

## **RULE REVIEW ANALYSIS**

**Introduction:** THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR  
CONSIDERATION AS A PROPOSED REVIEW

**Short Title:** Pharmacists

**Rule Number:** Chapter 295

**Statutory Authority:** Government Code, §2001.039, added by Acts 1999, 76<sup>th</sup> Legislature,  
Chapter 1499, Article 1, Section 1.11.

**Background:** Review of these sections follow the Board's rule review plan.

**TITLE 22 EXAMINING BOARDS**

**PART 15 TEXAS STATE BOARD OF PHARMACY**

**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:

(A) sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.); and

(B) paying a fee of \$20.

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

(A) return the original certificate; and

(B) pay a fee of \$35.

(3) An amended license and/or certificate reflecting the new name of the pharmacist will be issued by the board.

**§295.2 Change of Employment**

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.

**§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) Prior to October 1, 2015, the fee for the initial license shall be \$281 for a two year registration and for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006. Effective October 1, 2015, the fee for an initial license shall be \$235 for a two year registration and for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006.

(2) In addition, the following fees shall be collected:

(A) \$13 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) \$5 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) \$5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, and Occupations Code.

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

(c) Renewal Fee.

(1) Prior to October 1, 2015, the fee for biennial renewal of a pharmacist license shall be \$281 for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006. Effective October 1, 2015, the fee for biennial renewal of a pharmacist license shall be \$235 for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006.

(2) In addition, the following fees shall be collected:

(A) \$13 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) \$5 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) \$2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(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 (b) of this section.

(e) Duplicate or Amended Certificates.

(1) The fee for issuance of an amended pharmacist's license renewal certificate shall be \$20.

(2) The fee for issuance of an amended license to practice pharmacy (wall certificate) only, or renewal certificate and wall certificate shall be \$35.

#### **§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) Sponsoring pharmacy--a pharmacy licensed by the Board in which the emergency temporary pharmacist will practice.

(3) 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:

(A) 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; and

(B) be sponsored by a pharmacy with an active license in Texas.

(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;

(B) name and license number of the pharmacist-in-charge of the sponsoring pharmacy;

(C) name and license number of the sponsoring pharmacy; and

(D) 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.

(4) The board will notify the sponsoring pharmacy of the approval of an emergency temporary pharmacist license.

(c) Limitations on practice. A holder of an emergency temporary pharmacist license:

(1) may only practice in the sponsoring pharmacy; and

(2) must notify the board in writing, prior to beginning employment in another sponsoring pharmacy.

#### **§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 - 566, and 568 - 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 - 566 and 568 - 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.

- 151 (10) Credit hour--A unit of measurement for continuing education equal to 15 contact hours.
- 152 (11) Enduring Materials (Home Study)--Activities that are printed, recorded or computer assisted  
153 instructional materials that do not provide for direct interaction between faculty and participants.
- 154 (12) Initial license period--The time period between the date of issuance of a pharmacist's license  
155 and the next expiration date following the initial 30 day expiration date.
- 156 (13) License period--The time period between consecutive expiration dates of a license.
- 157 (14) Live programs--Activities that provide for direct interaction between faculty and  
158 participants and may include lectures, symposia, live teleconferences, workshops, etc.
- 159 (15) Standardized pharmacy examination--The North American Pharmacy Licensing  
160 Examination (NAPLEX).
- 161 (c) Methods for obtaining continuing education. A pharmacist may satisfy the continuing  
162 education requirements by either:
- 163 (1) successfully completing the number of continuing education hours necessary to renew a  
164 license as specified in subsection (a)(1) of this section;
- 165 (2) successfully completing during the preceding license period, one credit hour for each year of  
166 their license period, which is a part of the professional degree program in a college of pharmacy  
167 the professional degree program of which has been accredited by ACPE; or
- 168 (3) taking and passing the standardized pharmacy examination (NAPLEX) during the preceding  
169 license period, which shall be equivalent to the number of continuing education hours necessary  
170 to renew a license as specified in subsection (a)(1) of this section.
- 171 (d) Reporting Requirements.
- 172 (1) Renewal of a pharmacist license. To renew a license to practice pharmacy, a pharmacist must  
173 report on the renewal application completion of at least thirty contact hours (3.0 CEUs) of  
174 continuing education. The following is applicable to the reporting of continuing education  
175 contact hours.
- 176 (A) For renewals received after January 1, 2015, at least one contact hour (0.1 CEU) specified in  
177 paragraph (1) of this subsection shall be related to Texas pharmacy laws or rules.
- 178 (B) Any continuing education requirements which are imposed upon a pharmacist as a part of a  
179 board order or agreed board order shall be in addition to the requirements of this section.
- 180 (2) Failure to report completion of required continuing education. The following is applicable if  
181 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.

