CHAPTER 295 – PHARMACISTS

§295.1 Change of Address and/or Name

(a) Change of address. A pharmacist shall notify the board in writing within 10 days of a change of address, giving the old and new address and license number.

(b) Change of name.

(1) A pharmacist shall notify the board in writing within 10 days of a change of name by sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.).

(2) Pharmacists who change their name may retain the original license to practice pharmacy (wall certificate). However, if the pharmacist wants an amended license (wall certificate) issued which reflects the pharmacist's name change, the pharmacist must:

(A) return the original license (wall certificate); and

(B) pay a fee of $35.

(3) An amended electronic renewal certificate reflecting the new name of the pharmacist will be issued by the board without a fee.

§295.2 Change of Employment

(a) A pharmacist shall report in writing to the board within 10 days of a change of employment and be responsible for seeing that his or her name is removed from the pharmacy license of last employment and added to the pharmacy license of new employment.

(b) For the purposes of this section, the term "employment" means the pharmacy at which the pharmacist engages in work on a regular and routine basis, whether remunerative or not, including the practice of pharmacy, administrative or managerial duties, supervisory tasks, or direct or indirect contractual services for pay. The term does not include an isolated case of practicing pharmacy on a temporary basis in order to relieve another pharmacist, unless such isolated cases become regular and routine.

§295.3 Responsibility of Pharmacist

(a) The pharmacist-in-charge shall insure that a pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy.

(b) All pharmacists while on duty, shall be responsible for complying with all state and federal laws and rules governing the practice of pharmacy.

§295.4 Sharing Money Received for Prescription

No pharmacist may share or offer to share the money received from a customer for filling a prescription with the practitioner.

§295.5 Pharmacist License or Renewal Fees

(a) Biennial Registration. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacist licenses provided under the Pharmacy Act, §559.002.

(b) Initial License Fee.

(1) The fee for the initial license shall be $338 for a two year registration.

(2) New pharmacist licenses shall be assigned an expiration date and initial fee shall be prorated based on the assigned expiration date.

(c) Renewal Fee. The fee for biennial renewal of a pharmacist license shall be $335 for a two year registration.

(d) Exemption from fee. The license of a pharmacist who has been licensed by the Texas State Board of Pharmacy for at least 50 years or who is at least 72 years old shall be renewed without payment of a fee provided such pharmacist is not actively practicing pharmacy. The renewal certificate of such pharmacist issued by the board shall reflect an inactive status. A person whose license is renewed pursuant to this subsection may not engage in the active practice of pharmacy without first paying the renewal fee as set out in subsection (c) of this section.

§295.6 Emergency Temporary Pharmacist License

(a) Definitions. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Emergency situation--an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services.

(2) State--One of the 50 United States of America, the District of Columbia, and Puerto Rico.

(b) Emergency Temporary Pharmacist license. In an emergency situation, the board may grant a pharmacist who holds a license to practice pharmacy in another state an emergency temporary pharmacist license to practice in Texas. The following is applicable for the emergency temporary pharmacist license.

(1) An applicant for an emergency temporary pharmacist license under this section must hold a current pharmacist license in another state and that license and other licenses held by the applicant in any other state may not be suspended, revoked, canceled, surrendered, or otherwise restricted for any reason.

(2) To qualify for an emergency temporary pharmacist license, the applicant must submit an application including the following information:

(A) name, address, and phone number of the applicant; and

(B) any other information the required by the board.

(3) An emergency temporary pharmacist license shall be valid for a period as determined by the board not to exceed six months. The executive director of the board, in his/her discretion, may renew the license for an additional six months, if the emergency situation still exists.

(c) Exception. This section is not applicable to pharmacists enrolled in a volunteer health registry maintained by the Texas Department of State Health Services.

§295.7 Pharmacist License Renewal

For the purposes of the Act, Chapter 559, Subchapter A.

(1) A license to practice pharmacy expires on the last day of the assigned expiration month.

(2) Before the expiration date of the license means the receipt in the board's office of a completed application and renewal fee on or before the last day of the assigned expiration month.

(3) As specified in §559.003, if the completed application and renewal fee is not received on or before the last day of the assigned expiration month, the person's license to practice pharmacy shall expire. A person shall not practice pharmacy with an expired license. An expired license may be renewed according to the following schedule.

(A) If license has been expired for 90 days or less, the person may become licensed by making application and paying to the board a renewal fee that is equal to one and one-half times the renewal fee for the license as specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees).

(B) If license has been expired for more than 90 days but less than one year, the person may become licensed by making application and paying to the board a renewal fee that is equal to two times the renewal fee for the license as specified in §295.5 of this title.

(C) If license has been expired for one year or more, the person shall apply for a new license as specified in §283.10 of this title (relating to Requirements for Application for a Pharmacist License Which Has Expired).

§295.8 Continuing Education Requirements

(a) Authority and purpose.

(1) Authority. In accordance with §559.053 of the Texas Pharmacy Act, (Chapters 551 - 569, Occupations Code), all pharmacists must complete and report 30 contact hours (3.0 CEUs) of approved continuing education obtained during the previous license period in order to renew their license to practice pharmacy.

(2) Purpose. The board recognizes that the fundamental purpose of continuing education is to maintain and enhance the professional competency of pharmacists licensed to practice in Texas, for the protection of the health and welfare of the citizens of Texas.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 569, Occupations Code.

(3) Approved programs--Live programs, home study, and other mediated instruction delivered by an approved provider or a program specified by the board and listed as an approved program in subsection (e) of this section.

(4) Approved provider--An individual, institution, organization, association, corporation, or agency that is approved by the board.

(5) Board--The Texas State Board of Pharmacy.

(6) Certificate of completion--A certificate or other official document presented to a participant upon the successful completion of an approved continuing education program.

