CHAPTER 315 – CONTROLLED SUBSTANCES

§315.1 Definitions - Effective September 1, 2016

The following terms in this section, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

(1) TCSA--The Texas Controlled Substances Act (Texas Health and Safety Code, Chapter 481).

(2) Advanced practice registered nurse--A registered nurse licensed by the Texas Board of Nursing to practice as an advanced practice registered nurse on the basis of completion of an advanced educational program. The term includes a nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with "advanced nurse practitioner" and "advanced practice nurse."

(3) Day--A calendar day unless the context clearly indicates a business day.

(4) Drug Enforcement Administration (DEA)--The Federal Drug Enforcement Administration.

(5) Electronic transmission--The transmission of information in electronic form such as computer to computer, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic media.

(6) Emergency situation--A situation described in the Code of Federal Regulations, Title 21, §1306.11(d).

(7) Individual practitioner--A physician, dentist, veterinarian, optometrist, podiatrist, or other individual licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(8) Institutional practitioner--A hospital or other person (other than an individual practitioner) licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(9) Locum tenen--An individual practitioner who practices in a temporary position in this state and licensed by the appropriate Texas state licensing board.

(10) Long-term care facility (LTCF)--An establishment licensed as such by the Texas Department of Aging and Disability Services.

(11) NDC #--A National Drug Code number.

(12) Physician assistant--An individual licensed as such by the Texas Physician Assistant Board.

(13) Record--A notification, order form, statement, invoice, prescription, inventory information, or other document for the acquisition or disposal of a controlled substance, precursor, or apparatus in any manner by a registrant or permit holder under a record keeping or inventory requirement of federal law, the TCSA, or this chapter.

(14) Reportable prescription--A prescription for a controlled substance:

(A) listed in Schedule II through V; and

(B) not excluded from this chapter by a rule adopted under the TCSA, §481.0761(b).

(15) Temporary controlled substances registration (TCSR)--A controlled substances registration issued to a locum tenen or a health practitioner for a period of time not to exceed 90 days.

§315.2 Official Prescription Form - Effective September 1, 2016

(a) A practitioner may order official prescription forms from the board only if the practitioner is registered by the DEA to prescribe a Schedule II controlled substance.

(b) The board is the sole source for the official prescription forms.

(c) This subsection applies only to an institutional practitioner who is employed by a hospital or other training institution. An institutional practitioner authorized by a hospital or institution to prescribe a Schedule II controlled substance under the DEA registration of the hospital or institution may order official prescription forms under this section if:

(1) the practitioner prescribes a controlled substance in the usual course of the practitioner's training, teaching program, or employment at the hospital or institution;

(2) the appropriate state health regulatory agency has assigned an institutional permit or similar number to the practitioner; and

(3) the hospital or institution:

(A) maintains a current list of each institutional practitioner and each assigned institutional permit number; and

(B) makes the list available to another registrant or a member of a state health regulatory or law enforcement agency for the purpose of verifying the authority of the practitioner to prescribe the substance.

(d) An advanced practice registered nurse or physician assistant operating under a prescriptive authority agreement pursuant to Texas Occupations Code, Chapter 157 may order official prescription forms under this section if authority to prescribe has been delegated by a physician. Upon withdrawal of the delegating physician's authority such forms are void and must be returned to the board.

§315.3 Prescriptions - Effective September 1, 2016

(a) Schedule II Prescriptions.

(1) Except as provided by subsection (e) of this section, a practitioner, as defined in the TCSA, §481.002(39)(A), must issue a written prescription for a Schedule II controlled substance only on an official Texas prescription form or through an electronic prescription that meets all requirements of the TCSA. This subsection also applies to a prescription issued in an emergency situation.

(2) A practitioner who issues a written prescription for any quantity of a Schedule II controlled substance must complete an official prescription form.

(3) A practitioner may issue multiple written prescriptions authorizing a patient to receive up to a 90-day supply of a Schedule II controlled substance provided:

(A) each prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(B) the practitioner provides written instructions on each prescription, other than the first prescription if the practitioner intends for that prescription to be filled immediately, indicating the earliest date on which a pharmacy may dispense each prescription; and

(C) the practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

(4) A schedule II prescription must be dispensed no later than 21 days after the date of issuance or, if the prescription is part of a multiple set of prescriptions, issued on the same day, no later than 21 days after the earliest date on which a pharmacy may dispense the prescription as indicated on each prescription.