(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 continued 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.

(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.



215 (4) Exemptions from reporting requirements.

216 (A) All pharmacists licensed in Texas shall be exempt from the continuing education  
217 requirements during their initial license period.

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

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

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

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

232 (e) Approved Programs.

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

234 (A) Pharmacists may receive credit for the completion of the same ACPE course only once  
235 during a license period.

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

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

240 (i) name of the participant;

241 (ii) title and completion date of the program;

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

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

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

246 (vi) either:

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

248 (II) the CPE Monitor logo.

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

252 (A) Pharmacists may receive credit for the completion of the same course only once during a  
253 license period.

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

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

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

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

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

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

280 (B) A maximum of six contact hours (0.6 CEUs) are allowed for attendance at a board meeting  
281 during a license period.

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

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

286 (A) Pharmacists shall receive credit for three contact hours (0.3 CEUs) towards their continuing  
287 education requirement for participating in a Texas State Board of Pharmacy appointed Task  
288 Force.

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

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

293 (A) Pharmacists shall receive credit for the number of hours for the program or course as stated  
294 by the Texas State Board of Pharmacy.

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

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

300 (A) Pharmacists shall receive credit for the number of hours for the program or course as  
301 specified by the other state board of pharmacy.

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

304 (i) name of the participant;

305 (ii) title and completion date of the program;

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

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

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

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

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

313 (A) Pharmacists shall receive credit for three contact hours (0.3 CEUs) towards their continuing  
314 education requirement for completion of an ISMP Medication Safety Self Assessment.

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

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

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

319 (11) Pharmacists shall receive credit for three contact hours (0.3 CEUs) toward their continuing  
320 education requirements for taking and successfully passing the initial Geriatric Pharmacy  
321 Practice certification examination administered by the Commission for Certification in Geriatric  
322 Pharmacy. Proof of successfully passing the examination shall be a certificate issued by the  
323 Commission for Certification in Geriatric Pharmacy.

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

329 (13) Programs approved by the American Medical Association (AMA) as Category 1 Continuing  
330 Medical Education (CME) and accredited by the Accreditation Council for Continuing Medical  
331 Education subject to the following conditions.

332 (A) Pharmacists may receive credit for the completion of the same CME course only once during  
333 a license period.

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

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

338 (i) name of the participant;

339 (ii) title and completion date of the program;

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

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

- 342 (v) a dated certifying signature of the approved provider.
- 343 (f) Retention of continuing education records and audit of records by the board.
- 344 (1) Retention of records. Pharmacists are required to maintain certificates of completion of  
345 approved continuing education for three years from the date of reporting the contact hours on a  
346 license renewal application. Such records may be maintained in hard copy or electronic format.
- 347 (2) Audit of records by the board. The board shall audit the records of pharmacists for  
348 verification of reported continuing education credit. The following is applicable for such audits.
- 349 (A) Upon written request, a pharmacist shall provide to the board documentation of proof for all  
350 continuing education contact hours reported during a specified license period(s). Failure to  
351 provide all requested records during the specified time period constitutes prima facie evidence of  
352 failure to keep and maintain records and shall subject the pharmacist to disciplinary action by the  
353 board.
- 354 (B) Credit for continuing education contact hours shall only be allowed for approved programs  
355 for which the pharmacist submits documentation of proof reflecting that the hours were  
356 completed during the specified license period(s). Any other reported hours shall be disallowed. A  
357 pharmacist who has received credit for continuing education contact hours disallowed during an  
358 audit shall be subject to disciplinary action.
- 359 (C) A pharmacist who submits false or fraudulent records to the board shall be subject to  
360 disciplinary action by the board.

