BILL ANALYSIS

C.S.S.B. 195 By: Schwertner Public Health Committee Report (Substituted)

BACKGROUND AND PURPOSE

The Texas Prescription Program collects prescription data on all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas. Created in the early 1980s, the program was established within the Department of Public Safety to monitor and prevent the diversion of prescription drugs. Access to the database is statutorily restricted, and only certain individuals are authorized to access the information to inquire about patients, verify prescription records, and collect useful information about prescription trends, as applicable. Interested parties contend that the operation of and certain requirements relating to the program are in need of updating. C.S.S.B. 195 seeks to address this need.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority previously granted to the public safety director of the Department of Public Safety is transferred to the Texas State Board of Pharmacy in SECTIONS 3, 9, 10, 12, and 13 of this bill. It is the committee's opinion that rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTIONS 13, 23, and 24 of this bill.

ANALYSIS

C.S.S.B. 195 repeals provisions of the Health and Safety Code and the Occupations Code regarding a requirement that a person register with the Department of Public Safety (DPS) to manufacture, distribute, analyze, or dispense a controlled substance or conduct research with a controlled substance under the Texas Controlled Substances Act. The bill amends the Health and Safety Code, including provisions amended by S.B. 219, Acts of the 84th Legislature, Regular Session, 2015, to instead require a person to be registered with or exempt from registration with the Federal Drug Enforcement Administration under the federal Controlled Substances Act to manufacture, distribute, prescribe, possess, analyze, dispense, or conduct research with a controlled substance under the Texas Controlled Substances Act. The bill repeals a provision requiring the use of an order form to distribute or order a Schedule I or II substance to or from another registrant.

C.S.S.B. 195 provides for the transfer of the regulation of the official prescription program for certain controlled substances from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy. The bill requires DPS, not later than September 1, 2016, to transfer to the board all appropriate records received by DPS under certain provisions of the Texas Controlled Substances Act regulating prescriptions for controlled substances and the official prescription program, regardless of whether the records were received before, on, or after the effective date of

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the bill. The bill requires the board to adopt any rules required by the Texas Controlled Substances Act, as amended by the bill, not later than March 1, 2016. The bill specifies that a rule, form, policy, procedure, or decision adopted under the Texas Controlled Substances Act, as it existed before the effective date of the bill, continues in effect as a rule, form, policy, procedure, or decision and remains in effect until amended or replaced. The bill specifies 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 the board by the bill is a reference to the board.

C.S.S.B. 195 transfers rulemaking authority relating to prescriptions for controlled substances and the official prescription program, including the authority to adopt rules regarding the communication of prescriptions by an agent, regulating prescriptions for a controlled substance, official prescription information, the electronic transfer of certain controlled substance prescription information, the controlled substances included in the official prescription program, and contracts relating to the operation of the official prescription program, from the public safety director to the board.

C.S.S.B. 195 includes an investigator for the Texas Optometry Board and an authorized employee of the Texas State Board of Pharmacy among the persons and organizations authorized to have access to specified information regarding prescriptions of certain controlled substances. The bill removes from a provision authorizing certain law enforcement or prosecutorial officials, pharmacists, and health care practitioners to access the information regarding prescriptions of certain controlled substances the condition that proper need has been shown to the public safety director. The bill includes a medical examiner conducting an investigation and one or more states or an association of states with which the Texas State Board of Pharmacy has an interoperability agreement among the persons and organizations authorized to have access to the information regarding prescriptions of certain controlled substances. The bill includes a pharmacist or pharmacy technician acting at the direction of an optometrist and an employee or other agent of a practitioner acting at the direction of a practitioner among the persons and organizations authorized to have access to the information regarding prescriptions of certain controlled substances and conditions the access of certain pharmacists and health care professionals on the person having the authority to access such information under the federal Health Insurance Portability and Accountability Act of 1996 and rules adopted under that act. The bill authorizes a medical examiner conducting an investigation to access the information through a health information exchange, subject to proper security measures.

