

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS PROPOSED RULES

Short Title: Records

Rule Numbers: §291.34

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, clarify and update the section to be consistent with other sections of this title and DPS and DEA laws/rules; require documentation of a consultation with a prescriber regarding a prescription; add rules regarding auto-refill programs; and update the rules regarding prescription transfers including no longer allowing interns to transfer prescriptions, specifying that the transfer must be confirmed by each pharmacist, and holding both the transferring and receiving pharmacist responsible for a dispensing error involving a transferred prescription.

Background: Board staff presents these amendments to update the Class A rules regarding the records of the pharmacy.

1 **TITLE 22 EXAMINING BOARDS**
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 291 PHARMACIES**
4 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

5
6 **§291.34 Records**
7

8 (a) Maintenance of records.
9

10 (1) Every inventory or other record required to be kept under the provisions of **Subchapter B**
11 **of this Chapter (relating to Community Pharmacy (Class A))** [~~§291.31 of this title (relating to~~
12 ~~Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to~~
13 ~~Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title~~
14 ~~(relating to Official Prescription Requirements), contained in Community Pharmacy (Class A)]~~
15 shall be:
16

17 (A) kept by the pharmacy and be available, for at least two years from the date of such
18 inventory or record, for inspecting and copying by the board or its representative and to other
19 authorized local, state, or federal law enforcement agencies; and
20

21 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
22 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
23 the requested records must be provided in a mutually agreeable electronic format if specifically
24 requested by the board or its representative. Failure to provide the records set out in this
25 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and
26 maintain records in violation of the Act.
27

28 (2) Records of controlled substances listed in Schedule[s ~~I and~~] II shall be maintained
29 separately from all other records of the pharmacy.
30

31 (3) Records of controlled substances, other than prescription drug orders, listed in Schedules
32 III-V shall be maintained separately or readily retrievable from all other records of the pharmacy.
33 For purposes of this subsection, readily retrievable means that the controlled substances shall
34 be asterisked, red-lined, or in some other manner readily identifiable apart from all other items
35 appearing on the record.
36

37 (4) Records, except when specifically required to be maintained in original or **hard copy** [~~hard-~~
38 ~~copy~~] form, may be maintained in an alternative data retention system, such as a data
39 processing system or direct imaging system provided:
40

41 (A) the records maintained in the alternative system contain all of the information required on
42 the manual record; and
43

44 (B) the data processing system is capable of producing a hard copy of the record upon the
45 request of the board, its representative, or other authorized local, state, or federal law
46 enforcement or regulatory agencies.
47

48 (b) Prescriptions.
49

50 (1) Professional responsibility.
51

52 (A) Pharmacists shall exercise sound professional judgment with respect to the accuracy and
53 authenticity of any prescription drug order they dispense. If the pharmacist questions the
54 accuracy or authenticity of a prescription drug order, he/she shall verify the order with the
55 practitioner prior to dispensing.

56 (B) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound
57 professional judgment, that the prescription is a valid prescription. A pharmacist may not
58 dispense a prescription drug if the pharmacist knows or should have known that the prescription
59 was issued on the basis of an Internet-based or telephonic consultation without a valid patient-
60 practitioner relationship.

61
62 (C) Subparagraph (B) of this paragraph does not prohibit a pharmacist from dispensing a
63 prescription when a valid patient-practitioner relationship is not present in an emergency
64 situation (e.g., a practitioner taking calls for the patient's regular practitioner).

65
66 (2) Written prescription drug orders.

67
68 (A) Practitioner's signature.

69
70 (i) **Dangerous drug prescriptions.** ~~[Except as noted in clause (ii) of this subparagraph,]~~
71 **Written** ~~[written]~~ prescription drug orders shall be:

72
73 (I) manually signed by the practitioner; or

74
75 (II) electronically signed by the practitioner using a system **that** ~~[which]~~ electronically
76 replicates the practitioner's manual signature on the written prescription, provided:

77
78 (-a-) that security features of the system require the practitioner to authorize each use;
79 and

80
81 (-b-) the prescription is printed on paper that is designed to prevent unauthorized copying
82 of a completed prescription and to prevent the erasure or modification of information written on
83 the prescription by the prescribing practitioner. (For example, the paper contains security
84 provisions against copying that results in some indication on the copy that it is a copy and
85 therefore render the prescription null and void.)

