

## **RULE REVIEW ANALYSIS**

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

**Short Title:** All Classes of Pharmacies

**Rule Number:** Chapter 291, Subchapter A

**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.

1 **TITLE 22 EXAMINING BOARDS**  
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**  
3 **CHAPTER 291 PHARMACIES**  
4 **SUBCHAPTER A ALL CLASSES OF PHARMACIES**

5  
6 **§291.1 Pharmacy License Application**  
7

8 (a) To qualify for a pharmacy license, the applicant must submit an application including the  
9 following information:

10  
11 (1) name and address of pharmacy;

12  
13 (2) type of ownership;

14  
15 (3) names, addresses, phone numbers, dates of birth, and social security numbers; however, if  
16 an individual is unable to obtain a social security number, an individual taxpayer identification  
17 number may be provided in lieu of a social security number along with documentation indicating  
18 why the individual is unable to obtain a social security number, of all owners; if a partnership or  
19 corporation, for all managing officers, the name, title, addresses, phone numbers, dates of birth,  
20 and social security numbers; however, if an individual is unable to obtain a social security  
21 number, an individual taxpayer identification number may be provided in lieu of a social security  
22 number along with documentation indicating why the individual is unable to obtain a social  
23 security number;

24  
25 (4) name and license number of the pharmacist-in-charge and of other pharmacists employed  
26 by the pharmacy;

27  
28 (5) anticipated date of opening and hours of operation;

29  
30 (6) copy of lease agreement or if the location of the pharmacy is owned by the applicant, a  
31 notarized statement certifying such location ownership;

32  
33 (7) the signature of the pharmacist-in-charge;

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35 (8) the notarized signature of the owner, or if the pharmacy is owned by a partnership or  
36 corporation, the notarized signature of an owner or managing officer;

37  
38 (9) federal tax ID number of the owner;

39  
40 (10) description of business services that will be offered;

41  
42 (11) name and address of malpractice insurance carrier or statement that the business will be  
43 self-insured;

44  
45 (12) the certificate of authority, if applicant is an out-of-state corporation;

46  
47 (13) the articles of incorporation, if the applicant is a corporation;

48  
49 (14) a current Texas Franchise Tax Certificate of Good Standing; and

50  
51 (15) any other information requested on the application.

52  
53 (b) Subsection (c) of this section applies to new pharmacy applications for Class A  
54 (Community), Class C (Institutional), or Class F (Freestanding Emergency Medical Care Center)  
55 pharmacies owned by a management company with the following exceptions.

56  
57 (1) Subsection (c) of this section does not apply to a new pharmacy application submitted by  
58 an entity which already owns a pharmacy licensed in Texas.

59  
60 (2) Subsection (c)(1) and (3) of this section do not apply to each individual owner or managing  
61 officer listed on a new pharmacy application if the individual possesses an active pharmacist  
62 license in Texas.

63  
64 (c) If the pharmacy is to be licensed as a Class A (Community), Class C (Institutional), or Class  
65 F (Freestanding Emergency Medical Care Center) pharmacy owned by a management  
66 company, the applicant must submit copies of the following documents in addition to the  
67 information required in subsection (a) of this section:

68  
69 (1) the birth certificate or passport of each individual owner, or, if the pharmacy is owned by a  
70 partnership or a closely held corporation:

71  
72 (A) one of these documents for each managing officer; and

73  
74 (B) a list of all owners of the corporation;

75  
76 (2) an approved credit application from a primary wholesaler or other documents showing  
77 credit worthiness as approved by the board; and

78  
79 (3) a current driver license or state issued photo ID card of each individual owner, or, if the  
80 pharmacy is owned by a partnership or a closely held corporation, a current driver license or  
81 state issued photo ID card for each managing officer.

82  
83 (d) The applicant may be required to meet all requirements necessary in order for the Board to  
84 access the criminal history record information, including submitting fingerprint information and  
85 being responsible for all associated costs. The criminal history information may be required for  
86 each individual owner, or if the pharmacy is owned by a partnership or a closely held  
87 corporation for each managing officer.

88  
89 (e) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
90 for the issuance of a pharmacy license.

91  
92 (f) For purpose of this section, managing officers are defined as the top four executive officers,  
93 including the corporate officer in charge of pharmacy operations, who are designated by the  
94 partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

95  
96 (g) Prior to the issuance of a license for a pharmacy located in Texas, the board shall conduct  
97 an on-site inspection of the pharmacy in the presence of the pharmacist-in-charge and owner or  
98 representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the  
99 requirements of the Texas Pharmacy Act and Board Rules.

100

101 (h) If the applicant holds an active pharmacy license in Texas on the date of application for a  
102 new pharmacy license or for other good cause shown as specified by the board, the board may  
103 waive the pre-inspection as set forth in subsection (g) of this section.  
104

### 105 **§291.2 Definitions**

106 Any term not defined in this chapter shall have the definition set out in the Act, §551.003.  
107

### 108 **§291.3 Required Notifications**

109 (a) Change of Location and/or Name.

110 (1) When a pharmacy changes location and/or name, the following is applicable.  
111

112 (A) A new completed pharmacy application containing the information outlined in §291.1 of  
113 this title (relating to Pharmacy License Application), must be filed with the board within 10 days  
114 of the change of location of the pharmacy.  
115

116 (B) The previously issued license must be returned to the board office.  
117

118 (C) An amended license reflecting the new location and/or name of the pharmacy will be  
119 issued by the board; and  
120

121 (D) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be  
122 charged for issuance of the amended license.  
123

124 (2) At least 14 days prior to the change of location of a pharmacy that dispenses prescription  
125 drug orders, the pharmacist-in-charge shall post a sign in a conspicuous place indicating that  
126 the pharmacy is changing locations. Such sign shall be in the front of the prescription  
127 department and at all public entrance doors to the pharmacy and shall indicate the date the  
128 pharmacy is changing locations.  
129

130 (3) Disasters, accidents, and emergencies which require the pharmacy to change location shall  
131 be immediately reported to the board. If a pharmacy changes location suddenly due to  
132 disasters, accidents, or other emergency circumstances and the pharmacist-in-charge cannot  
133 provide notification 14 days prior to the change of location, the pharmacist-in-charge shall  
134 comply with the provisions of paragraph (2) of this subsection as far in advance of the change of  
135 location as allowed by the circumstances.  
136

137 (b) Change of Managing Officers.  
138

139 (1) The owner of a pharmacy shall notify the board in writing within 10 days of a change of any  
140 managing officer of a partnership or corporation which owns a pharmacy. The written  
141 notification shall include the effective date of such change and the following information for all  
142 managing officers:  
143

144 (A) name and title;

145 (B) home address and telephone number;  
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- 152  
153 (C) date of birth; and  
154  
155 (D) social security number.  
156

157 (2) For purposes of this subsection, managing officers are defined as the top four executive  
158 officers, including the corporate officer in charge of pharmacy operations, who are designated  
159 by the partnership or corporation to be jointly responsible for the legal operation of the  
160 pharmacy.

161  
162 (c) Change of Ownership.

163  
164 (1) When a pharmacy changes ownership, a new/completed pharmacy application must be  
165 filed with the board and the license issued to previous owner shall be returned to the board.  
166

167 (2) The new application shall include the following information:

- 168 (A) the name and address of pharmacy;  
169  
170 (B) the type of ownership;  
171  
172 (C) the names, home addresses, dates of birth, phone numbers, and social security numbers  
173 of all owners; if a partnership or corporation, the name, title, home address, home phone  
174 number, date of birth, and social security number of all managing officers;  
175  
176 (D) the name and license number of the pharmacist-in-charge and of other pharmacists  
177 employed by the pharmacy;  
178  
179 (E) a copy of lease agreement or if the location of the pharmacy is owned by the applicant, a  
180 notarized statement certifying such location ownership;  
181  
182 (F) a copy of the purchase contract or mutual agreement between the buyer and seller, or a  
183 notarized statement of intent to convey ownership signed by both the buyer and seller, stating  
184 the proposed date of ownership change;  
185  
186 (G) the signature of the pharmacist-in-charge;  
187  
188 (H) the notarized signature of the owner, or if the pharmacy is owned by a partnership or  
189 corporation, the notarized signature of an owner or managing officer;  
190  
191 (I) federal tax ID number;  
192  
193 (J) description of business services that will be offered;  
194  
195 (K) name and address of malpractice insurance carrier or statement that the business will be  
196 self-insured;  
197  
198 (L) the certificate of authority, if applicant is an out-of-state corporation;  
199  
200 (M) the articles of incorporation, if the applicant is a corporation;  
201  
202

203 (N) a current Texas Franchise Tax Certificate of Good Standing; and

204

205 (O) any other information requested on the application.