C.S.S.B. 195 requires the Texas State Board of Pharmacy to ensure that DPS has unrestricted access at all times to specified information regarding prescriptions of certain controlled substances submitted to the board. The bill requires DPS's access to be provided through a secure electronic portal under the exclusive control of DPS and requires DPS to pay all expenses associated with the electronic portal. The bill specifies that DPS is responsible for the expenses of the initial implementation and ongoing operation of the secure electronic portal. The bill specifies that a law enforcement or prosecutorial official engaged in specified activities regarding illicit drugs is authorized to obtain the information submitted to the board only if the official submits a request to DPS. The bill requires DPS, on finding that the official has shown proper need for the information, to provide access to the relevant information. The bill establishes that records relating to the access of such 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. The bill prohibits the board from tracking or monitoring DPS's access to information. The bill specifies that the system design for the submission of information regarding the prescriptions of certain controlled substances to the board must be submitted to the public safety director for review and comment and removes the requirement that the system design be submitted for the purpose of approval by the Texas State Board of Pharmacy and the Texas Medical Board.

C.S.S.B. 195 authorizes the Texas State Board of Pharmacy to enter into an interoperability

agreement with one or more states or an association of states authorizing the board 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. The bill authorizes the board, pursuant to an interoperability agreement, to authorize the prescription monitoring program of one or more states or an association of states to access information submitted to the board, including by submitting or sharing information through a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect. The bill entitles a medical examiner conducting an investigation who is registered with the board for electronic access to certain information regarding prescriptions of controlled substances to directly access the information available from other states pursuant to an interoperability agreement. The bill specifies that the bill's changes to statutory provisions regarding official prescription information and related duties of the board apply to information submitted or accessed on or after September 1, 2016. The bill authorizes the board to enter into an interoperability agreement before September 1, 2016, but prohibits the agreement from going into effect until on or after September 1, 2016.

C.S.S.B. 195 authorizes the board to adopt rules providing for certain pharmacists, health care providers, and employees or agents of an eligible practitioner to be enrolled in electronic access to information submitted to the board relating to prescriptions of certain controlled substances at the time the person obtains or renews the person's applicable professional or occupational license or registration.

C.S.S.B. 195 removes certain grounds on which DPS may impose an administrative penalty under the Texas Controlled Substances Act. The bill specifies that the executive director of the board, or the executive director's designee, serves as the chair of the Interagency Prescription Monitoring Work Group and revises the composition of the work group. The bill removes a specification that the fee for issuing official prescription forms to certain health care practitioners covers the actual cost of printing, process, and mailing the forms at 100 a package.

C.S.S.B. 195 amends the Occupations Code to require the Texas State Board of Pharmacy 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 official prescription program for certain controlled substances. The bill authorizes the board to assess such fees on individuals or entities authorized to prescribe or dispense controlled substances under the Texas Controlled Substances Act and to access the official prescription program. The bill requires each agency that licenses individuals or entities authorized to prescribe or dispense controlled substances under the Texas Controlled Substances Act and to access the official prescription program 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 the board. The bill requires such a fee collected by an agency to be transferred to the board for the purpose of establishing and maintaining the official prescription program. The bill authorizes grants received by the board to implement or operate the official prescription program to be used by the board to offset or reduce the amount of fees paid by each agency that licenses individuals or entities who are or may be authorized to prescribe or dispense controlled substances under the Texas Controlled Substances Act.

C.S.S.B. 195 amends the Government Code to make conforming changes.

C.S.S.B. 195 establishes that its provisions relating to certain rulemaking authority transferred or granted to the Texas State Board of Pharmacy, certain contract authority transferred to the board, and the composition of the Interagency Prescription Monitoring Work Group take effect on passage if the bill receives the necessary vote or, if the bill does not receive the necessary vote, on September 1, 2015.

C.S.S.B. 195 repeals the following provisions of the Health and Safety Code:

- Sections 481.061(c) and (d)
- Section 481.062(b)
- Section 481.063
- Section 481.064
- Section 481.0645
- Section 481.066
- Section 481.069

C.S.S.B. 195 repeals Section 156.0035, Occupations Code.