86
87 (ii) **Controlled substance prescriptions.** Prescription drug orders for Schedule II, **III, IV, or**
88 **V** controlled substances shall be **manually signed by the practitioner. Prescription drug**
89 **orders for Schedule II controlled substances shall be** issued on an official prescription form
90 as required by the Texas Controlled Substances Act, §481.075~~[, and be manually signed by the~~
91 ~~practitioner].~~

92
93 (iii) **Other provisions for a practitioner's signature.**

94
95 **(I)** A practitioner may sign a prescription drug order in the same manner as he
96 would sign a check or legal document, e.g., J.H. Smith or John H. Smith.

97
98 **(II)** ~~[(iv)]~~ Rubber stamped or otherwise reproduced signatures may not be used
99 except as authorized in clause (i) of this subparagraph.

100
101 **(III)** ~~[(v)]~~ The prescription drug order may not be signed by a practitioner's agent but
102 may be prepared by an agent for the signature of a practitioner. However, the

prescribing practitioner is responsible in case the prescription drug order does not conform in all essential respects to the law and regulations.

(B) Prescription drug orders written by practitioners in another state.

(i) Dangerous drug prescription orders. A pharmacist may dispense a prescription drug order for dangerous drugs issued by practitioners in a state other than Texas in the same manner as prescription drug orders for dangerous drugs issued by practitioners in Texas are dispensed.

(ii) Controlled substance prescription drug orders.

(I) A pharmacist may dispense prescription drug order for controlled substances in Schedule II issued by a practitioner in another state provided:

(-a-) the prescription is filled in compliance with a written plan approved by the Director of the Texas Department of Public Safety in consultation with the Board, which provides the manner in which the dispensing pharmacy may fill a prescription for a Schedule II controlled substance;

(-b-) the prescription drug order is an original written prescription issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state; and

(-c-) the prescription drug order is not dispensed after the end of the twenty-first [seventh] day after the date on which the prescription is issued.

(II) A pharmacist may dispense prescription drug orders for controlled substances in Schedule III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:

(-a-) the prescription drug order is a [~~written, oral, or telephonically or electronically communicated prescription, as allowed by the DEA~~] issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal DEA registration number, and who may legally prescribe Schedule III, IV, or V controlled substances in such other state;

(-b-) the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and

(-c-) if there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, a new prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(C) Prescription drug orders written by practitioners in the United Mexican States or the Dominion of Canada.

153 (i) Controlled substance prescription drug orders. A pharmacist may not dispense a
154 prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a
155 practitioner in the Dominion of Canada or the United Mexican States.
156

157 (ii) Dangerous drug prescription drug orders. A pharmacist may dispense a dangerous drug
158 prescription issued by a person licensed in the Dominion of Canada or the United Mexican
159 States as a physician, dentist, veterinarian, or podiatrist provided:
160

161 (I) the prescription drug order is an original written prescription; and
162

163 (II) if there are no refill instructions on the original written prescription drug order (which
164 shall be interpreted as no refills authorized) or if all refills authorized on the original written
165 prescription drug order have been dispensed, a new written prescription drug order shall be
166 obtained from the prescribing practitioner prior to dispensing any additional quantities of
167 dangerous drugs.
168

169 (D) Prescription drug orders carried out or signed by an advanced practice nurse, physician
170 assistant, or pharmacist.
171

172 (i) A pharmacist may dispense a prescription drug order that ~~[which]~~ is:
173

174 (I) carried out or signed by an advanced practice nurse or physician assistant provided the
175 advanced practice nurse or physician assistant is practicing in accordance with Subtitle B,
176 Chapter 157, Occupations Code, and
177

178 (II) for a dangerous drug and signed by a pharmacist under delegated authority of a
179 physician as specified in Subtitle B, Chapter 157, Occupations Code.
180

181 (ii) Each practitioner shall designate in writing the name of each advanced practice nurse or
182 physician assistant authorized to carry out or sign a prescription drug order pursuant to Subtitle
183 B, Chapter 157, Occupations Code. A list of the advanced practice nurses or physician
184 assistants designated by the practitioner must be maintained in the practitioner's usual place of
185 business. On request by a pharmacist, a practitioner shall furnish the pharmacist with a copy of
186 the written authorization for a specific advanced practice nurse or physician assistant.
187