206

207 (3) Paragraph (4) of this subsection applies to all change of ownership applications for Class A  
208 (Community) pharmacies, Class C (Institutional) pharmacies, or Class F (Freestanding  
209 Emergency Medical Care Center) pharmacies, owned by a management company with the  
210 following exceptions.

211

212 (A) Paragraph (4) of this subsection does not apply to a change of ownership application  
213 submitted by an entity which already owns a pharmacy licensed in Texas.

214

215 (B) Paragraph (4)(A) and (C) of this subsection do not apply to each individual owner or  
216 managing officer listed on a new pharmacy application if the individual possesses an active  
217 pharmacist license in Texas.

218

219 (4) If the pharmacy is to be licensed as a Class A (Community) Pharmacy, a Class C  
220 (Institutional) pharmacy, or a Class F (Freestanding Emergency Medical Care Center)  
221 pharmacy owned by a management company, the applicant must submit copies of the following  
222 documents in addition to the information required in paragraph (2) of this subsection:

223

224 (A) the birth certificate, passport, or other document proving the date of birth of the owner, or,  
225 if the pharmacy is owned by a partnership or a closely held corporation:

226

227 (i) one of these documents for each managing officer; and

228

229 (ii) a list of all owners of the corporation;

230

231 (B) an approved credit application from a primary wholesaler or other documents showing  
232 credit worthiness as approved by the board; and

233

234 (C) a current driver license or state issued photo ID card of each individual owner, or, if the  
235 pharmacy is owned by a partnership or a closely held corporation, a current driver license or  
236 state issued photo ID card for each managing officer.

237

238 (5) A fee as specified in §291.6 of this title will be charged for issuance of a new license.

239

240 (d) Change of Pharmacist Employment.

241

242 (1) Change of pharmacist employed in a pharmacy. When a change in pharmacist employment  
243 occurs, the pharmacist shall report such change in writing to the board within 10 days.

244

245 (2) Change of pharmacist-in-charge of a pharmacy.

246

247 (A) On the date of change of the pharmacist-in-charge of a Class A (Community), Class C  
248 (Institutional), or Class F (Freestanding Emergency Medical Care Center) pharmacy, an  
249 inventory specified in §291.17 of this title (relating to Inventory Requirements) shall be taken.

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251 (B) This inventory shall constitute, for the purpose of this section, the closing inventory of the  
252 departing pharmacist-in-charge and the beginning inventory of the incoming pharmacist-in-  
253 charge.

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(C) If the departing and the incoming pharmacists-in-charge are unable to conduct the inventory together, a closing inventory shall be conducted by the departing pharmacist-in-charge and a new and separate beginning inventory shall be conducted by the incoming pharmacist-in-charge.

(D) The incoming pharmacist-in-charge shall be responsible for notifying the board within 10 days in writing on a form provided by the board, that a change of pharmacist-in-charge has occurred. The notification shall include the following:

- (i) the name and license number of the departing pharmacist-in-charge;
- (ii) the name and license number of the incoming pharmacist-in-charge;
- (iii) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and
- (iv) a statement signed by the incoming pharmacist-in-charge attesting that:

(I) an inventory has been conducted by the departing and incoming pharmacists-in-charge; if the inventory was not taken by both pharmacists, the statement shall provide an explanation; and

(II) the incoming pharmacist-in-charge has read and understands the laws and rules relating to this class of pharmacy.

(e) Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.

(1) Controlled substances. For the purposes of the Act, §562.106, the theft or significant loss of any controlled substance by a pharmacy shall be reported in writing to the board immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

(2) Dangerous drugs. A pharmacy shall report in writing to the board immediately on discovery the theft or significant loss of any dangerous drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

(f) Fire or Other Disaster. If a pharmacy experiences a fire or other disaster, the following requirements are applicable.

(1) Responsibilities of the pharmacist-in-charge.

(A) The pharmacist-in-charge shall be responsible for reporting the date of the fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of the injury, illness, and disease; such notification shall be immediately reported to the board, but in no event shall exceed 10 days from the date of the disaster.

(B) The pharmacist-in-charge or designated agent shall comply with the following procedures.

305 (i) If controlled substances, dangerous drugs, or Drug Enforcement Administration (DEA)  
306 order forms are lost or destroyed in the disaster, the pharmacy shall:

307  
308 (I) notify the DEA, Department of Public Safety (DPS), and Texas State Board of Pharmacy  
309 (board) of the loss of the controlled substances or order forms. A pharmacy shall be in  
310 compliance with this section by submitting to each of these agencies a copy of the DEA's report  
311 of theft or loss of controlled substances, DEA Form-106, immediately on discovery of the loss;  
312 and

313  
314 (II) notify the Texas State Board of Pharmacy in writing of the loss of the dangerous drugs  
315 by submitting a list of the dangerous drugs lost.

316  
317 (ii) If the extent of the loss of controlled substances or dangerous drugs is not able to be  
318 determined, the pharmacy shall:

319  
320 (I) take a new, complete inventory of all remaining drugs specified in §291.17(c) of this title  
321 (relating to Inventory Requirements);

322  
323 (II) submit to DEA and DPS a statement attesting that the loss of controlled substances is  
324 indeterminable and that a new, complete inventory of all remaining controlled substances was  
325 conducted and state the date of such inventory; and

326  
327 (III) submit to the board a statement attesting that the loss of controlled substances and  
328 dangerous drugs is indeterminable and that a new, complete inventory of the drugs specified in  
329 §291.17(c) of this title was conducted and state the date of such inventory.

330  
331 (C) If the pharmacy changes to a new, permanent location, the pharmacist-in-charge shall  
332 comply with subsection (a) of this section.

333  
334 (D) If the pharmacy moves to a temporary location, the pharmacist shall comply with  
335 subsection (a) of this section. If the pharmacy returns to the original location, the pharmacist-in-  
336 charge shall again comply with subsection (a) of this section.

337  
338 (E) If the pharmacy closes due to fire or other disaster, the pharmacy may not be closed for  
339 longer than 90 days as specified in §291.11 of this title (relating to Operating a Pharmacy).

340  
341 (F) If the pharmacy discontinues business (ceases to operate as a pharmacy), the  
342 pharmacist-in-charge shall comply with §291.5 of this title (relating to Closing a Pharmacy).

343  
344 (G) The pharmacist-in-charge shall maintain copies of all inventories, reports, or notifications  
345 required by this section for a period of two years.

346  
347 (2) Drug stock.

348  
349 (A) Any drug which has been exposed to excessive heat, smoke, or other conditions which  
350 may have caused deterioration shall not be dispensed.

351  
352 (B) Any potentially adulterated or damaged drug shall only be sold, transferred, or otherwise  
353 distributed pursuant to the provisions of the Texas Food Drug and Cosmetics Act (Chapter 431,  
354 Health and Safety Code) administered by the Bureau of Food and Drug Safety of the Texas  
355 Department of State Health Services.

356  
357 (g) Notification to Consumers.

358  
359 (1) Pharmacy.

360  
361 (A) Every licensed pharmacy shall provide notification to consumers of the name, mailing  
362 address, Internet site address, and telephone number of the board for the purpose of directing  
363 complaints concerning the practice of pharmacy to the board. Such notification shall be provided  
364 as follows.

365  
366 (i) If the pharmacy serves walk-in customers, the pharmacy shall either:

367  
368 (I) post in a prominent place that is in clear public view where prescription drugs are  
369 dispensed a sign furnished by the board which notifies the consumer that complaints concerning  
370 the practice of pharmacy may be filed with the board and list the board's name, mailing address,  
371 Internet site address, telephone number of the board, and if applicable a toll-free telephone  
372 number for filing complaints; or

373  
374 (II) provide with each dispensed prescription a written notification in a type size no smaller  
375 than ten-point Times Roman which states the following: "Complaints concerning the practice of  
376 pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address,  
377 Internet site address, telephone number of the board, and if applicable a toll-free telephone  
378 number for filing complaints)."

379  
380 (ii) If the prescription drug order is delivered to patients at their residence or other  
381 designated location, the pharmacy shall provide with each dispensed prescription a written  
382 notification in type size no smaller than ten-point Times Roman which states the following:  
383 "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of  
384 Pharmacy at: (list the mailing address, Internet site address, telephone number of the board,  
385 and if applicable a toll-free telephone number for filing complaints)." If multiple prescriptions are  
386 delivered to the same location, only one such notice shall be required.

387  
388 (iii) The provisions of this subsection do not apply to prescriptions for patients in facilities  
389 where drugs are administered to patients by a person required to do so by the laws of the state  
390 (i.e., nursing homes).