(b) Schedules III through V Prescriptions.

(1) A practitioner, as defined in the TCSA, §481.002(39)(A), (C), (D), may use prescription forms and order forms through individual sources. A practitioner may issue, or allow to be issued by a person under the practitioner's direction or supervision, a Schedule III through V controlled substance on a prescription form for a valid medical purpose and in the course of medical practice.

(2) Schedule III through V prescriptions may be refilled up to five times within six months after date of issuance.

(c) Electronic prescription. A practitioner is permitted to issue and to dispense an electronic controlled substance prescription only in accordance with the requirements of the Code of Federal Regulations, Title 21, Part 1311.

(d) Controlled substance prescriptions may not be postdated.

(e) Advanced practice registered nurses or physician assistants may only use the official prescription forms issued with their name, address, phone number, and DEA numbers, and the delegating physician's name and DEA number.

§315.4 Exceptions to Use of Form - Effective September 1, 2016

(a) An official prescription form is not required for a medication order written for a patient who is admitted to a hospital at the time the medication order is written and dispensed.

(1) A practitioner may dispense or cause to be dispensed a Schedule II controlled substance to a patient who:

(A) is admitted to the hospital; and

(B) will require an emergency quantity of a controlled substance upon release from the hospital.

(2) Under paragraph (1) of this subsection, the controlled substance:

(A) may only be dispensed in a properly labeled container; and

(B) may not be more than a seven-day supply or the minimum amount needed for proper treatment of the patient until the patient can obtain access to a pharmacy, whichever is less.

(b) Subsection (a) of this section applies to a patient who is admitted to a hospital, including a patient:

(1) admitted to:

(A) a general hospital, special hospital, licensed ambulatory surgical center, surgical suite in a dental school, or veterinary medical school; or

(B) a hospital clinic or emergency room, if the clinic or emergency room is under the control, direction, and administration as an integral part of a general or special hospital;

(2) receiving treatment with a Schedule II controlled substance from a member of a Life Flight or similar medical team or an emergency medical ambulance crew or a paramedic-emergency medical technician operating as an extension of an emergency room of a general or special hospital; or

(3) receiving treatment with a Schedule II controlled substance while the patient is an inmate incarcerated in a correctional facility operated by the Texas Department of Criminal Justice or a correctional facility operating in accordance with the Health Services Plan adopted by the Texas Commission on Jail Standards.

(c) Subsection (a) of this section applies to an animal admitted to an animal hospital, including an animal that is a permanent resident of a zoo, wildlife park, exotic game ranch, wildlife management program, or state or federal research facility.

(d) An official prescription form is not required in a long-term care facility (LTCF) if:

(1) an individual administers the substance to an inpatient from the facility's medical emergency kit;

(2) the individual administering the substance is an authorized practitioner or an agent acting under the practitioner's order; and

(3) the facility maintains the proper records as required for an emergency medical kit in an LTCF.

(e) An official prescription form is not required when a therapeutic optometrist administers a topical ocular pharmaceutical agent in compliance with:

(1) the Texas Optometry Act; and

(2) a rule adopted by the Texas Optometry Board under the authority of the Texas Optometry Act.

§315.5 Pharmacy Responsibility - Generally - Effective September 1, 2016

(a) Upon receipt of a properly completed prescription form, a dispensing pharmacist must:

(1) if the prescription is for a Schedule II controlled substance, ensure the date the prescription is presented is not later than 21 days after the date of issuance;

(2) if multiple prescriptions are issued by the prescribing practitioner allowing up to a 90-day supply of Schedule II controlled substances, ensure each prescription is neither dispensed prior to the earliest date intended by the practitioner nor dispensed beyond 21 days from the earliest date the prescription may be dispensed;

(3) record the date dispensed and the pharmacy prescription number;

(4) indicate whether the pharmacy dispensed to the patient a quantity less than the quantity prescribed; and

(5) if issued on an official prescription form, record the following information, if different from the prescribing practitioner's information:

(A) the brand name or, if none, the generic name of the controlled substance dispensed; or

(B) the strength, quantity, and dosage form of the Schedule II controlled substance used to prepare the mixture or compound.