188 (E) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled
189 substance may be dispensed without a written prescription drug order of a practitioner on an
190 official prescription form as required by the Texas Controlled Substances Act, §481.075.
191

192 (3) Verbal prescription drug orders.
193

194 (A) A verbal prescription drug order from a practitioner or a practitioner's designated agent
195 may only be received by a pharmacist or a pharmacist-intern under the direct supervision of a
196 pharmacist.
197

198 (B) A practitioner shall designate in writing the name of each agent authorized by the
199 practitioner to communicate prescriptions verbally for the practitioner. The practitioner shall
200 maintain at the practitioner's usual place of business a list of the designated agents. The
201 practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a
202 specific agent on the pharmacist's request.
203

204 (C) A pharmacist may not dispense a verbal prescription drug order for a dangerous drug or a
205 controlled substance issued by a practitioner licensed in the Dominion of Canada or the United
206 Mexican States unless the practitioner is also licensed in Texas.

207
208 (4) Electronic prescription drug orders. [~~For the purpose of this subsection, prescription drug~~
209 ~~orders shall be considered the same as verbal prescription drug orders.~~]

210
211 **(A) Dangerous drugs.**

212
213 **(i)** An electronic prescription drug order **for a dangerous drug** may be transmitted by a
214 practitioner or a practitioner's designated agent:

215
216 **(I)** ~~{(i)}~~ directly to a pharmacy; or

217
218 **(II)** ~~{(ii)}~~ through the use of a data communication device provided:

219
220 **(-a-)** ~~{(1)}~~ the confidential prescription information is not altered during transmission; and

221
222 **(-b-)** ~~{(2)}~~ confidential patient information is not accessed or maintained by the operator of
223 the data communication device other than for legal purposes under federal and state law.

224
225 **(ii)** ~~{(B)}~~ A practitioner shall designate in writing the name of each agent authorized by the
226 practitioner to electronically transmit prescriptions for the practitioner. The practitioner
227 shall maintain at the practitioner's usual place of business a list of the designated
228 agents. The practitioner shall provide a pharmacist with a copy of the practitioner's
229 written authorization for a specific agent on the pharmacist's request.

230
231 **(B) ~~{(C)}~~ Controlled substances.** A pharmacist may **only** dispense an electronic
232 prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance
233 with the federal and state laws and the rules of the Drug Enforcement Administration
234 **outlined in Part 1300 of the Code of Federal Regulations** and Texas Department of
235 Public Safety.

236
237 **(C) ~~{(D)}~~ Prescriptions issued by a practitioner licensed in the Dominion of Canada or**
238 **the United States.** A pharmacist may not dispense an electronic prescription drug order
239 for a dangerous drug or controlled substance issued by a practitioner licensed in the
240 Dominion of Canada or the United Mexican States unless the practitioner is also licensed
241 in Texas.

242
243 **(5) Facsimile (Faxed) Prescriptions**

244 **(i) A pharmacist may dispense a prescription drug order for a dangerous drug**
245 **transmitted to the pharmacy by facsimile.**

246
247 **(ii) A pharmacist may dispense a prescription drug order for a controlled substance**
248 **transmitted to the pharmacy by facsimile provided the prescription is manually signed by**
249 **the practitioner and not electronically signed using a system that electronically**
250 **replicates the practitioner's manual signature on the prescription drug order.**

251
252 **(iii) A pharmacist may not dispense a facsimile prescription drug order for a**
253 **dangerous drug or controlled substance issued by a practitioner licensed in the**

254 **Dominion of Canada or the United Mexican States unless the practitioner is also licensed**
255 **in Texas.**

256
257 **(6)** ~~[(5)]~~ Original prescription drug order records.
258

259 (A) Original prescriptions may be dispensed only in accordance with the prescriber's
260 authorization as indicated on the original prescription drug order including clarifications to the
261 order given to the pharmacist by the practitioner or the practitioner's agent and recorded on the
262 prescription.