391  
392 (B) A pharmacy that maintains a generally accessible site on the Internet that is located in  
393 Texas or sells or distributes drugs through this site to residents of this state shall post the  
394 following information on the pharmacy's initial home page and on the page where a sale of  
395 prescription drugs occurs.

396  
397 (i) Information on the ownership of the pharmacy, to include at a minimum, the:

398  
399 (I) owner's name or if the owner is a partnership or corporation, the partnership's or  
400 corporation's name and the name of the chief operating officer;

401  
402 (II) owner's address;

403  
404 (III) owner's telephone number; and

405  
406 (IV) year the owner began operating pharmacies in the United States.

407  
408 (ii) The Internet address and toll free telephone number that a consumer may use to:  
409  
410 (I) report medication/device problems to the pharmacy; and  
411  
412 (II) report business compliance problems.  
413  
414 (iii) Information about each pharmacy that dispenses prescriptions for this site, to include at  
415 a minimum, the:  
416  
417 (I) pharmacy's name, address, and telephone number;  
418  
419 (II) name of the pharmacist responsible for operation of the pharmacy;  
420  
421 (III) Texas pharmacy license number for the pharmacy and a link to the Internet site  
422 maintained by the Texas State Board of Pharmacy; and  
423  
424 (IV) the names of all other states in which the pharmacy is licensed, the license number in  
425 that state, and a link to the Internet site of the entity that regulates pharmacies in that state, if  
426 available.  
427  
428 (C) A pharmacy whose Internet site has been awarded a Verified Internet Pharmacy Practice  
429 Site (VIPPS) certification by the National Association of Boards of Pharmacy shall be in  
430 compliance with subparagraph (B) of this paragraph by displaying the VIPPS seal on the  
431 pharmacy internet site.  
432  
433 (2) Texas State Board of Pharmacy. On or before January 1, 2005, the board shall establish a  
434 pharmacy profile system as specified in §2054.2606, Government Code.  
435  
436 (A) The board shall make the pharmacy profiles available to the public on the agency's  
437 Internet site.  
438  
439 (B) A pharmacy profile shall contain at least the following information:  
440  
441 (i) name, address, and telephone number of the pharmacy;  
442  
443 (ii) pharmacy license number, licensure status, and expiration date of the license;  
444  
445 (iii) the class and type of the pharmacy;  
446  
447 (iv) ownership information for the pharmacy;  
448  
449 (v) names and license numbers of all pharmacists working at the pharmacy;  
450  
451 (vi) whether the pharmacy has had prior disciplinary action by the board;  
452  
453 (vii) whether the pharmacy's consumer service areas are accessible to disabled persons, as  
454 defined by law;  
455  
456 (viii) the type of language translating services, including translating services for persons with  
457 impairment of hearing, that the pharmacy provides for consumers; and

458  
459 (ix) insurance information including whether the pharmacy participates in the state Medicaid  
460 program.  
461

462 (C) The board shall gather this information on initial licensing and update the information in  
463 conjunction with the license renewal for the pharmacy.  
464

465 (h) Notification of Licensees or Registrants Obtaining Controlled Substances or Dangerous  
466 Drugs by Forged Prescriptions. If a licensee or registrant obtains controlled substances or  
467 dangerous drugs from a pharmacy by means of a forged prescription, the pharmacy shall report  
468 in writing to the board immediately on discovery of such forgery. A pharmacy shall be in  
469 compliance with this subsection by submitting to the board the following:  
470

471 (1) name of licensee or registrant obtaining controlled substances or dangerous drugs by  
472 forged prescription;  
473

474 (2) date(s) of forged prescription(s);  
475

476 (3) name(s) and amount(s) of drug(s); and  
477

478 (4) copies of forged prescriptions.  
479  
480

#### 481 **§291.5 Closing a Pharmacy** 482

483 (a) Prior to closing. At least 14 days prior to the closing of a pharmacy the pharmacist-in-charge  
484 shall comply with the following.  
485

486 (1) If the pharmacy is registered to possess controlled substances, send a written notification  
487 to the appropriate divisional office of the Drug Enforcement Administration (DEA) containing the  
488 following information:  
489

490 (A) the name, address, and DEA registration number of the pharmacy;  
491

492 (B) the anticipated date of closing;  
493

494 (C) the name, address, and DEA registration number of the pharmacy acquiring the  
495 controlled substances; and  
496

497 (D) the date on which the transfer of controlled substances will occur.  
498

499 (2) If the pharmacy dispenses prescription drug orders, post a closing notice sign in a  
500 conspicuous place in the front of the prescription department and at all public entrance doors to  
501 the pharmacy. Such closing notice sign shall contain the following information:  
502

503 (A) the date of closing; and  
504

505 (B) the name, address, and telephone number of the pharmacy acquiring the prescription  
506 drug orders, including refill information and patient medication records of the pharmacy.  
507

508 (b) Closing day. On the date of closing, the pharmacist-in-charge shall comply with the  
509 following:  
510  
511 (1) take an inventory as specified in §291.17 of this title (relating to Inventory Requirements);  
512  
513 (2) remove all prescription drugs from the pharmacy by one or a combination of the following  
514 methods:  
515  
516 (A) return prescription drugs to manufacturer or supplier (for credit/disposal);  
517  
518 (B) transfer (sell or give away) prescription drugs to a person who is legally entitled to  
519 possess drugs, such as a hospital, or another pharmacy; and  
520  
521 (C) destroy the prescription drugs following procedures specified in §303.2 of this title  
522 (relating to Disposal of Stock Prescription Drugs);  
523  
524 (3) if the pharmacy dispenses prescription drug orders:  
525  
526 (A) transfer the prescription drug order files, including refill information, and patient  
527 medication records to a licensed pharmacy within a reasonable distance of the closing  
528 pharmacy; and  
529  
530 (B) move all signs or notify the landlord or owner of the property that it is unlawful to use the  
531 word "pharmacy" either in English or any other language, or any other word or combination of  
532 words of the same or similar meaning, or any graphic representation that would mislead or tend  
533 to mislead the public that a pharmacy is located at the address.  
534  
535 (c) After closing.  
536  
537 (1) Within ten days after the closing of the pharmacy, the pharmacist-in-charge shall forward to  
538 the board a written notice of the closing which includes the following information:  
539  
540 (A) the actual date of closing;  
541  
542 (B) the license issued to the pharmacy;  
543  
544 (C) a statement attesting:  
545  
546 (i) that an inventory as specified in §291.17 of this title (relating to Inventory Requirements)  
547 has been conducted; and  
548  
549 (ii) the manner by which the dangerous drugs and controlled substances possessed by the  
550 pharmacy were transferred or disposed; and  
551  
552 (D) if the pharmacy dispenses prescription drug orders, the name and address of the  
553 pharmacy to which the prescription drug orders, including refill information, and patient  
554 medication records were transferred.  
555  
556 (2) If the pharmacy is registered to possess controlled substances, send a letter to the:  
557

558 (A) appropriate DEA divisional office explaining that the pharmacy has closed. Include the  
559 following items with the letter:

560 (i) DEA registration certificate;

561  
562 (ii) all unused DEA order forms (222) with the word VOID written on the face of each order  
563 form; and  
564

565 (iii) copy 2 of any DEA order forms (222) used to transfer Schedule II controlled from the  
566 closed pharmacy;  
567

568 (B) the Texas Department of Public Safety (DPS) explaining that the pharmacy has closed  
569 and include the DPS registration certificate.  
570

571 (3) Once the pharmacy has notified the board that the pharmacy is closed, the license may not  
572 be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title  
573 (relating to Pharmacy License Application).  
574

575 (d) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster,  
576 death, property seizure, eviction, bankruptcy, or other emergency circumstances and the  
577 pharmacist-in-charge cannot provide notification 14 days prior to the closing, the pharmacist-in-  
578 charge shall comply with the provisions of subsection (a) of this section as far in advance of the  
579 closing as allowed by the circumstances.  
580

581 (e) Joint responsibility. If the pharmacist-in-charge is not available to comply with the  
582 requirements of this section, the owner shall be responsible for compliance with the provisions  
583 of this section.  
584

585  
586

### 587 **§291.6 Pharmacy License Fees**

588 (a) Initial License Fee.  
589

590 (1) Prior to October 1, 2015, the fee for an initial license shall be \$500 for the initial registration  
591 period and for processing the application and issuance of the pharmacy license as authorized  
592 by the Act §554.006. Effective October 1, 2015, the fee for an initial license shall be \$401 for the  
593 initial registration period and for processing the application and issuance of the pharmacy  
594 license as authorized by the Act §554.006.  
595

596 (2) In addition, the following fees shall be collected:  
597

598 (A) \$15 surcharge to fund a program to aid impaired pharmacists and pharmacy students as  
599 authorized by the Act §564.051;  
600

601 (B) prior to October 1, 2015, \$15 surcharge to fund TexasOnline as authorized by Chapter  
602 2054, Subchapter I, Government Code; and effective October 1, 2015, \$12 surcharge to fund  
603 TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and  
604

605 (C) \$5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101,  
606 Subchapter G, Occupations Code.  
607  
608

609 (b) Biennial License Renewal. The Texas State Board of Pharmacy shall require biennial  
610 renewal of all pharmacy licenses provided under the Act §561.002.