(7) Contact hour--A unit of measure of educational credit which is equivalent to approximately 60 minutes of participation in an organized learning experience.

(8) Continuing education unit (CEU)--A unit of measure of education credit which is equivalent to 10 contact hours (i.e., one CEU = 10 contact hours).

(9) CPE Monitor--A collaborative service from the National Association of Boards of Pharmacy and ACPE that provides an electronic system for pharmacists to track their completed CPE credits.

(10) Credit hour--A unit of measurement for continuing education equal to 15 contact hours.

(11) Enduring Materials (Home Study)--Activities that are printed, recorded or computer assisted instructional materials that do not provide for direct interaction between faculty and participants.

(12) Initial license period--The time period between the date of issuance of a pharmacist's license and the next expiration date following the initial 30 day expiration date. This time period ranges from eighteen to thirty months depending upon the birth month of the licensee.

(13) License period--The time period between consecutive expiration dates of a license.

(14) Live programs--Activities that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences, workshops, etc.

(15) Standardized pharmacy examination--The North American Pharmacy Licensing Examination (NAPLEX).

(c) Methods for obtaining continuing education. A pharmacist may satisfy the continuing education requirements by either:

(1) successfully completing the number of continuing education hours necessary to renew a license as specified in subsection (a)(1) of this section;

(2) successfully completing during the preceding license period, one credit hour for each year of their license period, which is a part of the professional degree program in a college of pharmacy the professional degree program of which has been accredited by ACPE; or

(3) taking and passing the standardized pharmacy examination (NAPLEX) during the preceding license period as a Texas licensed pharmacist, which shall be equivalent to the number of continuing education hours necessary to renew a license as specified in subsection (a)(1) of this section.

(d) Reporting Requirements.

(1) Renewal of a pharmacist license. To renew a license to practice pharmacy, a pharmacist must report on the renewal application completion of at least thirty contact hours (3.0 CEUs) of continuing education. The following is applicable to the reporting of continuing education contact hours:

(A) at least one contact hour (0.1 CEU) specified in paragraph (1) of this subsection shall be related to Texas pharmacy laws or rules;

(B) for renewals received after August 31, 2021 and before September 1, 2023, at least one contact hour (0.1 CEU) annually, for a total of two contact hours (0.2 CEU) specified in paragraph (1) of this subsection, shall be related to best practices, alternative treatment options, and multi-modal approaches to pain management as specified in §481.0764 of the Texas Health and Safety Code;

(C) not later than the first anniversary of becoming licensed to practice pharmacy, a pharmacist must have completed at least two contact hours (0.2 CEU) specified in paragraph (1) of this subsection related to approved procedures of prescribing and monitoring controlled substances as specified in §481.07635 of the Texas Health and Safety Code;

(D) for renewals received after August 31, 2021 and before September 1, 2023, at least one contact hour (0.1 CEU) specified in paragraph (1) of this subsection shall be related to mental health awareness;

(E) any continuing education requirements which are imposed upon a pharmacist as a part of a board order or agreed board order shall be in addition to the requirements of this section; and

(F) a pharmacist must have completed the human trafficking prevention course required in §116.002 of the Texas Occupations Code.

(2) Failure to report completion of required continuing education. The following is applicable if a pharmacist fails to report completion of the required continuing education:

(A) the license of a pharmacist who fails to report completion of the required number of continuing education contact hours shall not be renewed and the pharmacist shall not be issued a renewal

certificate for the license period until such time as the pharmacist successfully completes the required continuing education and reports the completion to the board; and

(B) a pharmacist who practices pharmacy without a current renewal certificate is subject to all penalties of practicing pharmacy without a license including the delinquent fees specified in the Act, §559.003.

(3) Extension of time for reporting. A pharmacist who has had a physical disability, illness, or other extenuating circumstances which prohibits the pharmacist from obtaining continuing education credit during the preceding license period may be granted an extension of time to complete the continuing education requirement. The following is applicable for this extension:

(A) the pharmacist shall submit a petition to the board with his/her license renewal application which contains:

(i) the name, address, and license number of the pharmacist;

(ii) a statement of the reason for the request for extension;

(iii) if the reason for the request for extension is health related, a statement from the attending physician(s) treating the pharmacist which includes the nature of the physical disability or illness and the dates the pharmacist was incapacitated; and

(iv) if the reason for the request for the extension is for other extenuating circumstances, a detailed explanation of the extenuating circumstances and if because of military deployment, documentation of the dates of the deployment;

(B) after review and approval of the petition, a pharmacist may be granted an extension of time to comply with the continuing education requirement which shall not exceed one license renewal period;

(C) an extension of time to complete continuing education credit does not relieve a pharmacist from the continuing education requirement during the current license period; and

(D) if a petition for extension to the reporting period for continuing education is denied, the pharmacist shall:

(i) have 60 days to complete and report completion of the required continuing education requirements; and

(ii) be subject to the requirements of paragraph (2) of this subsection relating to failure to report completion of the required continuing education if the required continuing education is not completed and reported within the required 60-day time period.

(4) Exemptions from reporting requirements.

(A) All pharmacists licensed in Texas shall be exempt from the continuing education requirements in paragraph (1) of this subsection during their initial license period, with the exception of the requirements in paragraph (1)(B), (C), and (F) of this subsection which must be completed during the time periods specified in the subparagraphs.