EFFECTIVE DATE

Except as otherwise provided, September 1, 2016.

COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE

While C.S.S.B. 195 may differ from the engrossed in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the engrossed and committee substitute versions of the bill.

SENATE ENGROSSED

HOUSE COMMITTEE SUBSTITUTE

SECTION 1. Section 552.118, Government Code, is amended.

SECTION 1. Same as engrossed version.

SECTION 2. Section 481.002, Health and Safety Code, as amended by S.B. No. 219, Acts of the 84th Legislature, Regular Session, 2015, is amended by amending Subdivisions (4) and (45) and adding Subdivision (56) to read as follows:

- (4) "Controlled premises" means:
- (A) a place where original or other records or documents required under this chapter are kept or are required to be kept; or
- (B) a place, including a factory, warehouse, other establishment, or conveyance, where a person registered under this chapter may lawfully hold, manufacture, distribute, dispense, administer, possess, or otherwise dispose of a controlled substance or other item governed by the federal Controlled Substances Act (21 U.S.C. Section 801 et seq.) [this chapter], including a chemical precursor and a chemical laboratory apparatus.
- (45) "Registrant" means a person who <u>has a current Federal Drug Enforcement</u>
 Administration registration number [is

SECTION 2. Section 481.002, Health and Safety Code, is amended by amending Subdivisions (4) and (45) and adding Subdivision (55) to read as follows:

- (4) "Controlled premises" means:
- (A) a place where original or other records or documents required under this chapter are kept or are required to be kept; or
- (B) a place, including a factory, warehouse, other establishment, or conveyance, where a person registered under this chapter may lawfully hold, manufacture, distribute, dispense, administer, possess, or otherwise dispose of a controlled substance or other item governed by the federal Controlled Substances Act (21 U.S.C. Section 801 et seq.) or this chapter, including a chemical precursor and a chemical laboratory apparatus.
- (45) "Registrant" means a person who <u>has a current Federal Drug Enforcement</u>

 Administration registration number [is

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registered under Section 481.063].

(56) "Board" means the Texas State Board of Pharmacy.

SECTION 3. 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, other than Sections 481.075, 481.076, and 481.0761. The board may adopt rules to administer Sections 481.075, 481.076, and 481.0761.

SECTION 4. The heading to Section 481.061, Health and Safety Code, is amended.

SECTION 5. Sections 481.061(a) and (b), Health and Safety Code, are amended to read as follows:

- (a) Except as otherwise provided by this chapter, a person who is not <u>registered with</u> the Federal Drug Enforcement Administration [a registrant] may not manufacture, distribute, prescribe, possess, analyze, or dispense a controlled substance in this state.
- (b) A person who is registered with [by] the Federal Drug Enforcement Administration [director] to manufacture, distribute, analyze, dispense, or conduct research with a controlled substance may 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.

No equivalent provision.

registered under Section 481.063].

(55) "Board" means the Texas State Board of Pharmacy.

SECTION 3. 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, other than Sections 481.073, 481.074, 481.075, 481.076, and 481.0761. The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.076, and 481.0761.

SECTION 4. Same as engrossed version.

SECTION 5. Sections 481.061(a) and (b), Health and Safety Code, are amended to read as follows:

- (a) Except as otherwise provided by this chapter, a person who is not registered with or exempt from registration with the Federal Drug Enforcement Administration [a registrant] may not manufacture, distribute, prescribe, possess, analyze, or dispense a controlled substance in this state.
- (b) A person who is registered with [by] the Federal Drug Enforcement Administration [director] to manufacture, distribute, analyze, dispense, or conduct research with a controlled substance may 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. Section 481.062(a), Health and Safety Code, as amended by S.B. No. 219, Acts of the 84th Legislature, Regular Session, 2015, is amended to read as follows:

- (a) The following persons [are not required to register and] may possess a controlled substance under this chapter:
- (1) an agent or employee of a [registered] manufacturer, distributor, analyzer, or dispenser of the controlled substance who is registered with the Federal Drug

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<u>Enforcement Administration and acting in</u> the usual course of business or employment;