611  
612 (c) Renewal Fee.

613  
614 (1) Prior to October 1, 2015, the fee for biennial renewal of a pharmacy license shall be \$500  
615 for processing the application and issuance of the pharmacy license as authorized by the Act  
616 §554.006. Effective October 1, 2015, the fee for biennial renewal of a pharmacy license shall be  
617 \$401 for processing the application and issuance of the pharmacy license as authorized by the  
618 Act §554.006.

619  
620 (2) In addition, the following fees shall be collected:

621  
622 (A) \$15 surcharge to fund a program to aid impaired pharmacists and pharmacy students as  
623 authorized by the Act §564.051;

624  
625 (B) prior to October 1, 2015, \$15 surcharge to fund TexasOnline as authorized by Chapter  
626 2054, Subchapter I, Government Code; and effective October 1, 2015, \$12 surcharge to fund  
627 TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

628  
629 (C) \$2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101,  
630 Subchapter G, Occupations Code.

631  
632 (d) Duplicate or Amended Certificates. The fee for issuance of an amended pharmacy license  
633 renewal certificate shall be \$20.

634  
635  
636 **§291.7 Prescription Drug Recalls by the Manufacturer**

637  
638 (a) The pharmacist-in-charge shall develop and implement a written procedure for proper  
639 management of drug recalls by the manufacturer. Such procedures shall include, where  
640 appropriate, contacting patients to whom the recalled drug products have been dispensed.

641  
642 (b) The written procedure shall include, but not be limited to, the following:

643  
644 (1) the pharmacist-in-charge shall reasonably ensure that a recalled drug has been removed  
645 from inventory no more than 24 hours after receipt of the recall notice, and quarantined until  
646 proper disposal or destruction of the drug; and

647  
648 (2) if the drug that is the subject to a recall is maintained by the pharmacy in a container  
649 without a lot number, the pharmacist-in-charge shall consider this drug included in the recall.

650  
651  
652 **§291.8 Return of Prescription Drugs**

653  
654 (a) General prohibition on return of prescription drugs. As specified in §431.021(w), Health and  
655 Safety Code, a pharmacist may not accept an unused prescription or drug, in whole or in part,  
656 for the purpose of resale or re-dispensing to any person, after the prescription or drug has been  
657 originally dispensed, or sold except as provided in subsection (b) of this section.

658  
659 (b) Return of prescription drugs from health care facilities.

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(1) Purpose. The purpose of this subsection is to outline procedures for the return of unused drugs from a health care facility or a penal institution to a dispensing pharmacy as specified in the §562.1085 of the Occupations Code. Nothing in this section shall require a consultant pharmacist, health care facility, penal institution, or pharmacy to participate in the return of unused drugs.

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

(A) Consultant pharmacist--A pharmacist who practices in or serves as a consultant for a health care facility in this state.

(B) Health care facility--A facility regulated under Chapter 242, Health and Safety Code.

(C) Licensed health care professional--A person licensed by the Texas Medical Board, Texas Board of Nurse Examiners, or the Texas State Board of Pharmacy.

(D) Penal institution--A place designated by law for confinement of persons arrested for, charged with, or convicted of an offense. A penal institution includes a city, county or state jail or prison.

(3) Responsibilities. A licensed health care professional in a penal institution or a consultant pharmacist may return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy.

(A) The unused drugs must:

(i) be approved by the federal Food and Drug Administration and be:

(I) sealed in unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging;

(II) oral or parenteral medication in sealed single-dose containers approved by the federal Food and Drug Administration;

(III) topical or inhalant drugs in sealed unit-of-use containers approved by the federal Food and Drug Administration; or

(IV) parenteral medications in sealed multiple-dose containers approved by the federal Food and Drug Administration from which doses have not been withdrawn.

(ii) not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer; and

(iii) have not been in the physical possession of the person for whom it was prescribed.

(B) A healthcare facility or penal institution may not return any drug product that:

(i) has been compounded;

711 (ii) appears on inspection to be adulterated;

712

713 (iii) requires refrigeration; or

714

715 (iv) has less than 120 days until the expiration date or end of the shelf life.

716

717 (C) The consultant pharmacist or licensed health care professional in a penal institution shall  
718 be responsible for assuring an inventory of the drugs to be returned to a pharmacy is  
719 completed. The following information shall be included on this inventory:

720

721 (i) name and address of the facility or institution;

722

723 (ii) name and pharmacist license number of the consultant pharmacist or name and license  
724 number of the licensed health care professional;

725

726 (iii) date of return;

727

728 (iv) date the prescription was dispensed;

729

730 (v) unique identification number assigned to the prescription by the pharmacy;

731

732 (vi) name of dispensing pharmacy;

733

734 (vii) name, strength, and quantity of drug;

735

736 (viii) signature of consultant pharmacist or licensed healthcare professional responsible for  
737 the administration of drugs in a penal institution.

738

739 (D) The health care facility/penal institution shall send a copy of the inventory specified in  
740 subparagraph (C) of this paragraph to:

741

742 (i) the pharmacy with the drugs returned; and

743

744 (ii) the Health and Human Services Commission.

745

746 (4) Dispensing/Receiving pharmacy responsibilities. If a pharmacy accepts the return of  
747 unused drugs from a health care facility/penal institution, the following is applicable.

748

749 (A) A pharmacist employed by the pharmacy shall examine the drugs to ensure the integrity  
750 of the drug product.

751

752 (B) The pharmacy shall reimburse or credit the entity that paid for the drug including the state  
753 Medicaid program for an unused drug returned to the pharmacy. The pharmacy shall maintain a  
754 record of the credit or reimbursement containing the following information:

755

756 (i) name and address of the facility or institution which returned the drugs;

757

758 (ii) date and amount of the credit or reimbursement was issued;

759

760 (iii) name of the person or entity to whom the credit or reimbursement was issued;

761

762 (iv) date the prescription was dispensed;

763

764 (v) unique identification number assigned to the prescription by the pharmacy;

765

766 (vi) name, strength, and quantity of drug;

767

768 (vii) signature of the pharmacist responsible for issuing the credit.

769

770 (C) After the pharmacy has issued credit or reimbursement, the pharmacy may restock and  
771 redispense the unused drugs returned under this section.

772

773 (5) Limitation on Liability.

774

775 (A) A pharmacy that returns unused drugs and a manufacturer that accepts the unused drugs  
776 under §562.1085, Occupations Code, and the employees of the pharmacy or manufacturer are  
777 not liable for harm caused by the accepting, dispensing, or administering of drugs returned in  
778 strict compliance with §562.1085, Occupations Code, unless the harm is caused by:

779

780 (i) wilful or wanton acts of negligence;

781

782 (ii) conscious indifference or reckless disregard for the safety of others; or

783

784 (iii) intentional conduct.

785

786 (B) This section does not limit, or in any way affect or diminish, the liability of a drug seller or  
787 manufacturer under Chapter 82, Civil Practice and Remedies Code.

788

789 (C) This section does not apply if harm results from the failure to fully and completely comply  
790 with the requirements of §562.1085, Occupations Code.

791

792 (D) This section does not apply to a pharmacy or manufacturer that fails to comply with the  
793 insurance provisions of Chapter 84, Civil Practice and Remedies Code.

794

795

#### 796 **§291.9 Prescription Pick Up Locations**

797

798 Except as provided in §291.155 of this title (relating to Limited Prescription Delivery Pharmacy  
799 (Class H)), no person, firm, or business establishment may have, participate, in, or permit an  
800 arrangement, branch, connection or affiliation whereby prescriptions are solicited, collected,  
801 picked up, or advertised to be picked up, from or at any location other than a pharmacy which is  
802 licensed and in good standing with the board. Provided, however, that nothing in this regulation  
803 shall prohibit a pharmacist or pharmacy by means of its employee or by use of a common  
804 carrier or the U.S. Mail, at the request of the patient, from picking up prescription orders or  
805 delivering prescription drugs at the office or home of the prescriber, at the residence or place of  
806 employment of the person for whom the prescription was issued, or at the hospital or medical  
807 care facility in which the patient is receiving treatment.