(B) Pharmacists who are not actively practicing pharmacy shall be granted an exemption to the reporting requirements for continuing education provided the pharmacists submit a completed renewal application for each license period which states that they are not practicing pharmacy. Upon submission of the completed renewal application, the pharmacist shall be issued a renewal certificate which states that pharmacist is inactive. Pharmacists who wish to return to the practice of pharmacy after being exempted from the continuing education requirements as specified in this subparagraph must:

(i) notify the board of their intent to actively practice pharmacy;

(ii) pay the fee as specified in §295.9 of this title (relating to Inactive License); and

(iii) provide copies of completion certificates from approved continuing education programs as specified in subsection (e) of this section for 30 contact hours (3.0 CEUs). Approved continuing education earned within two years prior to the licensee applying for the return to active status may be applied toward the continuing education requirement for reactivation of the license but may not be counted toward subsequent renewal of the license.

(e) Approved Programs.

(1) Any program presented by an ACPE approved provider subject to the following conditions:

(A) pharmacists may receive credit for the completion of the same ACPE course only once during a license period;

(B) pharmacists who present approved ACPE continuing education programs may receive credit for the time expended during the actual presentation of the program. Pharmacists may receive credit for the same presentation only once during a license period; and

(C) proof of completion of an ACPE course shall contain the following information:

(i) name of the participant;

(ii) title and completion date of the program;

(iii) name of the approved provider sponsoring or cosponsoring the program;

(iv) number of contact hours and/or CEUs awarded;

(v) the assigned ACPE universal program number and a "P" designation indicating that the CE is targeted to pharmacists; and

(vi) either:

(I) a dated certifying signature of the approved provider and the official ACPE logo; or

(II) the CPE Monitor logo.

(2) Courses which are part of a professional degree program or an advanced pharmacy degree program offered by a college of pharmacy which has a professional degree program accredited by ACPE.

(A) Pharmacists may receive credit for the completion of the same course only once during a license period. A course is equivalent to one credit hour for each year of the renewal period.

(B) Pharmacists who teach these courses may receive credit towards their continuing education, but such credit may be received only once for teaching the same course during a license period.

(3) Basic cardiopulmonary resuscitation (CPR) courses which lead to CPR certification by the American Red Cross or the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacists may receive credit for one contact hour (0.1 CEU) towards their continuing education requirement for completion of a CPR course only once during a license period. Proof of completion of a CPR course shall be the certificate issued by the American Red Cross or the American Heart Association or its equivalent.

(4) Advanced cardiovascular life support courses (ACLS) or pediatric advanced life support (PALS) courses which lead to initial ACLS or PALS certification by the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacists may receive credit for twelve contact hours (1.2 CEUs) towards their continuing education requirement for completion of an ACLS or PALS course only once during a license period. Proof of completion of an ACLS or PALS course shall be the certificate issued by the American Heart Association or its equivalent.

(5) Advanced cardiovascular life support courses (ACLS) or pediatric advanced life support (PALS) courses which lead to ACLS or PALS recertification by the American Heart Association or its equivalent shall be recognized as approved programs. Pharmacists may receive credit for four contact hours (0.4 CEUs) towards their continuing education requirement for completion of an ACLS or PALS recertification course only once during a license period. Proof of completion of an ACLS or PALS recertification course shall be the certificate issued by the American Heart Association or its equivalent.

(6) Attendance at Texas State Board of Pharmacy Board Meetings shall be recognized for continuing education credit as follows:

(A) pharmacists shall receive credit for three contact hours (0.3 CEUs) towards their continuing education requirement for attending a full, public board business meeting in its entirety;

(B) a maximum of six contact hours (0.6 CEUs) are allowed for attendance at a board meeting during a license period; and

(C) proof of attendance for a complete board meeting shall be a certificate issued by the Texas State Board of Pharmacy.

(7) Participation in a Texas State Board of Pharmacy appointed Task Force shall be recognized for continuing education credit as follows:

(A) pharmacists shall receive credit for three contact hours (0.3 CEUs) towards their continuing education requirement for participating in a Texas State Board of Pharmacy appointed Task Force; and

(B) proof of participation for a Task Force shall be a certificate issued by the Texas State Board of Pharmacy.

(8) Attendance at programs presented by the Texas State Board of Pharmacy or courses offered by the Texas State Board of Pharmacy as follows:

(A) pharmacists shall receive credit for the number of hours for the program or course as stated by the Texas State Board of Pharmacy; and

(B) proof of attendance at a program presented by the Texas State Board of Pharmacy or completion of a course offered by the Texas State Board of Pharmacy shall be a certificate issued by the Texas State Board of Pharmacy.

(9) Pharmacists shall receive credit toward their continuing education requirements for programs or courses approved by other state boards of pharmacy as follows:

(A) pharmacists shall receive credit for the number of hours for the program or course as specified by the other state board of pharmacy; and

(B) proof of attendance at a program or course approved by another state board of pharmacy shall be a certificate or other documentation that indicates:

(i) name of the participant;

(ii) title and completion date of the program;

(iii) name of the approved provider sponsoring or cosponsoring the program;

(iv) number of contact hours and/or CEUs awarded;

(v) a dated certifying signature of the provider; and

(vi) documentation that the program is approved by the other state board of pharmacy.

(10) Completion of an Institute for Safe Medication Practices' (ISMP) Medication Safety Self Assessment for hospital pharmacies or for community/ambulatory pharmacies shall be recognized for continuing education credit as follows:

(A) pharmacists shall receive credit for three contact hours (0.3 CEUs) towards their continuing education requirement for completion of an ISMP Medication Safety Self Assessment; and

(B) proof of completion of an ISMP Medication Safety Self Assessment shall be:

(i) a continuing education certificate provided by an ACPE approved provider for completion of an assessment; or

(ii) a document from ISMP showing completion of an assessment.

(11) Pharmacists shall receive credit for three contact hours (0.3 CEUs) toward their continuing education requirements for taking and successfully passing an initial Board of Pharmaceutical Specialties certification examination administered by the Board of Pharmaceutical Specialties. Proof of successfully passing the examination shall be a certificate issued by the Board of Pharmaceutical Specialties.