263
264 (B) Original prescriptions shall be maintained by the pharmacy in numerical order and remain
265 legible for a period of two years from the date of filling or the date of the last refill dispensed.
266

267 (C) If an original prescription drug order is changed, such prescription order shall be invalid
268 and of no further force and effect; if additional drugs are to be dispensed, a new prescription
269 drug order with a new and separate number is required. However, an original prescription drug
270 order for a dangerous drug may be changed in accordance with paragraph **(10)** ~~[(9)]~~ of this
271 subsection relating to accelerated refills.
272

273 (D) Original prescriptions shall be maintained in three separate files as follows:
274

275 (i) prescriptions for controlled substances listed in Schedule II;
276

277 (ii) prescriptions for controlled substances listed in Schedules III-V; and
278

279 (iii) prescriptions for dangerous drugs and nonprescription drugs.
280

281 (E) Original prescription records other than prescriptions for Schedule II controlled
282 substances may be stored in a ~~[on microfilm, microfiche, or other]~~ system that ~~[which]~~ is
283 capable of producing a direct image of the original prescription record, e.g., digitalized imaging
284 system. **(Note: Even though the prescription is stored in an electronic system, the**
285 **original hard copy prescription should be maintained by the pharmacy since this record**
286 **is required to be maintained by federal controlled substances regulations and many**
287 **third-party payers.)** If original prescription records are stored in a direct imaging system, the
288 following is applicable:
289

290 (i) the record of refills recorded on the original prescription must also be stored in this
291 system;
292

293 (ii) the original prescription records must be maintained in numerical order and separated in
294 three files as specified in subparagraph (D) of this paragraph; and
295

296 (iii) the pharmacy must provide immediate access to equipment necessary to render the
297 records easily readable.
298

299 **(7)** ~~[(6)]~~ Prescription drug order information.
300

301 (A) All original prescriptions shall bear:
302

303 (i) name of the patient, or if such drug is for an animal, the species of such animal and the
304 name of the owner;

305
306 (ii) address of the patient, provided, however, a prescription for a dangerous drug is not
307 required to bear the address of the patient if such address is readily retrievable on another
308 appropriate, uniformly maintained pharmacy record, such as medication records;
309
310 (iii) name, **address and telephone number of the practitioner at the practitioner's**
311 **usual place of business, legibly printed or stamped** and if for a controlled substance, the
312 [~~address and~~] DEA registration number of the practitioner;
313
314 (iv) name and strength of the drug prescribed;
315
316 (v) quantity prescribed **numerically and if for a controlled substance:**
317
318 **(I) numerically, followed by the number written as a word, if the prescription is**
319 **written;**
320
321 **(II) numerically, if the prescription is electronic; or**
322
323 **(III) if the prescription is communicated orally or telephonically, as transcribed by the**
324 **receiving pharmacist.**
325
326 (vi) directions for use;
327
328 (vii) intended use for the drug unless the practitioner determines the furnishing of this
329 information is not in the best interest of the patient; [~~and~~]
330
331 (viii) date of issuance;
332
333 **(ix) if a faxed prescription:**
334 **(I) a statement that indicates that the prescription has been faxed (e.g., Faxed to);**
335 **and**
336 **(II) if transmitted by a designated agent, the full name of the designated agent;**
337
338 **(x) if electronically transmitted:**
339
340 **(I) the date the prescription drug order was electronically transmitted to the**
341 **pharmacy, if different from the date of issuance of the prescription; and**
342
343 **(II) if transmitted by a designated agent, the full name of the designated agent; and**
344
345 **(xii) if issued by an advanced practice nurse or physician assistant in accordance**
346 **with Subtitle B, Chapter 157, Occupations Code the;**
347
348 **(I) name, address, telephone number, and if the prescription is for a controlled**
349 **substance, the DEA number of the supervising practitioner; and**
350
351 **(II) address and telephone number of the clinic where the prescription drug order**
352 **was carried out or signed.**
353
354 [~~(B) All original electronic prescription drug orders shall bear:~~
355