808

809

#### 810 **§291.10 Pharmacy Balance Registration/Inspection**

811

812 (a) Definitions. The following words and terms, when used in this section, shall have the  
813 following meanings, unless the context clearly indicates otherwise. Pharmacy balance--An  
814 instrument for weighing including balances and scales.

815

816 (b) Registration.

817

818 (1) A pharmacy shall annually or biennially register each pharmacy balance. The fee for the  
819 annual registration shall be \$12.50 per pharmacy balance. The fee for the biennial registration  
820 shall be \$25.00 per pharmacy balance.

821

822 (2) The expiration date for pharmacy balance registrations shall coincide with the pharmacy  
823 license expiration date.

824

825 (c) Inspection.

826

827 (1) The Board shall periodically inspect pharmacy balances to verify accuracy.

828

829 (2) If a pharmacy balance fails the accuracy inspection, the following is applicable.

830

831 (A) The pharmacy balance may not be used until it is repaired by an authorized repair person.

832

833 (B) A tag indicating that the pharmacy balance failed the inspection and may not be used  
834 shall be placed on the pharmacy balance.

835

836

### 837 **§291.11 Operation of a Pharmacy**

838

839 (a) For the purposes of §565.002(7) of the Texas Pharmacy Act, the following words and terms  
840 shall be defined as follows.

841

842 (1) "Failure to engage in the business described in the application for a license" means the  
843 holder of a pharmacy license has not commenced operating the pharmacy within six months of  
844 the date of issuance of the license.

845

846 (2) "Ceased to engage in the business described in the application for a license" means the  
847 holder of a pharmacy license, once it has been in operation, discontinues operating the  
848 pharmacy for a period of 30 days or longer unless the pharmacy experiences a fire or disaster,  
849 in which case the pharmacy must comply with §291.3(f) of this title (relating to Notifications).

850

851 (b) For the purposes of this section, the term "operating the pharmacy" means the pharmacy  
852 shall demonstrate observable pharmacy business activity on a regular, routine basis, including a  
853 sufficient number of transactions of receiving, processing, or dispensing prescription drug orders  
854 or medication drug orders.

855

856 (c) No person may operate a pharmacy in a personal residence.

857

858

### 859 **§291.14 Pharmacy License Renewal**

860

861 (a) Renewal requirements.

862

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

864

865 (2) Timely receipt of the completed application and renewal fee means the receipt in the  
866 board's office of such application and renewal fee.

867

868 (3) The provision of the Act, §561.005, shall apply if the completed application and a renewal  
869 fee is not received on or before the last day of the assigned expiration month.

870

871 (4) An expired license may be renewed according to the following schedule:

872

873 (A) If the license has been expired for 90 days or less, the license may be renewed by paying  
874 to the board a renewal fee that is equal to one and one-half times the required renewal fee as  
875 specified in §291.6 of this title (relating to Pharmacy License Fees).

876

877 (B) If the license has been expired for more than 90 days but less than one year, the license  
878 may be renewed by paying to the board a renewal fee that is equal to two times the required  
879 renewal fee as specified in §291.6 of this title.

880

881 (C) If the license has been expired for one year or more, the license may not be renewed.  
882 The pharmacy may apply for a new license as specified in §291.1 of this title (relating to  
883 Pharmacy License Application).

884

885 (b) Additional renewal requirements for Class E pharmacies. In addition to the renewal  
886 requirements in subsection (a) of this section, a Class E pharmacy shall have on file with the  
887 Board an inspection report issued:

888

889 (1) not more than three years before the date the renewal application is received; and

890

891 (2) by the pharmacy licensing board in the state of the pharmacy's physical location except as  
892 provided in §291.104 of this title (relating to Operational Standards).

893

894

#### 895 **§291.15 Storage of Drugs**

896

897 All drugs shall be stored at the proper temperature and conditions as defined by the following  
898 terms:

899

900 (1) Freezer--A place in which the temperature is maintained thermostatically between minus 25  
901 degrees Celsius and minus 10 degrees Celsius (minus 13 degrees Fahrenheit and 14 degrees  
902 Fahrenheit).

903

904 (2) Cold--Any temperature not exceeding 8 degrees Celsius (46 degrees Fahrenheit). A  
905 refrigerator is a cold place in which the temperature is maintained thermostatically between 2  
906 degrees Celsius and 8 degrees Celsius (36 degrees Fahrenheit and 46 degrees Fahrenheit).

907

908 (3) Cool--Any temperature between 8 degrees Celsius and 15 degrees Celsius (46 degrees  
909 Fahrenheit and 59 degrees Fahrenheit). An article for which storage in a cool place is directed  
910 may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the  
911 individual monograph.

912

913 (4) Room temperature--The temperature prevailing in a working area.

- 914  
915 (5) Controlled room temperature--A temperature maintained thermostatically between 15  
916 degrees Celsius and 30 degrees Celsius (59 degrees Fahrenheit and 86 degrees Fahrenheit).  
917  
918 (6) Warm--Any temperature between 30 degrees Celsius and 40 degrees Celsius (86 degrees  
919 Fahrenheit and 104 degrees Fahrenheit).  
920  
921 (7) Excessive heat--Any temperature above 40 degrees Celsius (104 degrees Fahrenheit).  
922  
923 (8) Protection from freezing--Where, in addition to the risk of breakage of the container,  
924 freezing subjects a product to loss of strength or potency, or to destructive alteration of the  
925 dosage form, the container label bears an appropriate instruction to protect the product from  
926 freezing.  
927  
928 (9) Dry place--A place that does not exceed 40% average relative humidity at controlled room  
929 temperature or the equivalent water vapor pressure at other temperatures.  
930

931  
932 **§291.16 Samples**  
933

934 Unless otherwise specified, a pharmacy may not sell, purchase, trade or possess prescription  
935 drug samples, unless the pharmacy meets all of the following conditions:  
936

- 937 (1) the pharmacy is owned by a charitable organization described in the Internal Revenue  
938 Code of 1986, or by a city, state or county government;  
939  
940 (2) the pharmacy is a part of a health care entity which provides health care primarily to  
941 indigent or low income patients at no or reduced cost;  
942  
943 (3) the samples are for dispensing or provision at no charge to patients of such health care  
944 entity; and  
945  
946 (4) the samples are possessed in compliance with the federal Prescription Drug Marketing Act  
947 of 1987.  
948  
949

950 **§291.17 Inventory Requirements**  
951

952 (a) General requirements.  
953

- 954 (1) The pharmacist-in-charge shall be responsible for taking all required inventories, but may  
955 delegate the performance of the inventory to another person(s).  
956  
957 (2) The inventory shall be maintained in a written, typewritten, or printed form. An inventory  
958 taken by use of an oral recording device must be promptly transcribed.  
959  
960 (3) The inventory shall be kept in the pharmacy and shall be available for inspection for two  
961 years.  
962  
963 (4) The inventory shall be filed separately from all other records.  
964

965 (5) The inventory shall be in a written, typewritten, or printed form and include all stocks of the  
966 following drugs on hand on the date of the inventory (including any which are out-of-date):

967 (A) all controlled substances;

968 (B) all dosage forms containing nalbuphine (e.g., Nubain); and

969  
970 (C) for any inventory taken after January 1, 2013, all dosage forms containing tramadol (e.g.,  
971 Ultram).

972 (6) The inventory may be taken either as of the opening of business or as of the close of  
973 business on the inventory date.

974  
975 (7) The inventory record shall indicate whether the inventory is taken as of the opening of  
976 business or as of the close of business on the inventory date. If the pharmacy is open 24 hours  
977 a day, the opening of business shall be 12:01 a.m. and the close of business shall be 12  
978 midnight. The inventory shall indicate that it is a record of drugs on-hand as of the opening or  
979 closing of the business day.

980  
981 (8) The person(s) taking the inventory shall make an exact count or measure of all substances  
982 listed in Schedule II.

983  
984 (9) The person(s) taking the inventory shall make an estimated count or measure of all  
985 substances listed in Schedule III, IV, or V and dangerous drugs, unless the container holds  
986 more than 1,000 tablets or capsules in which case, an exact count of the contents must be  
987 made.

988  
989 (10) The inventory of Schedule II controlled substances shall be listed separately from the  
990 inventory of Schedule III, IV, and V controlled substances which shall be listed separately from  
991 the inventory of dangerous drugs.

992 (11) If the pharmacy maintains a perpetual inventory of any of the drugs required to be  
993 inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

994  
995 (b) Initial inventory.