- (2) a common or contract carrier, a warehouseman, or an employee of a carrier or warehouseman whose possession of the controlled substance is in the usual course of business or employment;
- (3) an ultimate user or a person in possession of the controlled substance under a lawful order of a practitioner or in lawful possession of the controlled substance if it is listed in Schedule V;
- (4) an officer or employee of this state, another state, a political subdivision of this state or another state, or the United States who is lawfully engaged in the enforcement of a law relating to a controlled substance or drug or to a customs law and authorized to possess the controlled substance in the discharge of the person's official duties; or
- (5) if the substance is tetrahydrocannabinol or one of its derivatives:
- (A) a Department of State Health Services official, a medical school researcher, or a research program participant possessing the substance as authorized under Subchapter G; or
- (B) a practitioner or an ultimate user possessing the substance as a participant in a federally approved therapeutic research program that the commissioner has reviewed and found, in writing, to contain a medically responsible research protocol.

SECTION 6. Section 481.067(a), Health and Safety Code, is amended to read as follows:

(a) A person who is registered with the Federal Drug Enforcement Administration to manufacture, distribute, analyze, or dispense a controlled substance shall keep records and maintain inventories in compliance with recordkeeping and inventory requirements of federal law and with additional rules the board [director] adopts.

SECTION 7. Section 481.068, Health and Safety Code, as amended by S.B. No. 219, Acts of the 84th Legislature, Regular Session, 2015, is amended to read as follows:

Sec. 481.068. CONFIDENTIALITY. (a)

SECTION 7. Section 481.067(a), Health and Safety Code, is amended to read as follows:

(a) A person who is registered with the Federal Drug Enforcement Administration to manufacture, distribute, analyze, or dispense a controlled substance shall keep records and maintain inventories in compliance with recordkeeping and inventory requirements of federal law and with additional rules the board or director adopts.

No equivalent provision.

The <u>board</u> [director] may authorize a person engaged in research on the use and effects of a controlled substance to withhold the names and other identifying characteristics of individuals who are the subjects of the research. A person who obtains the authorization may not be compelled in a civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of the research for which the authorization is obtained.

- (b) Except as provided by Sections 481.074 and 481.075, a practitioner engaged in authorized medical practice or research may not be required to furnish the name or identity of a patient or research subject to the board [department], the Department of State Health Services, or any other agency, public official, or law enforcement officer. A practitioner may not be 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 confidential.
- (c) The <u>board</u> [director] may not provide to a federal, state, or local law enforcement agency the name or identity of a patient or research subject whose identity could not be obtained under Subsection (b).

SECTION 8. Section 481.073(a), Health and Safety Code, as amended by S.B. No. 219, Acts of the 84th Legislature, Regular Session, 2015, is amended.

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

(b) Except in an emergency as defined by rule of the <u>board</u> [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 a written prescription of a practitioner on an official prescription form or without an electronic prescription 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

SECTION 8. Same as engrossed version.

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

(b) Except in an emergency as defined by rule of the <u>board</u> [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 a written prescription of a practitioner on an official prescription form or without an electronic prescription 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

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- 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
- 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, Drug Federal Enforcement and Administration number issued prescribing a controlled substance in this state 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 or electronic prescription, completed in the manner required by Section 481.075, to be delivered to the dispensing pharmacist at the pharmacy where the prescription dispensed. A written prescription may be delivered in person or by mail. 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 a written prescription, the dispensing pharmacy shall file the transcription of the telephonically prescription communicated and pharmacy copy and shall send information to the board [director] as required by Section 481.075. On receipt of an electronic prescription, the pharmacist shall annotate the electronic prescription record with the original authorization and date of the telephonically emergency oral communicated prescription.
- (d) Except as specified in Subsections (e) and (f), the <u>board</u> [director], by rule and in consultation with the Texas Medical Board and the <u>department</u> [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.