356 ~~—(i) name of the patient, if such drug is for an animal, the species of such animal, and the~~
357 ~~name of the owner;~~
358
359 ~~—(ii) address of the patient, provided, however, a prescription for a dangerous drug is not~~
360 ~~required to bear the address of the patient if such address is readily retrievable on another~~
361 ~~appropriate, uniformly maintained pharmacy record, such as medication records;~~
362
363 ~~—(iii) name, and if for a controlled substance, the address and DEA registration number of the~~
364 ~~practitioner;~~
365
366 ~~—(iv) name and strength of the drug prescribed;~~
367
368 ~~—(v) quantity prescribed;~~
369
370 ~~—(vi) directions for use;~~
371
372 ~~—(vii) indications for use, unless the practitioner determines the furnishing of this information~~
373 ~~is not in the best interest of the patient;~~
374
375 ~~—(viii) date of issuance;~~
376
377 ~~—(ix) if a faxed prescription, a statement which indicates that the prescription has been faxed~~
378 ~~(e.g., Faxed to);~~
379
380 ~~—(x) telephone number of the prescribing practitioner;~~
381
382 ~~—(xi) date the prescription drug order was electronically transmitted to the pharmacy, if~~
383 ~~different from the date of issuance of the prescription; and~~
384
385 ~~—(xii) if transmitted by a designated agent, the full name of the designated agent.~~
386
387 ~~—(C) All original written prescriptions carried out or signed by an advanced practice nurse or~~
388 ~~physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code, shall bear:~~
389
390 ~~(i) name and address of the patient;~~
391
392 ~~—(ii) name, address, telephone number, and if the prescription is for a controlled substance,~~
393 ~~the DEA number of the supervising practitioner;~~
394
395 ~~—(iii) name, original signature, and if the prescription is for a controlled substance, the DEA~~
396 ~~number of the advanced practice nurse or physician assistant;~~
397
398 ~~—(iv) address and telephone number of the clinic at which the prescription drug order was~~
399 ~~carried out or signed;~~
400
401 ~~—(v) name, strength, and quantity of the drug;~~
402
403 ~~—(vi) directions for use;~~
404
405 ~~—(vii) indications for use, if appropriate;~~
406

407 —(viii) date of issuance; and
408
409 —(ix) number of refills authorized].

410 **(B)** ~~[(D)]~~ At the time of dispensing, a pharmacist is responsible for documenting the following
412 information on either the original **hard copy** ~~[hard-copy]~~ prescription or in the pharmacy's data
413 processing system:

414 (i) unique identification number of the prescription drug order;

415
416 (ii) initials or identification code of the dispensing pharmacist;

417
418 (iii) initials or identification code of the pharmacy technician or pharmacy technician trainee
419 performing data entry of the prescription, if applicable;

420
421 (iv) quantity dispensed, if different from the quantity prescribed;

422
423 (v) date of dispensing, if different from the date of issuance; and

424
425 (vi) brand name or manufacturer of the drug product actually dispensed, if the drug was
426 prescribed by generic name or if a drug product other than the one prescribed was dispensed
427 pursuant to the provisions of the Act, Chapters 562 and 563.

428
429 **(8)** ~~[(7)]~~ Refills.

430
431 (A) **General information.**

432
433 (i) Refills may be dispensed only in accordance with the prescriber's authorization as
434 indicated on the original prescription drug order except as authorized in paragraph
435 **(10)** ~~[(9)]~~ of this subsection relating to accelerated refills.

436
437 (ii) ~~[(B)]~~ If there are no refill instructions on the original prescription drug order (which
438 shall be interpreted as no refills authorized) or if all refills authorized on the original
439 prescription drug order have been dispensed, authorization from the prescribing
440 practitioner shall be obtained prior to dispensing any refills **and documented as**
441 **specified in subsection (I) of this section.**

442
443 **(B)** ~~[(C)]~~ Refills of prescription drug orders for dangerous drugs or nonprescription drugs.

444 (i) Prescription drug orders for dangerous drugs or nonprescription drugs may not be refilled
445 after one year from the date of issuance of the original prescription drug order.

446 (ii) If one year has expired from the date of issuance of an original prescription drug order for
447 a dangerous drug or nonprescription drug, authorization shall be obtained from the prescribing
448 practitioner prior to dispensing any additional quantities of the drug.

449
450 **(C)** ~~[(D)]~~ Refills of prescription drug orders for Schedules III-V controlled substances.

451 (i) Prescription drug orders for Schedules III-V controlled substances may not be refilled
452 more than five times or after six months from the date of issuance of the original prescription
453 drug order, whichever occurs first.

458
459 (ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been
460 refilled a total of five times or if six months have expired from the date of issuance of the original
461 prescription drug order, whichever occurs first, a new and separate prescription drug order shall
462 be obtained from the prescribing practitioner prior to dispensing any additional quantities of
463 controlled substances.