1000  
1001 (1) A new Class A (Community) pharmacy, Class C (Institutional) pharmacy, or Class F (Free  
1002 Standing Emergency Medical Care Center) pharmacy shall take an inventory on the opening  
1003 day of business. Such inventory shall include all stocks (including any out-of-date drugs) of the  
1004 drugs specified in subsection (a)(5) of this section.

1005  
1006 (2) In the event the Class A, C, or F pharmacy commences business with none of the drugs  
1007 specified in subsection (a)(5) of this section on hand, the pharmacy shall record this fact as the  
1008 initial inventory.

1009  
1010 (3) The initial inventory shall serve as the pharmacy's inventory until the next May 1, or until  
1011 the pharmacy's regular general physical inventory date, at which time the Class A, C, or F  
1012 pharmacy shall take an annual inventory as specified in subsection (c) of this section. Such  
1013 inventory may be taken within four days of the specified inventory date and shall include all  
1014 stocks (including out-of-date drugs).

1016 (c) Annual inventory.

1017

1018 (1) A Class A, C, or F pharmacy shall take an inventory on May 1 of each year, or on the  
1019 pharmacy's regular general physical inventory date. Such inventory may be taken within four  
1020 days of the specified inventory date and shall include all stocks (including out-of-date drugs) of  
1021 the drugs specified in subsection (a)(5) of this section.

1022

1023 (2) A Class A, C, or F pharmacy applying for renewal of a pharmacy license shall include as a  
1024 part of the pharmacy license renewal application a statement attesting that an annual inventory  
1025 has been conducted, the date of the inventory, and the name of the person taking the inventory.

1026

1027 (3) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the  
1028 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and  
1029 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-  
1030 charge and the date of the inventory shall be notarized within three days after the day the  
1031 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

1032

1033 (d) Change of ownership.

1034

1035 (1) A Class A, C, or F pharmacy that changes ownership shall take an inventory of all of the  
1036 following drugs on the date of the change of ownership. Such inventory shall include all stocks  
1037 (including any out-of-date drugs) of the drugs specified in subsection (a)(5) of this section.

1038

1039 (2) Such inventory shall constitute, for the purpose of this section, the closing inventory for the  
1040 seller and the initial inventory for the buyer.

1041

1042 (3) Transfer of any controlled substances listed in Schedule II shall require the use of official  
1043 DEA order forms (Form 222C).

1044

1045 (4) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the  
1046 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and  
1047 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-  
1048 charge and the date of the inventory shall be notarized within three days after the day the  
1049 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

1050

1051 (e) Closed pharmacies.

1052

1053 (1) The pharmacist-in-charge of a Class A, C, or F pharmacy that ceases to operate as a  
1054 pharmacy shall forward to the board, within 10 days of the cessation of operation, a statement  
1055 attesting that an inventory of the drugs specified in subsection (a)(5) of this section on hand has  
1056 been conducted, the date of closing, and a statement attesting the manner by which the  
1057 dangerous drugs and controlled substances possessed by such pharmacy were transferred or  
1058 disposed.

1059

1060 (2) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the  
1061 time the inventory was taken (as specified in subsection (a)(7) of this section) and shall sign and  
1062 date the inventory with the date the inventory was taken. The signature of the pharmacist-in-  
1063 charge and the date of the inventory shall be notarized within three days after the day the  
1064 inventory is completed, excluding Saturdays, Sundays, and federal holidays.

1065

1066 (f) Additional requirements for Class C (Institutional) pharmacies.

1067  
1068 (1) Perpetual inventory.  
1069  
1070 (A) A Class C pharmacy shall maintain a perpetual inventory of all Schedule II controlled  
1071 substances.  
1072  
1073 (B) The perpetual inventory shall be reconciled on the date of the annual inventory.  
1074  
1075 (2) Annual inventory. The inventory of the institution shall be maintained in the pharmacy; if an  
1076 inventory is conducted in other departments within the institution, the inventory of the pharmacy  
1077 shall be listed separately, as follows:  
1078  
1079 (A) the inventory of drugs on hand in the pharmacy shall be listed separately from the  
1080 inventory of drugs on hand in the other areas of the institution; and  
1081  
1082 (B) the inventory of drugs on hand in all other departments shall be identified by department.  
1083  
1084 (g) Change of pharmacist-in-charge of a pharmacy.  
1085  
1086 (1) For an inventory taken after June 1, 2013, on the date of the change of change of the  
1087 pharmacist-in-charge of a Class A (Community), Class C (Institutional), or Class F (Free  
1088 Standing Emergency Medical Care Center) pharmacy, an inventory shall be taken. Such  
1089 inventory shall include all stocks (including any out-of-date drugs) of the drugs specified in  
1090 subsection (a)(5) of this section. For an inventory taken prior to June 1, 2013, on the date of  
1091 change of the pharmacist-in-charge of a Class A (Community), Class C (Institutional), or Class  
1092 F (Free Standing Emergency Medical Care Center) pharmacy, an inventory of the following  
1093 drugs shall be taken.  
1094  
1095 (A) all Schedule II controlled substances;  
1096  
1097 (B) all dosage forms containing pentazocine (e.g., Talwin);  
1098  
1099 (C) all dosage forms containing phentermine (e.g., Adipex-P, etc.);  
1100  
1101 (D) all dosage forms containing diazepam (e.g., Valium);  
1102  
1103 (E) all dosage forms containing phendimetrazine (e.g., Bontril, Prelu-2, etc.);  
1104  
1105 (F) all dosage forms containing codeine;  
1106  
1107 (G) all dosage forms containing hydrocodone (e.g., Tussionex, Tussend, Vicodin, etc.);  
1108  
1109 (H) all dosage forms containing alprazolam (e.g., Xanax);  
1110  
1111 (I) all dosage forms containing triazolam (e.g., Halcion);  
1112  
1113 (J) all dosage forms containing butorphanol (e.g., Stadol);  
1114  
1115 (K) all dosage forms containing nalbuphine (e.g., Nubain);  
1116  
1117 (L) all dosage forms containing carisoprodol (e.g., Soma); and

1118  
1119 (M) for any inventory taken after January 1, 2013, all dosage forms containing tramadol (e.g.,  
1120 Ultram).

1121  
1122 (2) This inventory shall constitute, for the purpose of this section, the closing inventory of the  
1123 departing pharmacist-in-charge and the beginning inventory of the incoming pharmacist-in-  
1124 charge.

1125  
1126 (3) If the departing and the incoming pharmacists-in-charge are unable to conduct the  
1127 inventory together, a closing inventory shall be conducted by the departing pharmacist-in-  
1128 charge and a new and separate beginning inventory shall be conducted by the incoming  
1129 pharmacist-in-charge.

1130  
1131 (4) The incoming pharmacist-in-charge shall be responsible for notifying the board within 10  
1132 days in writing on a form provided by the board, that a change of pharmacist-in-charge has  
1133 occurred. The notification shall include the following:

1134  
1135 (A) the name and license number of the departing pharmacist-in-charge;

1136  
1137 (B) the name and license number of the incoming pharmacist-in-charge;

1138  
1139 (C) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and

1140  
1141 (D) a statement signed by the incoming pharmacist-in-charge attesting that:

1142  
1143 (i) an inventory has been conducted by the departing and incoming pharmacists-in-charge; if  
1144 the inventory was not taken by both pharmacists, the statement shall provide an explanation;  
1145 and

1146  
1147 (ii) the incoming pharmacist-in-charge has read and understands the laws and rules relating  
1148 to this class of pharmacy.

1149  
1150

1151 **§291.18 Time Limit for Filing a Complaint**

1152  
1153 For the purposes of the Act, §556.055, the board determines that a "reasonable time" to be no  
1154 less than 10 days from the date of an inspection giving rise to a possible complaint; provided,  
1155 however, in situations presenting imminent danger to the public health and safety, the board  
1156 may obtain an injunction under the Act, §566.051, to restrain or enjoin a person from continuing  
1157 to violate the Act or rules promulgated pursuant to the Act without waiting the 10-day period set  
1158 out in this section.

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1161 **§291.19 Administrative Actions as a Result of a Compliance Inspection**

1162  
1163 As a result of a compliance inspection or compliance reinspection of a pharmacy wherein  
1164 violations of the Texas Pharmacy Act, Controlled Substances Act, Dangerous Drug Act, Texas  
1165 Food, Drug and Cosmetic Act, or rules adopted pursuant to such acts as observed:

1166  
1167 (1) an agent of the board may issue a written report of areas of non-compliance that need  
1168 improvement;

1169  
1170 (2) an agent of the board may issue a written warning notice listing specific violations to which  
1171 the licensee shall respond in writing to the board by the date stated on the warning notice,  
1172 indicating that the violations listed in the warning notice have been corrected;

1173  
1174 (3) an agent of the board may recommend the institution of disciplinary action against a  
1175 licensee if such agent determines that:

1176  
1177 (A) previously cited violations are continuing to occur; or

1178  
1179 (B) violations observed are of a nature that written notice of non-compliance or a written  
1180 warning notice would not be in the best interest of the public; or

1181  
1182 (4) an agent of the board, upon determination that the violations observed are of a nature that  
1183 pose an imminent peril to the public health, safety, or welfare, may recommend to the director of  
1184 compliance, the institution of action by a district court in Travis County, Texas, to restrain or  
1185 enjoin a licensee from continuing the violation, in addition to recommending the institution of  
1186 disciplinary action against a licensee.

