring a person to provide DPS with the person's Federal Drug Enforcement Administration number not later than the 45th day after the director issues a registration to the person under this subchapter), Health and Safety Code.

Repealer: Section 481.062(b) (authorizing the director by rule to waive the requirement for registration of certain manufacturers, distributors, or dispensers if the director finds it consistent with the public health and safety and if the attorney general of the United States has issued a similar waiver under the Federal Controlled Substances Act), Health and Safety Code.

Repealer: Section 481.063 (Registration Application; Issuance or Denial), Health and Safety Code.

Repealer: Section 481.064 (Registration Fees), Health and Safety Code.

Repealer: Section 481.0645 (Registration, Renewal, and Fees for Physicians), Health and Safety Code.

Repealer: Section 481.065 (Authorization for Certain Activities), Health and Safety Code.

Repealer: Section 481.066 (Voluntary Surrender, Cancellation, Suspension, Probation, or Revocation of Registration), Health and Safety Code.

Repealer: Section 481.069 (Order Forms), Health and Safety Code.

Repealer: Section 156.0035 (Renewal of Controlled Substance Registration), Occupations Code.

SECTION 26. (a) Provides that, notwithstanding any other provision of this Act, Sections 481.003(a), 481.076(c), and 481.0761(e) and (f), Health and Safety Code, as amended by this Act, and Section 481.0761(g), Health and Safety Code, as added by this Act, apply beginning on the effective date of this Act.

(b) Provides that the changes in law made by this Act to Section 481.076, Health and Safety Code, other than the changes made to Subsection (c) of that section, apply only to information submitted or accessed on or after September 1, 2016.

(c) Authorizes TSBP to enter into an interoperability agreement described by Section 481.076(j), Health and Safety Code, as added by this Act, before September 1, 2016, but the agreement may not go into effect until on or after September 1, 2016.

SECTION 27. (a) Requires DPS, not later than September 1, 2016, to transfer all appropriate records received by DPS under Sections 481.074, 481.076, and 481.0761, Health and Safety Code, regardless of whether the records were received before, on, or after the effective date of this Act, to TSBP.

(b) Requires TSBP to adopt any rules required by Chapter 481, Health and Safety Code, as amended by this Act, not later than March 1, 2016.

(c) Provides that a rule, form, policy, procedure, or decision adopted under Chapter 481, Health and Safety Code, as it existed before the effective date of this Act, continues in effect as a rule, form, policy, procedure, or decision and remains in effect until amended or replaced.

(d) Provides that a reference in law or an administrative rule to the public safety director of DPS relating to rulemaking authority given and duties transferred to TSBP by this Act is a reference to TSBP.

SECTION 28. Effective date: upon passage or September 1, 2015.