(12) Programs approved by the American Medical Association (AMA) as Category 1 Continuing Medical Education (CME) and accredited by the Accreditation Council for Continuing Medical Education subject to the following conditions:

(A) pharmacists may receive credit for the completion of the same CME course only once during a license period;

(B) pharmacists who present approved CME programs may receive credit for the time expended during the actual presentation of the program. Pharmacists may receive credit for the same presentation only once during a license period; and

(C) proof of completion of a CME course shall contain the following information:

(i) name of the participant;

(ii) title and completion date of the program;

(iii) name of the approved provider sponsoring or cosponsoring the program;

(iv) number of contact hours and/or CEUs awarded; and

(v) a dated certifying signature of the approved provider.

(f) Retention of continuing education records and audit of records by the board.

(1) Retention of records. Pharmacists are required to maintain certificates of completion of approved continuing education for three years from the date of reporting the contact hours on a license renewal application. Such records may be maintained in hard copy or electronic format.

(2) Audit of records by the board. The board shall audit the records of pharmacists for verification of reported continuing education credit. The following is applicable for such audits:

(A) upon written request, a pharmacist shall provide to the board documentation of proof for all continuing education contact hours reported during a specified license period(s). Failure to provide all

requested records during the specified time period constitutes prima facie evidence of failure to keep and maintain records and shall subject the pharmacist to disciplinary action by the board;

(B) credit for continuing education contact hours shall only be allowed for approved programs for which the pharmacist submits documentation of proof reflecting that the hours were completed during the specified license period(s). Any other reported hours shall be disallowed. A pharmacist who has received credit for continuing education contact hours disallowed during an audit shall be subject to disciplinary action; and

(C) a pharmacist who submits false or fraudulent records to the board shall be subject to disciplinary action by the board.

§295.9 Inactive License

(a) Placing a license on inactive status. A person who is licensed by the board to practice pharmacy but who is not eligible to renew the license for failure to comply with the continuing education requirements of the Act, Chapter 559, Subchapter A, and who is not engaged in the practice of pharmacy in this state, may place the license on inactive status at the time of license renewal or during a license period as follows:

(1) To place a license on inactive status at the time of renewal, the licensee shall:

(A) complete and submit before the expiration date a pharmacist license renewal application provided by the board;

(B) state on the renewal application that the license is to be placed on inactive status and that the licensee shall not practice pharmacy in Texas while the license is inactive; and

(C) pay the fee for renewal of the license as specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees).

(2) To place a license on inactive status at a time other than the time of license renewal, the licensee shall:

(A) return the current renewal certificate to the board;

(B) submit a signed statement stating that the licensee shall not practice pharmacy in Texas while the license is inactive, and the date the license is to be placed on inactive status; and

(C) pay the fee for issuance of an amended license as specified in §295.5(e) of this title (relating to Pharmacist License or Renewal Fees).

(b) Prohibition against practicing pharmacy in Texas with an inactive license. A holder of a license that is on inactive status shall not practice pharmacy in this state. The practice of pharmacy by a holder of a license that is on inactive status constitutes the practice of pharmacy without a license.

(c) Reactivation of an inactive license.

(1) A holder of a license that is on inactive status may return the license to active status by:

(A) applying for active status on a form prescribed by the board;

(B) providing copies of completion certificates from approved continuing education programs as specified in §295.8(e) of this title (relating to Continuing Education Requirements) for 30 hours including at least one contact hour (0.1 CEU) shall be related to Texas pharmacy laws or rules and, for applications received before September 1, 2023, at least one contact hour (0.1 CEU) shall be related to best practices, alternative treatment options, and multi-modal approaches to pain management as specified in §481.0764 of the Texas Health and Safety Code. Approved continuing education earned within two years prior to the licensee applying for the return to active status may be applied toward the continuing education requirement for reactivation of the license but may not be counted toward subsequent renewal of the license; and

(C) paying the fee specified in paragraph (2) of this subsection.

(2) If the application for reactivation of the license is made at the time of license renewal, the applicant shall pay the license renewal fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees). If the application for reactivation of the license is made at a time other than the time of license renewal, the applicant shall pay the fee for issuance of an amended license to practice pharmacy as specified in §295.5(e) of this title (relating to Pharmacist License or Renewal Fees).

(3) In an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services, the executive director of the board, in his/her discretion, may allow a pharmacist whose license has been inactive for no more than two years to reactivate their license prior to obtaining the required continuing education specified in paragraph (1)(B) of this subsection, provided the

pharmacist completes the continuing education requirement within six months of reactivation of the license. If the required continuing education is not provided within six months, the license shall return to an inactive status.

§295.11 Notification to Consumers

(a) Pharmacist. Every pharmacist who practices pharmacy other than in a licensed pharmacy shall provide notification to consumers of the name, mailing address, internet site address and telephone number of the board for the purpose of directing complaints concerning the practice of pharmacy to the board. Such notification shall be provided as follows.

(1) If the pharmacist maintains an office and provides pharmacy services to patients who come to the office, the pharmacist shall either:

(A) post in a prominent place that is in clear public view where pharmacy services are provided:

(i) a sign which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's mailing address, internet site address, telephone number, and a toll-free telephone number for filing complaints; or

(ii) an electronic messaging system in a type size no smaller than ten-point Times Roman which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, internet site address, and a toll-free number for filing complaints; or

(B) provide to the patient each time pharmacy services are provided a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, internet site address, telephone number of the board, and a toll-free telephone number for filing complaints)."

(2) If the pharmacist provides pharmacy services to patients not at the pharmacist's office, the pharmacist shall provide to the patient each time pharmacy services are provided, a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, telephone number of the board, internet site address, and a toll-free telephone number for filing complaints)." Such notification shall be included:

(A) in each written contract for pharmacist services; or

(B) on each bill for service provided by the pharmacist.