(b) The prescription presented for dispensing is void, and a new prescription is required, if:

(1) the prescription is for a Schedule II controlled substance, 21 days after issuance, or 21 days after any earliest dispense date; or

(2) the prescription is for a Schedule III, IV, or V controlled substance, more than six months after issuance or has been dispensed five times during the six months after issuance.

§315.6 Pharmacy Responsibility - Electronic Reporting - Effective September 1, 2016

(a) Not later than the next business day after the date a controlled substance prescription is dispensed, a pharmacy must electronically submit to the board the following data elements:

(1) the prescribing practitioner's DEA registration number including the prescriber's identifying suffix of the authorizing hospital or other institution's DEA number when applicable;

(2) the official prescription form control number if dispensed from a written official prescription form for a Schedule II controlled substance;

(3) the board's designated placeholder entered into the control number field if the prescription is electronic and meets the requirements of Code of Federal Regulations, Title 21, Part 1311;

(4) the patient's name, date of birth, and address including city, state, and zip code; or such information on the animal's owner if the prescription is for an animal;

(5) the date the prescription was issued and dispensed;

(6) the NDC # of the controlled substance dispensed;

(7) the quantity of controlled substance dispensed;

(8) the pharmacy's prescription number; and

(9) the pharmacy's DEA registration number.

(b) A pharmacy must electronically correct dispensing data submitted to the board within seven business days of identifying an omission, error, or inaccuracy in previously submitted dispensing data.

§315.7 Pharmacy Responsibility - Oral, Telephonic, or Emergency Prescription - Effective September 1, 2016

(a) If a pharmacy dispenses a controlled substance pursuant to an orally or telephonically communicated prescription from a practitioner or the practitioner's designated agent, the prescription must be promptly reduced to writing, including the information required:

(1) by law for a standard prescription; and

(2) by law and this subchapter for an official prescription, if issued for a Schedule II controlled substance in an emergency situation.

(b) After dispensing a Schedule II controlled substance pursuant to an orally or telephonically communicated prescription, the dispensing pharmacy must:

(1) maintain the written record created under subsection (a) of this section;

(2) note the emergency nature of the prescription;

(3) upon receipt from the practitioner, attach the original official prescription to the orally or telephonically communicated prescription; and

(4) retain both documents in the pharmacy records.

(c) A pharmacy that dispenses Schedule III, IV, or V controlled substances pursuant to an orally or telephonically communicated prescription must inform the prescribing practitioner in the event of an emergency refill of the prescription.

(d) All records generated under this section must be maintained for two years from the date the substance was dispensed.

§315.8 Pharmacy Responsibility - Modification of Prescription - Effective September 1, 2016

The pharmacy is responsible for documenting the following information regarding a modified prescription:

(1) date the change or adding of information was authorized;

(2) information that was authorized to be added or changed;

(3) name of the prescribing practitioner granting the authorization; and

(4) initials or identification code of the pharmacist.

§315.9 Pharmacy Responsibility - Out-of-State Practitioner - Effective September 1, 2016

(a) A Schedule II controlled substance prescription issued by a practitioner in another state not on the board's official prescription form may be dispensed if:

(1) the practitioner is authorized by the other state to prescribe the substance;

(2) the pharmacy has a plan approved by and on file with the board allowing the activity; and

(3) the pharmacy processes and submits the prescription according to the reporting requirements approved in the plan.

(b) The pharmacy may dispense a prescription for a Schedule III through V controlled substance issued by a practitioner in another state if the practitioner is authorized by the other state to prescribe the substance.

§315.10 Return of Unused Official Prescription Form - Effective September 1, 2016

(a) An unused official prescription form is invalid and the practitioner or another person acting on behalf of the practitioner must return the unused form to the board with an appropriate explanation not later than the 30th day after the date:

(1) the practitioner's license to practice, DEA number is canceled, revoked, suspended, denied, or surrendered or amended to exclude the handling of all Schedule II controlled substances; or

(2) the practitioner is deceased.

(b) An individual who is an institutional practitioner must return an unused official prescription form to the administrator of the hospital or other training institution upon completion or termination of the individual's training at the hospital or institution. The administrator must return an unused official prescription form to the board not later than the 30th day after the date the individual completes or terminates all training programs.