- 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
- 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, Federal Drug Enforcement and Administration number issued for prescribing a controlled substance in this state 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 telephonically emergency oral or communicated prescription, the prescribing practitioner shall cause a written or electronic prescription, completed in the manner required by Section 481.075, to be delivered to the dispensing pharmacist at the pharmacy where the prescription was dispensed. A written prescription may be delivered in person or by mail. 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 a written prescription, the dispensing pharmacy shall file the transcription of the telephonically prescription communicated and pharmacy copy and shall send information to the board [director] as required by Section 481.075. On receipt of an electronic prescription, the pharmacist shall annotate the electronic prescription record with the original authorization and date of the telephonically emergency oral or communicated prescription.
- (d) Except as specified in Subsections (e) and (f), the <u>board</u> [director], by rule and in consultation with the Texas Medical Board [and the 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.

- (p) On receipt of the prescription, the dispensing pharmacy shall file the facsimile copy of the prescription and shall send information to the <u>board</u> [director] as required by Section 481.075.
- (q) Each dispensing pharmacist shall send all <u>required</u> information [required by the director], including any information required to complete the Schedule III through V prescription forms, to the <u>board [director]</u> by electronic transfer or another form approved by the <u>board [director]</u> not later than the seventh day after the date the prescription is completely filled.

SECTION 10. Sections 481.075(c), (g), (i), (k), and (m), Health and Safety Code, are amended.

SECTION 11. The heading to Section 481.076, Health and Safety Code, is amended.

SECTION 12. Section 481.076, Health and Safety Code, is amended 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) to read as follows:

- (a) The <u>board</u> [<u>director</u>] may not permit any person to have access to information submitted to the <u>board</u> [<u>director</u>] under Section 481.074(q) or 481.075 except:
- (1) an investigator for the board, 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 [State] Board [of Pharmacy];
- (2) an authorized officer or member of the department or authorized employee of the board engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state; [off]
- (3) the department on behalf of [if the director finds that proper need has been shown to the 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

- (p) On receipt of the prescription, the dispensing pharmacy shall file the facsimile copy of the prescription and shall send information to the <u>board</u> [director] as required by Section 481.075.
- (q) Each dispensing pharmacist shall send all <u>required</u> information [<u>required by the director</u>], including any information required to complete the Schedule III through V prescription forms, to the <u>board [director]</u> by electronic transfer or another form approved by the <u>board [director]</u> not later than the seventh day after the date the prescription is completely filled.

SECTION 10. Same as engrossed version.

SECTION 11. Same as engrossed version.

SECTION 12. Section 481.076, Health and Safety Code, is amended 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) to read as follows:

- (a) The <u>board</u> [<u>director</u>] may not permit any person to have access to information submitted to the <u>board</u> [<u>director</u>] under Section 481.074(q) or 481.075 except:
- (1) an investigator for the board, 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 [State] Board [of Pharmacy];
- (2) an authorized officer or member of the department or authorized employee of the board engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state; [of]
- (3) the department on behalf of [if the director finds that proper need has been shown to the 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) a medical examiner conducting an investigation;
- (5) [(B)] 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) or an employee or other agent of a practitioner [a nurse licensed under Chapter 301, Occupations Code, 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; [or]
- (6) [(C)] a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or
- (7) one or more states or an association of states with which the board has an interoperability agreement, as provided by Subsection (j).
- (a-1) A person authorized to receive information under Subsection (a)(4), (5), [(a)(3)(B)] or (6) [(C)] may access that information through a health information exchange, subject to proper security measures to ensure against disclosure to unauthorized persons.
- (a-2) A person authorized to receive information under Subsection (a)(5) [(a)(3)(B)] may include that information in any form in the medical or pharmacy record of the patient who is the subject of the information. 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) The board shall ensure that the department has unrestricted access at all times to information received by the board under this section.