361 **§295.9 Inactive License**

- 362 (a) Placing a license on inactive status. A person who is licensed by the board to practice  
363 pharmacy but who is not eligible to renew the license for failure to comply with the continuing  
364 education requirements of the Act, Chapter 559, Subchapter A, and who is not engaged in the  
365 practice of pharmacy in this state, may place the license on inactive status at the time of license  
366 renewal or during a license period as follows.
- 367 (1) To place a license on inactive status at the time of renewal, the licensee shall:
- 368 (A) complete and submit before the expiration date a pharmacist license renewal application  
369 provided by the board;
- 370 (B) state on the renewal application that the license is to be placed on inactive status and that the  
371 licensee shall not practice pharmacy in Texas while the license is inactive; and
- 372 (C) pay the fee for renewal of the license as specified in §295.5 of this title (relating to  
373 Pharmacist License or Renewal Fees).

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

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

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

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

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

385 (c) Reactivation of an inactive license.

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

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

388 (B) providing copies of completion certificates from approved continuing education programs as  
389 specified in §295.8(e) of this title (relating to Continuing Education Requirements) for 30 hours.  
390 Approved continuing education earned within two years prior to the licensee applying for the  
391 return to active status may be applied toward the continuing education requirement for  
392 reactivation of the license but may not be counted toward subsequent renewal of the license; and

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

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

400 (3) In an emergency caused by a natural or manmade disaster or any other exceptional situation  
401 that causes an extraordinary demand for pharmacist services, the executive director of the board,  
402 in his/her discretion, may allow pharmacists whose license has been inactive for no more than  
403 two years to reactivate their license prior to obtaining the required continuing education specified  
404 in paragraph (1)(B) of this subsection, provided the pharmacist completes the continuing  
405 education requirement within six months of reactivation of the license. If the required continuing  
406 education is not provided within six months, the license shall return to an inactive status.

407 **§295.11 Notification to Consumers**

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

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

414 (A) post in a prominent place that is in clear public view where pharmacy services are provided a  
415 sign furnished by the Texas State Board of Pharmacy which notifies the consumer that  
416 complaints concerning the practice of pharmacy may be filed with the board and list the mailing  
417 address, Internet site address, telephone number of the board, and if applicable a toll-free  
418 telephone number for filing complaints; or

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

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

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

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

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

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

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

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

441 (A) pharmacist's name;



- 442 (B) pharmacist's license number, licensure status, and expiration date of the license;
- 443 (C) name, address, telephone number, and license number of all Texas pharmacies where the  
444 pharmacist works;
- 445 (D) the number of years the person has practiced in Texas;
- 446 (E) professional pharmacy degree held by the licensee, the year it was received, and the name of  
447 the institution that awarded the degree;
- 448 (F) whether the pharmacist is preceptor;
- 449 (G) any speciality certification held by the pharmacist; and
- 450 (H) whether the pharmacist has had prior disciplinary action by the board.
- 451 (3) The board shall gather this information on initial licensing and update the information in  
452 conjunction with the license renewal for the pharmacist.

453 **§295.12 Pharmacist Certification Programs**

- 454 (a) Purpose. The purpose of this section is to provide standards for the recognition and approval  
455 of pharmacist certification programs as authorized by §554.0021, Occupations Code.
- 456 (b) Definitions. The following words and terms, when used in this section, shall have the  
457 following meanings, unless the context clearly indicates otherwise.
- 458 (1) ACPE--The Accreditation Council for Pharmacy Education.
- 459 (2) Approved Provider of Pharmacist Certificate Programs--An individual, institution,  
460 organization, association, corporation, or agency that is approved by the board and recognized by  
461 ACPE in accordance with its policy and procedures, as having:
- 462 (A) met criteria indicative of the ability to provide quality continuing education programs; and
- 463 (B) met the procedures outlines in the ACPE "Guidance Document for Practice Based  
464 Activities."
- 465 (3) Board--The Texas State Board of Pharmacy.
- 466 (c) Recognized Certification Programs.
- 467 (1) The board shall recognize as certified, any pharmacist that successfully completes:
- 468 (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;

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

500 (C) ordering drug therapy related laboratory tests;

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

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

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

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

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

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

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

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

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

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

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

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

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

531 (c) Physician delegation to a pharmacist.