(3) The provisions of this section do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(b) Texas State Board of Pharmacy. On or before January 1, 2005, the board shall establish a pharmacist profile system as specified in §2054.2606, Government Code.

(1) The board shall make the pharmacist profiles available to the public on the agency's internet site.

(2) A pharmacist profile shall contain at least the following information:

(A) pharmacist's name;

(B) pharmacist's license number, licensure status, and expiration date of the license;

(C) name, address, telephone number, and license number of all Texas pharmacies where the pharmacist works;

(D) the number of years the person has practiced in Texas;

(E) professional pharmacy degree held by the licensee, the year it was received, and the name of the institution that awarded the degree;

(F) whether the pharmacist is preceptor;

(G) any speciality certification held by the pharmacist; and

(H) whether the pharmacist has had prior disciplinary action by the board.

(3) The board shall gather this information on initial licensing and update the information in conjunction with the license renewal for the pharmacist.

§295.12 Pharmacist Certification Programs

(a) Purpose. The purpose of this section is to provide standards for the recognition and approval of pharmacist certification programs as authorized by §554.0021, Occupations Code.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--The Accreditation Council for Pharmacy Education.

(2) Approved Provider of Pharmacist Certificate Programs--An individual, institution, organization, association, corporation, or agency that is approved by the board and recognized by ACPE in accordance with its policy and procedures, as having:

(A) met criteria indicative of the ability to provide quality continuing education programs; and

(B) met the procedures outlines in the ACPE "Guidance Document for Practice Based Activities."

(3) Board--The Texas State Board of Pharmacy.

(c) Recognized Certification Programs.

(1) The board shall recognize as certified, any pharmacist that successfully completes:

(A) any program offered by an approved provider of pharmacist certificate programs;

(B) any program that meets the requirements of §295.15 of this title (relating to Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol of a Physician);

(C) any certification offered by the:

(i) Board of Pharmaceutical Specialties;

(ii) American Society of Consultant Pharmacists;

(iii) American Board of Clinical Pharmacology;

(iv) American Board of Applied Toxicology; and

(v) American Academy of Pain Management; or

(D) any additional certifications as published on the board's website.

(2) Texas pharmacists may not identify themselves as certified unless they have completed one of the programs specified in paragraph (1) of this subsection.

§295.13 Drug Therapy Management by a Pharmacist under Written Protocol of a Physician

(a) Purpose. The purpose of this section is to provide standards for the maintenance of records of a pharmacist engaged in the provision of drug therapy management as authorized in Chapter 157 of the Medical Practice Act and §554.005 of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Chapter 551 - 566 and 568 - 569, Occupations Code, as amended.

(2) Board--The Texas State Board of Pharmacy.

(3) Confidential record--Any health-related record maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(4) Drug therapy management--The performance of specific acts by pharmacists as authorized by a physician through written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician, unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from a standing protocol. Drug therapy management may include the following:

(A) collecting and reviewing patient drug use histories;

(B) ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration;

(C) ordering drug therapy related laboratory tests;

(D) implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol; or

(E) any other drug therapy related act delegated by a physician.

(5) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(6) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Medical Practice Act.

(A) A written protocol must contain at a minimum the following:

(i) a statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of drug therapy management;

(ii) a statement identifying the individual pharmacist authorized to dispense drugs and to engage in drug therapy management as delegated by the physician;

(iii) a statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:

(I) a statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and

(II) a specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority;

(iv) a statement of the activities the pharmacist shall follow in the course of exercising drug therapy management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) a statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated drug therapy management and the results of the drug therapy management.

(B) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient.

(c) Physician delegation to a pharmacist.

(1) As specified in Chapter 157 of the Texas Medical Practices Act, a physician may delegate to a properly qualified and trained pharmacist acting under adequate physician supervision the performance of specific acts of drug therapy management authorized by the physician through the physician's order, standing medical order, standing delegation order, or other order or protocol.

(2) A delegation under paragraph (1) of this subsection may include:

(A) the implementation or modification of a patient's drug therapy under a protocol, if:

(i) the delegation follows a diagnosis, initial patient assessment, and drug therapy order by the physician; and

(ii) the pharmacist maintains a copy of the protocol for inspection until at least the seventh anniversary of the expiration date of the protocol; or

(B) the authority to sign a prescription drug order for dangerous drugs, if:

(i) the delegation follows a diagnosis, initial patient assessment, and drug therapy order by the physician;

(ii) the pharmacist practices in a federally qualified health center, hospital, hospital-based clinic, or an academic health care institution; and

(iii) the federally qualified health center, hospital, hospital-based clinic, or academic health care institution in which the pharmacist practices has bylaws and a medical staff policy that permit a physician to delegate to a pharmacist the management of a patient's drug therapy.

(3) A pharmacist who signs a prescription for a dangerous drug under authority granted under paragraph (2) of this subsection shall:

(A) notify the board that a physician has delegated the authority to sign a prescription for dangerous drugs on an application provided by the board and prior to signing any prescription for a dangerous drug;

(B) submit a copy of the written protocol to the board at the time of initial notification;

(C) submit an updated copy of the written protocol to the board if the protocol has changed within 10 days of the change; and

(D) include the pharmacist's name, address, and telephone number as well as the name, address, and telephone number of the delegating physician on each prescription for a dangerous drug signed by the pharmacist.

(4) The board shall post the following information on its website:

(A) the name and license number of each pharmacist who has notified the board that a physician has delegated authority to sign a prescription for a dangerous drug; and

(B) the name and address of the physician who delegated the authority to the pharmacist.

(d) Pharmacist Training Requirements.