(c) No individual may continue to use an official prescription form issued under an institutional practitioner's DEA number or similar number after the individual has been properly and individually licensed as a practitioner by the appropriate state health regulatory agency.

§315.11 Release of Prescription Data - Effective September 1, 2016

(a) A person listed under §481.076(a) of the TCSA must show proper need for the information when requesting the release of prescription data. The showing of proper need is ongoing.

(b) A pharmacist may delegate access to prescription data to a pharmacy technician as defined by Texas Occupations Code, §551.003, employed at the pharmacy and acting under the direction of the pharmacist.

(c) A practitioner may delegate access to prescription data to an employee or other agent of the practitioner and acting at the direction of the practitioner.

§315.12 Schedule III through V Prescription Forms - Effective September 1, 2016

(a) A practitioner, as defined in the TCSA, §481.002(39)(A), (C), and (D), may use prescription forms ordered through individual sources or through an electronic prescription that includes the controlled substances registration number issued by the United States Drug Enforcement Administration and meets all requirements of the TCSA.

(b) If a written prescription form is to be used to prescribe a controlled substance the dispensing practitioner must be registered with the DEA under both state and federal law to prescribe controlled substances.

§315.13 Official Prescription Form - Effective September 1, 2016

(a) Accountability. A practitioner who obtains from the board an official prescription form is accountable for each numbered form.

(b) Prohibited acts. A practitioner may not:

(1) allow another practitioner to use the individual practitioner's official prescription form;

(2) pre-sign an official prescription blank;

(3) post-date an official prescription; or

(4) leave an official prescription blank in a location where the practitioner should reasonably believe another could steal or misuse a prescription.

(c) While not in use. While an official prescription blank is not in immediate use, a practitioner may not maintain or store the book at a location so the book is easily accessible for theft or other misuse.

(d) Voided. A practitioner must account for each voided official prescription form by sending the voided form to the board.

(e) Types of forms. Forms may be single or multiple copy forms as provided by the board.

(f) Faxed forms. Faxed official prescription forms will be accounted for as in the TCSA, §481.074(o).

§315.14 Official Prescription - Effective September 1, 2016

(a) Report lost forms. Not later than close of business on the day of discovery, a practitioner must report a lost or stolen official prescription form to:

(1) the local police department or sheriff's office in an effective manner; and

(2) the board.

(b) Recovery report. Not later than close of business on the day of recovery of an official prescription form previously reported lost or stolen, a practitioner must, before using the recovered form, notify:

(1) the local law enforcement agency to which the matter was originally reported; and

(2) the board.

(c) Replacement/lost form. Not later than the close of business on the day that an official prescription is replaced or reported lost, with or without a replacement, the prescribing practitioner, or designated agent, shall report to the board the following:

(1) patient name, address, date of birth or age;

(2) all drug information; and

(3) official prescription form control number.

§315.15 Access Requirements

(a) Effective September 1, 2019, a pharmacist before dispensing an opioid, benzodiazepine, barbiturate, or carisoprodol for a patient shall consult the Texas Prescription Monitoring Program (PMP) database to review the patient's controlled substance history.

(b) The duty to consult the PMP database as described in subsection (a) of this section does not apply in the following circumstances:

(1) the prescribing individual practitioner is a veterinarian;

(2) it is clearly noted in the prescription record that the patient has a diagnosis of cancer or is in hospice care; or

(3) the pharmacist is unable to access the PMP after making and documenting a good faith effort to do so.

(c) If a pharmacist uses pharmacy management systems that integrate data from the PMP, a review of the pharmacy management system with the integrated data shall be deemed compliant with the review of the PMP database as required under §481.0764(a) of the Texas Health and Safety Code and in subsection (a) of this section.

(d) Pharmacists and pharmacy technicians acting at the direction of a pharmacist may only access information contained in the PMP as authorized in §481.076 of Texas Controlled Substances Act. A person who is authorized to access the PMP may only do so utilizing that person's assigned identifier (i.e., login and password) and may not use the assigned identifier of another person. Unauthorized access of PMP information is a violation of Texas Controlled Substances Act, the Texas Pharmacy Act, and board rules.