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

537 (2) A delegation under paragraph (1) of this subsection may include the implementation or  
538 modification of a patient's drug therapy under a protocol, including the authority to sign a  
539 prescription drug order for dangerous drugs, if:

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

542 (B) the pharmacist practices in a hospital, hospital-based clinic, or an academic health care  
543 institution; and

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

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

549 (A) notify the board that a physician has delegated the authority to sign a prescription for  
550 dangerous drugs. Such notification shall:

551 (i) be made on an application provided by the board;

552 (ii) occur prior to signing any prescription for a dangerous drug;

553 (iii) be updated annually; and

554 (iv) include a copy of the written protocol.

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

558 (4) The board shall post the following information on its web-site:

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

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

562 (C) the expiration date of the protocol granting the authority to sign a prescription.

563 (d) Pharmacist Training Requirements.

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

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

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

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

574 (e) Supervision. Physician supervision shall be as specified in the Medical Practice Act, Chapter  
575 157 and shall be considered adequate if the delegating physician:

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

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

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

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

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

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

590 (f) Records.

591 (1) Maintenance of records.

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

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

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

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

603 (2) Written protocol.

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

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

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

614 (D) Written protocols, including standard protocols, any patient-specific deviations from a  
615 standard protocol, and any individual patient protocol, shall be reviewed by the physician and  
616 pharmacist at least annually and revised if necessary. Such review shall be documented in the  
617 pharmacist's records. Documentation of all services provided to the patient by the pharmacist  
618 shall be reviewed by the physician on the schedule established in the protocol.

619 (g) Confidentiality.

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

622 (A) the privacy provisions of the federal Health Insurance Portability and Accountability Act of  
623 1996 (Pub. L. No. 104-191) and any rules adopted pursuant to this act;

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

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

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

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

631 (h) Construction and Interpretation.

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

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

640 **§295.15 Administration of Immunizations or Vaccinations by a Pharmacist under Written**  
641 **Protocol of a Physician**

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

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

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

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

649 (3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion,  
650 or any other means to the body of a patient by:

651 (A) a practitioner, an authorized agent under his supervision, or other person authorized by law;  
652 or

- 653 (B) the patient at the direction of a practitioner.
- 654 (4) Antibody--A protein in the blood that is produced in response to stimulation by a specific  
655 antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen  
656 usually equate to immunity to that antigen.
- 657 (5) Antigen--A substance "recognized" by the body as being foreign; it results in the production  
658 of specific antibodies directed against it.
- 659 (6) Board--The Texas State Board of Pharmacy.
- 660 (7) Confidential record--Any health-related record that contains information that identifies an  
661 individual and that is maintained by a pharmacy or pharmacist such as a patient medication  
662 record, prescription drug order, or medication order.
- 663 (8) Data communication device--An electronic device that receives electronic information from  
664 one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).
- 665 (9) Immunization--The act of inducing antibody formation, thus leading to immunity.
- 666 (10) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as  
667 amended.
- 668 (11) Vaccination--Administration of any antigen in order to induce immunity; is not synonymous  
669 with immunization since vaccination does not imply success.
- 670 (12) Vaccine--A specially prepared antigen, which upon administration to a person will result in  
671 immunity.
- 672 (13) Written Protocol--A physician's order, standing medical order, standing delegation order, or  
673 other order or protocol as defined by rule of the Texas Medical Board under the Medical Practice  
674 Act.
- 675 (A) A written protocol must contain, at a minimum, the following:
- 676 (i) a statement identifying the individual physician authorized to prescribe drugs and responsible  
677 for the delegation of administration of immunizations or vaccinations;
- 678 (ii) a statement identifying the individual pharmacist authorized to administer immunizations or  
679 vaccinations as delegated by the physician;
- 680 (iii) a statement identifying the location(s) (i.e., address) at which the pharmacist may administer  
681 immunizations or vaccinations;
- 682 (iv) a statement identifying the immunizations or vaccinations that may be administered by the  
683 pharmacist;

684 (v) a statement identifying the activities the pharmacist shall follow in the course of  
685 administering immunizations or vaccinations, including procedures to follow in the case of  
686 reactions following administration; and

687 (vi) a statement that describes the content of, and the appropriate mechanisms for the pharmacist  
688 to report the administration of immunizations or vaccinations to the physician issuing the written  
689 protocol within the time frames specified in this section.