(1) Initial requirements. A pharmacist shall maintain and provide to the Board within 24 hours of request a statement attesting to the fact that the pharmacist has within the last year:

(A) completed at least six hours of continuing education related to drug therapy offered by a provider approved by the Accreditation Council for Pharmacy Education (ACPE); or

(B) engaged in drug therapy management as allowed under previous laws or rules. A statement from the physician supervising the acts shall be sufficient documentation.

(2) Continuing requirements. A pharmacist engaged in drug therapy management shall annually complete six hours of continuing education related to drug therapy offered by a provider approved by the Accreditation Council for Pharmacy Education (ACPE). (These hours may be applied towards the hours required for renewal of a license to practice pharmacy.)

(e) Supervision. Physician supervision shall be as specified in the Medical Practice Act, Chapter 157 and shall be considered adequate if the delegating physician:

(1) is responsible for the formulation or approval of the written protocol and any patient-specific deviations from the protocol and review of the written protocol and any patient-specific deviations from the protocol at least annually and the services provided to a patient under the protocol on a schedule defined in the written protocol;

(2) has established and maintains a physician-patient relationship with each patient provided drug therapy management by a delegated pharmacist and informs the patient that drug therapy will be managed by a pharmacist under written protocol;

(3) is geographically located so as to be able to be physically present daily to provide medical care and supervision;

(4) receives, on a schedule defined in the written protocol, a periodic status report on the patient, including any problem or complication encountered;

(5) is available through direct telecommunication for consultation, assistance, and direction; and

(6) determines that the pharmacist to whom the physician is delegating drug therapy management establishes and maintains a pharmacist-patient relationship with the patient.

(f) Records.

(1) Maintenance of records.

(A) Every record required to be kept under this section shall be kept by the pharmacist and be available, for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(i) the records maintained in the alternative system contain all of the information required on the manual record; and

(ii) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(2) Written protocol.

(A) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist.

(B) A pharmacist shall document all interventions undertaken under the written protocol within a reasonable time of each intervention. Documentation may be maintained in the patient medication record, patient medical chart, or in a separate log.

(C) A standard protocol may be used or the attending physician may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for that patient. A pharmacist shall maintain a copy of any deviations from the standard protocol ordered by the physician.

(D) Written protocols, including standard protocols, any patient-specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the physician and pharmacist at least annually and revised if necessary. Such review shall be documented in the pharmacist's records.

Documentation of all services provided to the patient by the pharmacist shall be reviewed by the physician on the schedule established in the protocol.

(g) Confidentiality.

(1) In addition to the confidentiality requirements specified in §291.27 of this title (relating to Confidentiality) a pharmacist shall comply with:

(A) the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and any rules adopted pursuant to this act;

(B) the requirements of Medical Records Privacy contained in Chapter 181, Health and Safety Code;

(C) the Privacy of Health Information requirements contained in Chapter 28B of the Insurance Code; and

(D) any other confidentiality provisions of federal or state laws.

(2) This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act, Chapter 159.

(h) Construction and Interpretation.

(1) As specified in the Medical Practice Act, Chapter 157, this section does not restrict the use of a pre-established health care program or restrict a physician from authorizing the provision of patient care by use of a pre-established health care program if the patient is institutionalized and the care is to be delivered in a licensed hospital with an organized medical staff that has authorized standing delegation orders, standing medical orders, or protocols.

(2) As specified in the Medical Practice Act, Chapter 157, this section may not be construed to limit, expand, or change any provision of law concerning or relating to therapeutic drug substitution or administration of medication, including the Act, §554.004.

§295.14 Dispensing of Opioid Antagonist by Pharmacist

(a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the dispensing of opioid antagonists as authorized in Chapter 483 of the Health and Safety Code.

(b) Definitions.

(1) Opioid antagonist--Any drug that binds to opioid receptors and blocks or otherwise inhibits the effects of opioids acting on those receptors.

(2) Opioid-related drug overdose--A condition, evidenced by symptoms such as extreme physical illness, decreased level of consciousness, constriction of the pupils, respiratory depression, or coma, that a layperson would reasonably believe to be the result of the consumption or use of an opioid.

(3) Prescriber--A person authorized by law to prescribe an opioid antagonist.

(c) Dispensing.

(1) A pharmacist may dispense an opioid antagonist under a valid prescription, including a prescription issued by a standing order, to:

(A) a person at risk of experiencing an opioid-related drug overdose; or

(B) a family member, friend, or other person in a position to assist a person described by subparagraph (A) of this paragraph.

(2) A prescription dispensed under this section is considered as dispensed for a legitimate medical purpose in the usual course of professional practice.

(3) A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:

(A) dispensing or failing to dispense the opioid antagonist; or

(B) if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.

§295.15 Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol of Physician

(a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the administration of immunizations or vaccinations as authorized in Chapter 554 of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--The Accreditation Council for Pharmacy Education.