464
465 **(D) ~~[(E)]~~ Pharmacist unable to contact prescribing practitioner.** If a pharmacist is unable
466 to contact the prescribing practitioner after a reasonable effort, a pharmacist may exercise his
467 professional judgment in refilling a prescription drug order for a drug, other than a controlled
468 substance listed in Schedule II, without the authorization of the prescribing practitioner,
469 provided:

470
471 (i) failure to refill the prescription might result in an interruption of a therapeutic regimen or
472 create patient suffering;

473
474 (ii) the quantity of prescription drug dispensed does not exceed a 72-hour supply;

475
476 (iii) the pharmacist informs the patient or the patient's agent at the time of dispensing that
477 the refill is being provided without such authorization and that authorization of the practitioner is
478 required for future refills;

479
480 (iv) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable
481 time;

482
483 (v) the pharmacist maintains a record of the emergency refill containing the information
484 required to be maintained on a prescription as specified in this subsection;

485
486 (vi) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of
487 this title; and

488
489 (vii) if the prescription was initially filled at another pharmacy, the pharmacist may exercise
490 his professional judgment in refilling the prescription provided:

491
492 (I) the patient has the prescription container, label, receipt or other documentation from the
493 other pharmacy **that** ~~[which]~~ contains the essential information;

494
495 (II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to
496 transfer the remaining prescription refills or there are no refills remaining on the prescription;

497
498 (III) the pharmacist, in his professional judgment, determines that such a request for an
499 emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph;
500 and

501
502 (IV) the pharmacist complies with the requirements of clauses (ii) - (vi) of this
503 subparagraph.

504
505 **(E) ~~[(F)]~~ Natural or manmade disasters.** If a natural or manmade disaster has occurred
506 that prohibits the pharmacist from being able to contact the practitioner, a pharmacist
507 may exercise his professional judgment in refilling a prescription drug order for a drug,

508 other than a controlled substance listed in Schedule II, without the authorization of the
509 prescribing practitioner, provided:

510
511 (i) failure to refill the prescription might result in an interruption of a therapeutic regimen or
512 create patient suffering;

513
514 (ii) the quantity of prescription drug dispensed does not exceed a 30-day supply;

515
516 (iii) the governor has declared a state of disaster;

517
518 (iv) the board, through the executive director, has notified pharmacies that pharmacists may
519 dispense up to a 30-day supply of prescription drugs;

520
521 (v) the pharmacist informs the patient or the patient's agent at the time of dispensing that the
522 refill is being provided without such authorization and that authorization of the practitioner is
523 required for future refills;

524
525 (vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable
526 time;

527
528 (vii) the pharmacist maintains a record of the emergency refill containing the information
529 required to be maintained on a prescription as specified in this subsection;

530
531 (viii) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7)
532 of this title; and

533
534 (ix) if the prescription was initially filled at another pharmacy, the pharmacist may exercise
535 his professional judgment in refilling the prescription provided:

536
537 (I) the patient has the prescription container, label, receipt or other documentation from the
538 other pharmacy **that** ~~which~~ contains the essential information;

539
540 (II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to
541 transfer the remaining prescription refills or there are no refills remaining on the prescription;

542
543 (III) the pharmacist, in his professional judgment, determines that such a request for an
544 emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph;
545 and

546
547 (IV) the pharmacist complies with the requirements of clauses (ii) - (viii) of this
548 subparagraph.

549
550 **(F) Auto-Refill Programs. A pharmacy may use a program that automatically refills**
551 **prescriptions that have existing refills available in order to improve patient compliance**
552 **with and adherence to prescribed medication therapy (e.g, auto-refill programs). The**
553 **following is applicable to an auto-refill program.**

554
555 **(i) Notice of the availability of an auto-refill program shall be given to patients and**
556 **patients must sign a document indicating that they wish to enroll in such a program.**

557
558 **(ii) Patients shall have the option to withdraw from such a program at any time.**

559
560 (iii) Prescription refills for controlled substances may not be dispensed by an auto-
561 refill program.

562
563 (iv) As is required for all prescriptions, a drug regimen review shall be completed on
564 all prescriptions filled as a result of the auto-refill program. Special attention shall be
565 noted for drug regimen review warnings of duplication of therapy and all such conflicts
566 shall be resolved with the prescribing practitioner prior to refilling the prescription.

567
568 **(9)** ~~[(8)]~~ Records Relating to Dispensing Errors.