690 (B) A standard protocol may be used or the physician may develop an immunization or  
691 vaccination protocol for the individual patient. If a standard protocol is used, the physician shall  
692 record what deviations, if any, from the standard protocol are ordered for the patient.

693 (c) Pharmacist certification requirements. Pharmacist who enter into a written protocol with a  
694 physician to administer immunizations or vaccinations shall:

695 (1) complete a course provided by an ACPE approved provider which:

696 (A) requires documentation by the pharmacist of current certification in the American Heart  
697 Association's Basic Cardiac Life Support for Health-Care Providers or its equivalent;

698 (B) is an evidence-based course which:

699 (i) includes study material;

700 (ii) includes hands-on training in techniques for administering immunizations or vaccines; and

701 (iii) requires testing with a passing score; and

702 (C) meets current Center for Disease Control training guidelines and provides a minimum of 20  
703 hours of instruction and experiential training in the following content areas:

704 (i) standards for pediatric, adolescent, and adult immunization practices;

705 (ii) basic immunology and vaccine protection;

706 (iii) vaccine-preventable diseases;

707 (iv) recommended immunization schedules (pediatric/adolescent/adult);

708 (v) vaccine storage and management;

709 (vi) informed consent;

710 (vii) physiology and techniques for vaccine administration;

711 (viii) pre and post-vaccine assessment and counseling;



712 (ix) immunization record management; and

713 (x) adverse events:

714 (I) identification and appropriate response; and

715 (II) documentation and reporting; and

716 (2) maintain documentation of:

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

718 (B) 3 hours of continuing education every 2 years which are designed to maintain competency in

719 the disease states, drugs, and administration of immunizations or vaccinations; and

720 (C) current certification in the American Heart Association's Basic Cardiac Life Support for

721 Health-Care Providers or its equivalent.

722 (d) Supervision. Pharmacists involved in the administration of immunizations or vaccinations

723 shall be under the supervision of a physician. Physician supervision shall be considered adequate

724 if the delegating physician:

725 (1) is responsible for the formulation or approval of the physician's order, standing medical

726 order, standing delegation order, or other order or protocol and periodically reviews the order or

727 protocol and the services provided to a patient under the order or protocol;

728 (2) has established a physician-patient relationship with each patient under 14 years of age and

729 referred the patient to the pharmacist; except a pharmacist may administer an influenza

730 vaccination to a patient over seven years of age without an established physician-patient

731 relationship;

732 (3) is geographically located so as to be easily accessible to the pharmacist administering the

733 immunization or vaccination;

734 (4) receives, as appropriate, a periodic status report on the patient, including any problem or

735 complication encountered; and

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

737 (e) Special Provisions. Pharmacists involved in the administration of immunizations or

738 vaccinations under their license to practice pharmacy shall meet the following restrictions and

739 requirements.

740 (1) Pharmacists may only administer immunizations or vaccinations pursuant to a written

741 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) 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.

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

779 (g) Notifications.

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

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

784 (B) the primary care physician of the patient, as provided by the patient or patient's agent, within  
785 14 days of administering the immunization or vaccination.

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

787 (A) name and address of the patient;

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

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

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

791 (E) amount administered;

792 (F) date the vaccine was administered;

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

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

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

797 (h) Records.

798 (1) Maintenance of records.

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

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

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

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

811 (2) Records of administration under written protocol.

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

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

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

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

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

822 (ii) name and address of the patient;

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

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

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

826 (vi) amount administered;

827 (vii) date the vaccine was administered;

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

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

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

832 (3) Written protocol.

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

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

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

844 (i) Confidentiality.

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

847 (A) the privacy provisions of the federal Health Insurance Portability and Accountability Act of  
848 1996 (Pub. L. No. 104-191) and any rules adopted pursuant to this act;

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

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

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

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

856