- state or another state;
- (4) a medical examiner conducting an investigation;
- (5) [(B)] 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) or an employee or other agent of a practitioner [a nurse licensed under Chapter 301, Occupations Code, 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; [or]
- (6) [(C)] a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or
- (7) one or more states or an association of states with which the board has an interoperability agreement, as provided by Subsection (j).
- (a-1) A person authorized to receive information under Subsection (a)(4), (5), [(a)(3)(B)] or (6) [(C)] may access that information through a health information exchange, subject to proper security measures to ensure against disclosure to unauthorized persons.
- (a-2) A person authorized to receive information under Subsection (a)(5) [(a)(3)(B)] may include that information in any form in the medical or pharmacy record of the patient who is the subject of the information. 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) The board shall ensure that the department has unrestricted access at all times to information submitted to the board under Sections 481.074(q) and 481.075. The department's access to the information shall be provided through a secure electronic portal under the exclusive control of the department. The department shall pay all expenses associated with the

- (a-4) A law enforcement or prosecutorial official described by Subsection (a)(3) may obtain information received by the board under this section only if the official submits a request to the department. The department shall review and process each request under this subsection. If the department shows that the official has shown proper need for the information, the department shall access the information on behalf of the official and submit the relevant information to the official.
- (a-5) Records relating to the access of information by the department or by the department on behalf of a law enforcement agency are confidential, including any information concerning the identities of the investigating agents or agencies. The board may not track or monitor the department's access to information.
- (b) This section does not prohibit the <u>board</u> [director] from creating, using, or disclosing statistical data about information received by the <u>board</u> [director] under this section if the <u>board</u> [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 [director] under this section and 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 <u>board</u> [director] under this section may be used only for:
- (1) the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

electronic portal.

- (a-4) A law enforcement or prosecutorial official described by Subsection (a)(3) may obtain information submitted to the board under Section 481.074(q) or 481.075 only if the official submits a request to the department. If the department finds that the official has shown proper need for the information, the department shall provide access to the relevant information.
- (a-5) Records relating to the access of information by the department or by the department on behalf of a law enforcement agency are confidential, including any information concerning the identities of the investigating agents or agencies. The board may not track or monitor the department's access to information.
- (b) This section does not prohibit the <u>board</u> [director] from creating, using, or disclosing statistical data about information <u>submitted</u> to [received by] the <u>board</u> [director] under this section if the <u>board</u> [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 <u>board</u> [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 [director] under this section and Sections 481.074 and 481.075. The <u>board</u> [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 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 <u>board</u> [director] under this section may be used 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 <u>board</u> [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 <u>board</u> [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 <u>board</u> [director] not later than the end of the 36th calendar month after the month in which the identity is entered into the system. However, the <u>board</u> [director] may retain a patient identity that is necessary for use in a specific ongoing investigation conducted 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.
- (g) If 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 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.
- (i) Information submitted to the <u>board</u> [director] under Section 481.074(q) or 481.075 is confidential and remains confidential regardless of whether the <u>board</u> [director] permits access to the information under this section.
- The board may enter into an interoperability agreement with one or more states or an association of states authorizing the board 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. Pursuant to interoperability agreement, the board may authorize the prescription monitoring program of one or more states or an association of states to access information submitted to the board under Sections 481.074(q) and 481.075, including by

- (2) investigatory or evidentiary purposes in connection with the functions of an agency listed in Subsection (a)(1); or
- (3) dissemination by the <u>board</u> [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 <u>board</u> [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 <u>board</u> [director] not later than the end of the 36th calendar month after the month in which the identity is entered into the system. However, the <u>board</u> [director] may retain a patient identity that is necessary for use in a specific ongoing investigation conducted 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.
- (g) If 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 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.
- (i) Information submitted to the <u>board</u> [director] under Section 481.074(q) or 481.075 is confidential and remains confidential regardless of whether the <u>board</u> [director] permits access to the information under this section.
- The board may enter into interoperability agreement with one or more states or an association of states authorizing the board 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 Pursuant InterConnect. to interoperability agreement, the board may authorize the prescription monitoring program of one or more states or an association of states to access information submitted to the board 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) A person authorized to access information under Subsection (a)(4) who is registered with the board for electronic access to the information is entitled to directly access the information available from other states pursuant to an interoperability agreement described by Subsection (j).

SECTION 13. Section 481.0761, Health and Safety Code, is amended.

SECTION 14. Section 481.077(c), Health and Safety Code, is amended to read as follows:

(c) This section and Section 481.078 do not apply to a person to whom a registration has been issued by the Federal Drug Enforcement Administration [under Section 481.063].