1187  
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### 1189 **§291.22 Petition to Establish an Additional Class of Pharmacy**

1190  
1191 (a) Purpose. The purpose of this section is to specify the procedures to be followed in  
1192 petitioning the board to establish an additional class of pharmacy as authorized by §560.053 of  
1193 the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). In  
1194 reviewing petitions, the board will only consider petitions that provide pharmaceutical care  
1195 services which contribute to positive patient outcomes. The board will not consider any petition  
1196 intended only to provide a competitive advantage.

1197  
1198 (b) Procedures for petitioning the board to establish an additional class of pharmacy. A person  
1199 who wishes the board to consider establishing an additional class of pharmacy shall submit to  
1200 the board a petition that contains at least the following information:

1201  
1202 (1) name, address, telephone number, and pharmacist's license number of the pharmacist  
1203 responsible for submitting the petition;

1204  
1205 (2) a detailed summary of the additional class of pharmacy which includes:

1206  
1207 (A) a description of the type of pharmacy and the pharmaceutical care services provided to  
1208 the public;

1209  
1210 (B) if a pharmacy of this type currently exists, the name, address, and license number of the  
1211 pharmacy;

1212  
1213 (C) a full explanation of the reasons:

1214  
1215 (i) the existing classifications of pharmacy licenses are not appropriate for this practice  
1216 setting; and

1217  
1218 (ii) that establishment of a new classification of pharmacy license is necessary to protect the  
1219 public health, safety, and welfare.

1220  
1221 (c) Review and approval or denial of the petition.  
1222

1223 (1) On receipt of a petition to establish an additional class of pharmacy, board staff shall  
1224 initially review the petition for completeness and appropriateness. If the petition is incomplete or  
1225 inappropriate for board consideration for any reason, board staff shall return the petition with a  
1226 letter of explanation. Such review shall be completed within 30 working days of receipt of the  
1227 petition.

1228  
1229 (2) Once board staff has determined that the petition is complete and appropriate, a task force  
1230 composed of board staff, at least one board member and, if deemed necessary, resource  
1231 personnel appointed by the board president, shall review the petition and make a written  
1232 recommendation to the board regarding approval. Such recommendation shall be presented to  
1233 the board at the next regularly scheduled meeting of the board that occurs at least three weeks  
1234 after completion of the review and written recommendation.

1235  
1236 (3) A copy of the recommendation shall be provided to the petitioner and the board at least two  
1237 weeks prior to the board meeting.

1238  
1239 (4) Both the petitioner and a representative of the task force shall be given equal time for  
1240 presentations to the board.

1241  
1242 (5) Upon hearing the presentations, the board shall approve or deny the petition. If the board  
1243 approves the petition, the board shall direct staff to develop rules for the new class of pharmacy  
1244 or appoint a task force to work with the staff to assist in developing rules for the new class of  
1245 pharmacy. The board shall approve or deny any petition to establish an additional class of  
1246 pharmacy not later than the board meeting following the meeting at which the petition is heard.

1247  
1248  
1249 **§291.23 Pilot or Demonstration Research Projects for Innovative Applications in the**  
1250 **Practice of Pharmacy**

1251  
1252 (a) Purpose. The purpose of this section is to specify the procedures to be followed in applying  
1253 for approval of a pilot or demonstration research project for innovative applications in the  
1254 practice of pharmacy as authorized by §554.011 of the Texas Pharmacy Act (Chapters 551- 566  
1255 and 568 - 569, Texas Occupations Code). In reviewing projects, the board will only consider  
1256 projects that expand pharmaceutical care services which contribute to positive patient  
1257 outcomes. The board will not consider any project intended only to provide a competitive  
1258 advantage.

1259  
1260 (b) Scope of pilot or demonstration research projects and the board's approval of such projects.

1261  
1262 (1) Pilot or demonstration research projects may not:

1263  
1264 (A) expand the definition of the practice of pharmacy as provided in the Act; or

1265  
1266 (B) include therapeutic substitution or substitution of medical devices used in patient care.

1267  
1268 (2) The board's approval of pilot or demonstration research projects may include the granting  
1269 of an exception to the rules adopted under the Texas Pharmacy Act, but may not include an

1270 exception from any law relating to the practice of pharmacy. Such exception to the rules shall be  
1271 for a specified period of time and such period may not exceed 18 months.

1272  
1273 (3) The board may extend the time an exception to a rule is granted as necessary for the board  
1274 to adopt an amendment or modification of the rule.

1275  
1276 (c) Procedures for applying for approval of pilot or demonstration research projects. A person  
1277 who wishes the board to consider approval of a pilot or demonstration research project shall  
1278 submit to the board a petition for approval which contains at least the following information:

1279  
1280 (1) name, address, telephone number, and pharmacist's license number of the pharmacist  
1281 responsible for overseeing the project;

1282  
1283 (2) specific location and, if a pharmacy, the pharmacy license number where the proposed pilot  
1284 or demonstration project will be conducted;

1285  
1286 (3) a detailed summary of the proposed pilot or demonstration project which includes:

1287  
1288 (A) the goals, hypothesis, and/or objectives of the proposed project;

1289  
1290 (B) a full explanation of the project and how it will be conducted;

1291  
1292 (C) the time frame for the project including the proposed start date and length of study. Such  
1293 time frame may not exceed 18 months;

1294  
1295 (D) background information and/or literature review to support the proposal;

1296  
1297 (E) the rule(s) that will have to be waived in order to complete the project and a request to  
1298 waive the rule(s);

1299  
1300 (F) procedures to be used during the project to ensure that the public's health and safety are  
1301 not compromised as a result of the rule waiver.

1302  
1303 (d) Review and approval or denial of the proposed projects.

1304  
1305 (1) On receipt of a petition for approval of a pilot or demonstration research project, board staff  
1306 shall initially review the petition for completeness and appropriateness. If the petition is  
1307 incomplete or inappropriate for board consideration for any reason, staff shall return the petition  
1308 with a letter of explanation. Such review shall be completed within 30 working days of receipt of  
1309 the petition.

1310  
1311 (2) Once board staff has determined that the petition is complete and appropriate, a task force  
1312 composed of board staff, at least one board member and, if deemed necessary, resource  
1313 personnel appointed by the board president, shall review the petition and make a written  
1314 recommendation to the board regarding approval. Such recommendation shall be presented to  
1315 the board at the next regularly scheduled meeting of the board that occurs at least three weeks  
1316 after completion of the review and written recommendation.

1317  
1318 (3) A copy of the recommendation shall be provided to the petitioner and the board at least two  
1319 weeks prior to the board meeting.

1320

1321 (4) Both the petitioner and a representative of the task force shall be given equal time for  
1322 presentations to the board.

1323  
1324 (5) Upon hearing the presentations, the board shall either approve or deny the petition. If the  
1325 board approves the petition, the approval:

1326 (A) shall be specific for that project and for a specific time period; and

1327  
1328 (B) may include conditions or qualifications, if deemed appropriate by the board.

1329  
1330 (6) The board or its representatives shall be allowed to inspect and review the project  
1331 documentation and site at any time during the review process and after the project is approved.

1332  
1333 (e) Presentation of results to the board.

1334  
1335 (1) The pharmacist responsible for overseeing the project shall forward to the board a  
1336 summary of the results of the project and conclusions drawn from the results within three  
1337 months after completion of the project.

1338  
1339 (2) A task force composed of board staff, at least one board member and, if deemed  
1340 necessary, resource personnel appointed by the board president, shall review the results and  
1341 make written recommendations to the board regarding the results of the project.

1342  
1343 (3) The board will receive the report of the task force at the next regularly scheduled meeting  
1344 of the board that occurs at least three weeks after the task force has completed its review and  
1345 issued written recommendations.

1346  
1347 (4) A copy of the task force recommendation shall be provided to the petitioner and the board  
1348 at least two weeks prior to the board meeting.

1349  
1350 (5) Both the petitioner and a representative of the task force shall be given equal time for  
1351 presentations to the board.