(2) Act--The Texas Pharmacy Act, Chapter 551 - 566 and 568 - 569, Occupations Code, as amended.
(3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:
(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or
(B) the patient at the direction of a practitioner.
(4) Antibody--A protein in the blood that is produced in response to stimulation by a specific antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen usually equate to immunity to that antigen.
(5) Antigen--A substance "recognized" by the body as being foreign; it results in the production of specific antibodies directed against it.
(6) Board--The Texas State Board of Pharmacy.
(7) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.
(8) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).
(9) Immunization--The act of inducing antibody formation, thus leading to immunity.
(10) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.
(11) Vaccination--Administration of any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.
(12) Vaccine--A specially prepared antigen, which upon administration to a person will result in immunity.
(13) Written Protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Medical Practice Act.
(A) A written protocol must contain, at a minimum, the following:
(i) a statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of immunizations or vaccinations;
(ii) a statement identifying the individual pharmacist authorized to administer immunizations or vaccinations as delegated by the physician;
(iii) a statement identifying the location(s) (i.e., address) at which the pharmacist may administer immunizations or vaccinations;
(iv) a statement identifying the immunizations or vaccinations that may be administered by the pharmacist;
(v) a statement identifying the activities the pharmacist shall follow in the course of administering immunizations or vaccinations, including procedures to follow in the case of reactions following administration; and
(vi) a statement that describes the content of, and the appropriate mechanisms for the pharmacist to report the administration of immunizations or vaccinations to the physician issuing the written protocol within the time frames specified in this section.
(B) A standard protocol may be used or the physician may develop an immunization or vaccination protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for the patient.
(c) Pharmacist certification requirements. Pharmacist who enter into a written protocol with a physician to administer immunizations or vaccinations shall:
(1) complete a course provided by an ACPE approved provider which:
(A) requires documentation by the pharmacist of current certification in the American Heart Association's Basic Cardiac Life Support for Health-Care Providers or its equivalent;
(B) is an evidence-based course which:
(i) includes study material;
(ii) includes hands-on training in techniques for administering immunizations or vaccines; and
(iii) requires testing with a passing score; and
(C) meets current Center for Disease Control training guidelines and provides a minimum of 20 hours of instruction and experiential training in the following content areas:
(i) standards for pediatric, adolescent, and adult immunization practices;

(ii) basic immunology and vaccine protection;
(iii) vaccine-preventable diseases;
(iv) recommended immunization schedules (pediatric/adolescent/adult);
(v) vaccine storage and management;
(vi) informed consent;
(vii) physiology and techniques for vaccine administration;
(viii) pre and post-vaccine assessment and counseling;
(ix) immunization record management; and
(x) adverse events:
(I) identification and appropriate response; and
(II) documentation and reporting; and

(2) maintain documentation of:

(A) completion of the initial course specified in paragraph (1) of this subsection;

(B) 3 hours of continuing education every 2 years which are designed to maintain competency in the disease states, drugs, and administration of immunizations or vaccinations; and

(C) current certification in the American Heart Association's Basic Cardiac Life Support for Health-Care Providers or its equivalent.

(d) Supervision. Pharmacists involved in the administration of immunizations or vaccinations shall be under the supervision of a physician. Physician supervision shall be considered adequate if the delegating physician:

(1) is responsible for the formulation or approval of the physician's order, standing medical order, standing delegation order, or other order or protocol and periodically reviews the order or protocol and the services provided to a patient under the order or protocol;

(2) has established a physician-patient relationship with each patient under 14 years of age and referred the patient to the pharmacist; except a pharmacist may administer an influenza vaccination to a patient over seven years of age without an established physician-patient relationship;

(3) is geographically located so as to be easily accessible to the pharmacist administering the immunization or vaccination;

(4) receives, as appropriate, a periodic status report on the patient, including any problem or complication encountered; and

(5) is available through direct telecommunication for consultation, assistance, and direction.

(e) Special Provisions. Pharmacists involved in the administration of immunizations or vaccinations under their license to practice pharmacy shall meet the following restrictions and requirements.

(1) Pharmacists may only administer immunizations or vaccinations pursuant to a written protocol from a physician authorizing the administration.

(2) Pharmacists may administer immunizations or vaccinations to a patient under 14 years of age only upon a referral from a physician who has an established physician-patient relationship with each patient. However, a pharmacist may administer an influenza vaccination to a patient over seven years of age without an established physician-patient relationship.

(3) Pharmacists may administer immunizations or vaccinations under written protocol of a physician within a pharmacy or at any other location specifically identified in the written protocol. Such other location may not include where the patient resides, except for a licensed nursing home or hospital.

(4) The authority of a pharmacist to administer immunizations or vaccinations may not be delegated.

(5) Pharmacists may administer immunizations and vaccinations only when a licensed health-care provider authorized to administer the medication is not reasonably available to administer the medication. For the purpose of this section, "reasonably available" means those times when the licensed health-care provider is immediately available to administer the immunization or vaccine and is specifically tasked to do so.

(6) Under the provisions of the National Vaccine Injury Compensation Program (NVICP), the health-care provider under whose authority a covered vaccine is administered (i.e., the physician issuing the written protocol) must maintain certain information in the patient's permanent record. In order for the physician to comply with the provisions of the NVICP, the pharmacist shall provide the physician with the information specified in subsection (g) of this section.

(7) Before preparing an immunization or vaccine and between each patient contact, the pharmacist shall cleanse his or her hands with an alcohol-based waterless antiseptic hand rub or shall wash his or her hands with soap and water. If gloves are worn, the pharmacist shall change gloves between patients.

(8) The pharmacist shall comply with all other state and federal requirements regarding immunizations or vaccinations.

(f) Drugs.

(1) Drugs administered by a pharmacist under the provisions of this section shall be in the legal possession of:

(A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or

(B) a physician who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination.

(2) Drugs shall be transported and stored at the proper temperatures indicated for each drug.

(3) Pharmacists while actively engaged in the administration of immunizations or vaccinations under written protocol, may have in their custody and control the drugs for immunization or vaccination that are identified in the written protocol and any other dangerous drugs listed in the written protocol to treat adverse reactions.

(4) After administering immunizations or vaccinations at a location other than a pharmacy, the pharmacist shall return all unused prescription medications to the pharmacy or physician responsible for the drugs.

(g) Notifications.

(1) A pharmacist engaged in the administration of immunizations or vaccinations shall provide notification of the administration to:

(A) the physician who issued the written protocol within 24 hours of administering the immunization or vaccination; and

(B) the primary care physician of the patient, as provided by the patient or patient's agent, within 14 days of administering the immunization or vaccination.