SECTION 15. Section 481.080(d), Health and Safety Code, is amended to read as follows:

(d) This section and Section 481.081 do not apply to a person to whom a registration has been issued by the Federal Drug Enforcement Administration [under Section 481.063].

SECTION 16. Section 481.124(b), Health and Safety Code, is amended.

SECTION 17. Section 481.127(a), Health and Safety Code, is amended.

SECTION 18. Sections 481.128(a) and (b), Health and Safety Code, are amended.

SECTION 19. Section 481.129(a), Health and Safety Code, is amended.

submitting or sharing information through a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect.

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

SECTION 13. Same as engrossed version.

SECTION 14. Section 481.077(c), Health and Safety Code, is amended to read as follows:

(c) 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 or who is exempt from such registration [under Section 481.063].

SECTION 15. Section 481.080(d), Health and Safety Code, is amended to read as follows:

(d) 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 or who is exempt from such registration [under Section 481.063].

SECTION 16. Same as engrossed version.

SECTION 17. Same as engrossed version.

SECTION 18. Same as engrossed version.

SECTION 19. Same as engrossed version.

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SECTION 20. Section 481.159(a), Health and Safety Code, is amended.

SECTION 20. Same as engrossed version.

SECTION 21. Section 481.301, Health and Safety Code, is amended to read as follows: Sec. 481.301. IMPOSITION OF PENALTY. The department or the board, as applicable, may impose an administrative penalty on a person who violates Section 481.061, [481.066,] 481.067, [481.069,] 481.074, 481.075, 481.077, 481.0771, 481.078, 481.080, or 481.081 or a rule or order adopted under any of those sections.

SECTION 22. Section 481.352, Health and SECT Safety Code, is amended to read as follows: Safety Sec. 481.352. MEMBERS. The work Sec.

(1) the <u>executive</u> director <u>of the board</u> or the <u>executive</u> director's designee, <u>who</u> <u>serves as chair of the work group;</u>

group is composed of:

- (2) the commissioner of state health services or the commissioner's designee;
- (3) [the executive director of the Texas State Board of Pharmacy or the executive director's designee;
- [(4)] the executive director of the Texas Medical Board or the executive director's designee;
- (4) [(5)] the executive director of the Texas Board of Nursing or the executive director's designee; and
- (5) [(6)] the executive director of the Texas Physician Assistant Board or the executive director's designee.

SECTION 21. Section 481.301, Health and Safety Code, is amended to read as follows: Sec. 481.301. IMPOSITION OF PENALTY. The department may impose an administrative penalty on a person who violates Section [481.061, 481.066,] 481.067, [481.069, 481.074, 481.075,] 481.077, 481.0771, 481.078, 481.080, or 481.081 or a rule or order adopted under any of those sections.

- SECTION 22. Section 481.352, Health and Safety Code, is amended to read as follows: Sec. 481.352. MEMBERS. The work group is composed of:
- (1) the <u>executive</u> director <u>of the board</u> or the <u>executive</u> director's designee, <u>who</u> <u>serves as chair of the work group;</u>
- (2) the commissioner of state health services or the commissioner's designee;
- (3) [the executive director of the Texas State Board of Pharmacy or the executive director's designee;
- [(4)] the executive director of the Texas Medical Board or the executive director's designee;
- (4) [(5)] the executive director of the Texas Board of Nursing or the executive director's designee; [and]
- (5) [(6)] the executive director of the Texas Physician Assistant Board or the executive director's designee;
- (6) the executive director of the Texas Board of Dental Examiners or the executive director's designee;
- (7) the executive director of the Texas Optometry Board or the executive director's designee;
- (8) the executive director of the Texas Board of Podiatric Medical Examiners or the executive director's designee;
- (9) the executive director of the Texas State Board of Veterinary Medical Examiners or the executive director's designee; and
- (10) a medical examiner appointed by the board.