1352  
1353  
1354

#### 1355 **§291.24 Pharmacy Residency Programs**

1356  
1357 For the purposes of Subchapter T, Chapter 61, Education Code, the standards for pharmacy  
1358 residency programs shall be the standards required by the American Society of Health-System  
1359 Pharmacists' Commission on Credentialing. The pharmacy residency programs approved by the  
1360 Board shall be published periodically in the minutes of the Board.

1361  
1362

#### 1363 **§291.27 Confidentiality**

1364  
1365 (a) A pharmacist shall provide adequate security of prescription drug orders, medication orders,  
1366 and patient medication records to prevent indiscriminate or unauthorized access to confidential  
1367 health information. If prescription drug orders, requests for refill authorization, or other  
1368 confidential health information are not transmitted directly between a pharmacy and a physician  
1369 but are transmitted through a data communication device, confidential health information may  
1370 not be accessed or maintained by the operator of the data communication device unless  
1371 specifically authorized to obtain the confidential information by this section.

- 1372  
1373 (b) Confidential records are privileged and may be released only to:  
1374  
1375 (1) the patient or the patient's agent;  
1376  
1377 (2) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the  
1378 release is necessary to protect the patient's health and well being;  
1379  
1380 (3) the board or to a person or another state or federal agency authorized by law to receive the  
1381 confidential record;  
1382  
1383 (4) a law enforcement agency engaged in investigation of a suspected violation of Chapter 481  
1384 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act  
1385 of 1970 (21 U.S.C. Section 801 et seq.);  
1386  
1387 (5) a person employed by a state agency that licenses a practitioner, if the person is  
1388 performing the person's official duties; or  
1389  
1390 (6) an insurance carrier or other third party payor authorized by a patient to receive such  
1391 information.  
1392  
1393 (c) A pharmacy shall provide written policies and procedures to prohibit the unauthorized  
1394 disclosure of confidential records.  
1395  
1396

1397 **§291.28 Access to Confidential Records**  
1398

- 1399 (a) Access to confidential records. A pharmacy shall comply with the request of a patient or a  
1400 patient's agent to inspect or obtain a copy of the patient's confidential records maintained by the  
1401 pharmacy, as defined in §551.003(10) of the Act. A pharmacy shall comply with all relevant  
1402 state and federal laws regarding release of confidential records to third party requestors.  
1403  
1404 (b) Form of request. The pharmacy may require a patient or a patient's agent or any authorized  
1405 third party to make requests for confidential records in writing, provided such a requirement has  
1406 been communicated to the requestor.  
1407  
1408 (c) Timely action by pharmacy. The pharmacy must respond to a request for confidential  
1409 records in a timely manner.  
1410  
1411 (1) The pharmacy must respond to a request for confidential records no later than thirty days  
1412 after receipt of the request by providing a copy of the records or, with the consent of the  
1413 requestor, a summary or explanation of such information. If the pharmacy is unable to take such  
1414 action within thirty days of receiving the request, the pharmacy may extend the time for such  
1415 action by no more than thirty days, provided that:  
1416  
1417 (A) the pharmacy provides the requestor with a written statement of the reasons for the delay  
1418 and the date by which the pharmacy will respond to the request; and  
1419  
1420 (B) the pharmacy shall have only one such extension of time.  
1421  
1422 (2) The pharmacy must provide confidential records as requested by either:

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(A) mailing a copy of the records; or

(B) with the consent of the requestor arranging for a convenient time and place for the individual to inspect or obtain a copy of the records.

(3) Access to confidential records may be expedited at the request of a patient or a patient's agent if there is a medical emergency. The pharmacy must respond to a request for expedited access to confidential records within 24 hours if the records are maintained at the pharmacy or within 72 hours if the records are stored off-site. The pharmacy may charge a reasonable fee, in addition to the fees outlined in subsection (d) of this section, of no more than \$25.00 for expediting a request for access to confidential records.

(d) Fees. The pharmacy may charge a reasonable, cost-based fee for providing a copy of confidential records or a summary or explanation of such information.

(1) A reasonable fee shall be a charge of no more than \$50.00 for the first twenty pages and \$0.50 per page for every page thereafter. A reasonable fee shall include only the cost of:

(A) copying, including the cost of supplies for and labor of copying;

(B) postage, when the individual has requested the records be mailed; and

(C) preparing an explanation or summary of the protected health information, if appropriate and consented to by the patient or patient's agent.

(2) If an affidavit is requested certifying that the information is a true and correct copy of the records, a reasonable fee of no more than \$15.00 may be charged for executing the affidavit.

(3) If an affidavit or questionnaire accompanies the request, the pharmacy may charge a reasonable fee of no more than \$50.00 to complete the written response.

**§291.29 Professional Responsibility of Pharmacists**

(a) Pharmacist shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed. If the pharmacist questions the accuracy or authenticity of a prescription drug order, the pharmacist shall verify the order with the practitioner prior to dispensing.

(b) A pharmacist shall make every reasonable effort to ensure that any prescription drug order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a practitioner in the course of medical practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued without a valid pre-existing patient-practitioner relationship as defined by the Texas Medical Board in 22 Texas Administrative Code (TAC) §190.8 (relating to Violation Guidelines) or without a valid prescription drug order.

(1) A prescription drug order may not be dispensed or delivered by means of the Internet unless pursuant to a valid prescription that was issued for a legitimate medical purpose in the

1473 course of medical practice by a practitioner, or practitioner covering for another practitioner, who  
1474 has conducted at least one in-person medical evaluation of the patient.

1475  
1476 (2) A prescription drug order may not be dispensed or delivered if the pharmacist has reason  
1477 to suspect that the prescription drug order may have been authorized in the absence of a valid  
1478 patient-practitioner relationship, or otherwise in violation of the practitioner's standard of practice  
1479 to include that the practitioner:

1480  
1481 (A) did not establish a diagnosis through the use of acceptable medical practices for the  
1482 treatment of patient's condition;

1483  
1484 (B) prescribed prescription drugs that were not necessary for the patient due to a lack of a  
1485 valid medical need or the lack of a therapeutic purpose for the prescription drugs; or

1486  
1487 (C) issued the prescriptions outside the usual course of medical practice.

1488  
1489 (3) Notwithstanding the provisions of this subsection and as authorized by the Texas Medical  
1490 Board in 22 TAC §190.8, a pharmacist may dispense a prescription when a physician has not  
1491 established a professional relationship with a patient if the prescription is for medications for:

1492  
1493 (A) sexually transmitted diseases for partners of the physician's established patient; or

1494  
1495 (B) a patient's family members if the patient has an illness determined by the Centers for  
1496 Disease Control and Prevention, the World Health Organization, or the Governor's office to be  
1497 pandemic.

1498  
1499 (c) If a pharmacist has reasons to suspect that a prescription was authorized solely based on  
1500 the results of a questionnaire and/or in the absence of a documented patient evaluation  
1501 including a physical examination, the pharmacist shall ascertain if that practitioner's standard of  
1502 practice allows that practitioner to authorize a prescription under such circumstances. Reasons  
1503 to suspect that a prescription may have been authorized in the absence of a valid patient-  
1504 practitioner relationship, or in violation of the practitioner's standard of practice, include:

1505  
1506 (1) the number of prescriptions authorized on a daily basis by the practitioner;

1507  
1508 (2) a disproportionate number of patients of the practitioner receive controlled substances;

1509  
1510 (3) the manner in which the prescriptions are authorized by the practitioner or received by the  
1511 pharmacy;

1512  
1513 (4) the geographical distance between the practitioner and the patient or between the  
1514 pharmacy and the patient;

1515  
1516 (5) knowledge by the pharmacist that the prescription was issued solely based on answers to a  
1517 questionnaire;

1518  
1519 (6) knowledge by the pharmacist that the pharmacy he/she works for directly or indirectly  
1520 participates in or is otherwise associated with an Internet site that markets prescription drugs to  
1521 the public without requiring the patient to provide a valid prescription order from the patients  
1522 practitioner; or

1523

1524 (7) knowledge by the pharmacist that the patient has exhibited doctor-shopping or pharmacy-  
1525 shopping tendencies.

1526  
1527 (d) A pharmacist shall ensure that prescription drug orders for the treatment of chronic pain  
1528 have been issued in accordance with the guidelines set forth by the Texas Medical Board in 22  
1529 TAC §170.3 (relating to Guidelines), prior to dispensing or delivering such prescriptions.

1530  
1531 (e) A prescription drug order may not be dispensed or delivered if issued by a practitioner  
1532 practicing at a pain management clinic that is not in compliance with the rules of the Texas  
1533 Medical Board in 22 TAC §§195.1 - 195.4 (relating to Pain Management Clinics).

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