(2) The notifications required in paragraph (1) of this subsection shall include the:

(A) name and address of the patient;

(B) age of the patient if under 14 years of age;

(C) name of the patient's primary care physician as provided by the patient or patient's agent;

(D) name, manufacturer, and lot number of the vaccine administered;

(E) amount administered;

(F) date the vaccine was administered;

(G) site of the immunization or vaccination (e.g., right arm, left leg, right upper arm);

(H) route of administration of the immunization or vaccination (e.g., intramuscular, subcutaneous, by mouth); and

(I) name, address, and title of the person administering the immunization or vaccination.

(h) Records.

(1) Maintenance of records.

(A) Every record, including notifications, required to be made under this section shall be kept by the pharmacist administering the immunization or vaccination and by the pharmacy when in legal possession of the drugs administered. Such records shall be available for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Records, including notifications, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(i) the records maintained in the alternative system contain all of the information required on the manual record; and

(ii) the data processing system is capable of producing a hard copy of the record upon request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(2) Records of administration under written protocol.

(A) Records of administration shall be maintained by the pharmacist administering immunizations or vaccinations. Such records shall include:

(i) all of the administration record requirements of subparagraph (B) of this paragraph; and

(ii) include the name and address of the pharmacy or physician in legal possession of the immunization or vaccination administered.

(B) A pharmacy, when responsible for drug accountability, shall maintain a record of administration of immunizations or vaccinations by a pharmacist. The records shall be kept and maintained by patient name. This record shall include:

(i) a copy of the written protocol under which the immunization or vaccination was administered and any patient-specific deviations from the protocol;

(ii) name and address of the patient;

(iii) age of the patient if under 14 years of age;

(iv) name of the patient's primary care physician as provided by the patient or patient's agent;

(v) name, manufacturer, and lot number of the vaccine administered;

(vi) amount administered;

(vii) date the vaccine was administered;

(viii) site of the immunization or vaccination (e.g., right arm, left leg, right upper arm);

(ix) route of administration of the immunization or vaccination (e.g., intramuscular, subcutaneous, by mouth); and

(x) name, address, and title of the person administering the immunization or vaccination.

(3) Written protocol.

(A) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained in accordance with paragraph (2) of this subsection.

(B) A standard protocol may be used or the attending physician may develop an immunization/vaccination protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for the patient. The pharmacy that is in possession of the vaccines administered shall maintain a copy of any deviations from the standard protocol ordered by the physician.

(C) Written protocols, including standard protocols, any patient-specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the physician and pharmacist at least annually and revised if necessary. Such review shall be documented in the records of the pharmacy that is in possession of the vaccines administered.

(i) Confidentiality.

(1) In addition to the confidentiality requirements specified in §291.27 of this title (relating to Confidentiality) a pharmacist shall comply with:

(A) the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and any rules adopted pursuant to this act;

(B) the requirements of Medical Records Privacy contained in Chapter 181, Health and Safety Code;

(C) the Privacy of Health Information requirements contained in Chapter 28B of the Insurance Code; and

(D) any other confidentiality provisions of federal or state laws.

(2) This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act, Chapter 159.

§295.16 Administration of Epinephrine by a Pharmacist

(a) Purpose. The purpose of this section is to allow pharmacists to administer epinephrine through an auto-injector device to a patient in an emergency situation as authorized in Chapter 562 of the Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Chapter 551 - 569, Occupations Code, as amended.

(2) Administer--The direct application of a prescription drug to the body of an individual by any means, including injection, by a pharmacist.

(3) Anaphylaxis--A sudden, severe, and potentially life-threatening allergic reaction that occurs when a person is exposed to an allergen. Symptoms may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma. Causes may include, but are not limited to, an insect sting, food allergy, drug reaction, and exercise.

(4) Epinephrine auto-injector--A disposable drug delivery system that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.

(c) Administration requirements.

(1) Pharmacists may administer epinephrine through an auto-injector to a patient in an emergency situation.

(2) The authority of a pharmacist to administer epinephrine through an auto-injector may not be delegated.

(3) Epinephrine administered by a pharmacist under the provisions of this section shall be in the legal possession of a pharmacist or the legal possession of a pharmacy which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the epinephrine.

(d) Limitation on liability.

(1) A pharmacist who in good faith administers epinephrine through an auto-injector in accordance with this section and Chapter 562 of the Act is not liable for civil damages for an act performed in the administration unless the act is willfully or wantonly negligent.

(2) A pharmacist may not receive remuneration for the administration of epinephrine through an auto-injector but may seek reimbursement for the cost of the epinephrine auto-injector.

(3) The administration of epinephrine through an auto-injector to a patient in accordance with the requirements of this section and Chapter 562 of the Act does not constitute the unlawful practice of any health care profession.

(e) Notifications.

(1) A pharmacist who administers epinephrine through an auto-injector to a patient shall report the use to the patient's primary care physician, as identified by the patient, as soon as practical, but in no event more than 72 hours from the time of administering the epinephrine.

(2) Immediately, after administering the epinephrine auto-injector, the pharmacist shall ensure that 911 is called and the patient is evaluated by emergency personnel for possible transfer to the nearest emergency department for additional evaluation, monitoring, and treatment.

(3) The notifications required in paragraph (1) of this subsection shall include the:

(A) name of the patient;

(B) age of the patient if under 8 years of age;

(C) name and manufacturer of the epinephrine auto-injector;

(D) date the epinephrine was administered;

(E) name and title of the person administering the epinephrine; and

(F) name, address, and telephone number of the pharmacy.

(f) Records.

(1) The notification required to be made under this section shall be kept by the pharmacy and such records shall be available for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(2) The notification may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(A) the records maintained in the alternative system contain all of the information required on the manual record; and

(B) the data processing system is capable of producing a hard copy of the record upon request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.