SECTION 23. Section 554.006, Occupations Code, is amended to read as SECTION 23. Section 554.006, Occupations Code, is amended to read as

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follows:

Sec. 554.006. FEES. (a) The board by rule shall establish reasonable and necessary fees so that the fees, in the aggregate, produce sufficient revenue to cover the cost of administering this subtitle.

- (b) The board by rule shall 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) The board may assess the fee described by Subsection (b) on 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.
- (d) 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, shall 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 the board.
- (e) A fee collected by an agency under Subsection (d) shall be transferred to the board 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. Section 554.051, Occupations Code, is amended by adding Subsection (a-1) to read as follows:

(a-1) The board may adopt rules to administer Sections 481.075, 481.076, and

follows:

Sec. 554.006. FEES. (a) The board by rule shall establish reasonable and necessary fees so that the fees, in the aggregate, produce sufficient revenue to cover the cost of administering this subtitle.

- (b) The board by rule shall 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) The board may assess the fee described by Subsection (b) on 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.
- (d) 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, shall 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 the board.
- (e) A fee collected by an agency under Subsection (d) shall be transferred to the board for the purpose of establishing and maintaining the program described by Sections 481.075, 481.076, and 481.0761, Health and Safety Code.
- (f) Grants received by the board to implement or operate the program described by Sections 481.075, 481.076, and 481.0761, Health and Safety Code, may be used by the board to offset or reduce the amount of fees paid by each agency that licenses individuals or entities who are or may be authorized to prescribe or dispense controlled substances under Chapter 481, Health and Safety Code.

SECTION 24. Section 554.051, Occupations Code, is amended by adding Subsection (a-1) to read as follows:

(a-1) The board may adopt rules to administer Sections 481.073, 481.074,

481.075, 481.076, and 481.0761, Health and Safety Code.

SECTION 25. The following provisions are repealed:

- (1) Sections 481.061(c) and (d), 481.062(b), 481.063, 481.064, 481.0645, 481.065, 481.066, and 481.069, Health and Safety Code; and
- (2) Section 156.0035, Occupations Code.
- SECTION 26. (a) 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) 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) The Texas State Board of Pharmacy may 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) Not later than September 1, 2016, the Department of Public Safety shall transfer all appropriate records received by the department 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 the Texas State Board of Pharmacy.
- (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 March 1, 2016.
- (c) A rule, form, policy, procedure, or decision adopted under Chapter 481, Health and Safety Code, as it existed before the

SECTION 25. The following provisions are repealed:

- (1) Sections 481.061(c) and (d), 481.062(b), 481.063, 481.064, 481.0645, 481.066, and 481.069, Health and Safety Code; and
- (2) Section 156.0035, Occupations Code.

SECTION 26.

- (a) 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.
- (b) The Texas State Board of Pharmacy may 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) Not later than September 1, 2016, the Department of Public Safety shall transfer all appropriate records received by the department under Sections 481.074(q) and 481.075, Health and Safety Code, regardless of whether the records were received before, on, or after the effective date of this Act, to the Texas State Board of Pharmacy.

(See SECTION 29(b) below.)

(b) A rule, form, policy, procedure, or decision adopted under Chapter 481, Health and Safety Code, as it existed before the

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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) 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.

No equivalent provision.

SECTION 28. This Act takes effect immediately if it receives a vote of two-thirds of all the 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, 2015.

(See SECTION 27(b) above.)

effective date of this Act, continues in effect as a rule, form, policy, procedure, or decision and remains in effect until amended or replaced.

(c) 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 28. The Department of Public Safety is responsible for the expenses of the initial implementation and ongoing operation of the secure electronic portal described by Section 481.076(a-3), Health and Safety Code, as added by this Act.

SECTION 29. (a) Except as otherwise provided by this section, this Act takes effect September 1, 2016.

- (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 March 1, 2016.
- (c) Sections 481.003(a), 481.076(c), 481.0761(a), (e), and (f), and 481.352, Health and Safety Code, as amended by this Act, and Section 481.0761(g), Health and Safety Code, as added by this Act, take effect immediately if this Act receives a vote of two-thirds of all the 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, these provisions take effect September 1, 2015.

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