569
570 ~~[(A) For purposes of this subsection, a dispensing error is defined as an action committed by~~
571 ~~a pharmacist or other pharmacy personnel that causes the patient or patient's agent to take~~
572 ~~possession of a dispensed prescription drug and an individual subsequently discovers that the~~
573 ~~patient has received an incorrect drug product, which includes incorrect strength, incorrect~~
574 ~~dosage form, and/or incorrect directions for use.]~~

575
576 ~~[(B)]~~ If a dispensing error occurs, the following is applicable.

577
578 **(A)** ~~[(+)]~~ Original prescription drug orders:

579
580 **(i)** ~~[(+)]~~ shall not be destroyed and must be maintained in accordance with subsection (a) of
581 this section; and

582
583 **(ii)** ~~[(+)]~~ shall not be altered. Altering includes placing a label or any other item over any of
584 the information on the prescription drug order (e.g., a dispensing tag or label that is affixed to
585 back of a prescription drug order must not be affixed on top of another dispensing tag or label in
586 such a manner as to obliterate the information relating to the error).

587
588 **(B)** ~~[(+)]~~ Prescription drug order records maintained in a data processing system:

589
590 **(i)** ~~[(+)]~~ shall not be deleted and must be maintained in accordance with subsection (a) of
591 this section;

592
593 **(ii)** ~~[(+)]~~ may be changed only in compliance with subsection (e)(2)(B) of this section; and

594
595 **(iii)** ~~[(+)]~~ if the error involved incorrect data entry into the pharmacy's data processing
596 system, this record must be either voided or cancelled in the data processing system, so that
597 the incorrectly entered prescription drug order may not be dispensed, or the data processing
598 system must be capable of maintaining an audit trail showing any changes made to the data in
599 the system.

600 **(10)** ~~[(9)]~~ Accelerated refills. In accordance with §562.0545 of the Act, a pharmacist may
601 dispense up to a 90-day supply of a dangerous drug pursuant to a valid prescription that
602 specifies the dispensing of a lesser amount followed by periodic refills of that amount if:

603
604 (A) the total quantity of dosage units dispensed does not exceed the total quantity of dosage
605 units authorized by the prescriber on the original prescription, including refills;

606
607 (B) the patient consents to the dispensing of up to a 90-day supply and the physician has
608 been notified electronically or by telephone;

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(C) the physician has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary;

(D) the dangerous drug is not a psychotropic drug used to treat mental or psychiatric conditions; and

(E) the patient is at least 18 years of age.

(c) Patient medication records.

(1) A patient medication record system shall be maintained by the pharmacy for patients to whom prescription drug orders are dispensed.

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months that [~~which~~] is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a prescription drug order is presented for dispensing.

(3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(A) full name of the patient for whom the drug is prescribed;

(B) address and telephone number of the patient;

(C) patient's age or date of birth;

(D) patient's gender;

(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such list shall contain the following information:

(i) date dispensed;

(ii) name, strength, and quantity of the drug dispensed;

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

659 (4) A patient medication record shall be maintained in the pharmacy for two years. If patient
660 medication records are maintained in a data processing system, all of the information specified
661 in this subsection shall be maintained in a retrievable form for two years and information for the
662 previous 12 months shall be maintained on-line. A patient medication record must contain
663 documentation of any modification, change, or manipulation to a patient profile.
664

665 (5) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record,
666 and maintain patient information other than prescription drug order information when a patient or
667 patient's agent refuses to provide the necessary information for such patient medication
668 records.
669

670 (d) Prescription drug order records maintained in a manual system.

671 (1) Original prescriptions shall be maintained in three files as specified in subsection **(b)(6)(D)**
672 ~~[(b)(5)(D)]~~ of this section.
673

674 (2) Refills.

675 (A) Each time a prescription drug order is refilled, a record of such refill shall be made:
676

677 (i) on the back of the prescription by recording the date of dispensing, the written initials or
678 identification code of the dispensing pharmacist, the initials or identification code of the
679 pharmacy technician or pharmacy technician trainee preparing the prescription label, if
680 applicable, and the amount dispensed. (If the pharmacist merely initials and dates the back of
681 the prescription drug order, he or she shall be deemed to have dispensed a refill for the full face
682 amount of the prescription drug order); or
683
684

685 (ii) on another appropriate, uniformly maintained, readily retrievable record, such as
686 medication records, **that** ~~[which]~~ indicates by patient name the following information:
687

688 (I) unique identification number of the prescription;
689

690 (II) name and strength of the drug dispensed;
691

692 (III) date of each dispensing;
693

694 (IV) quantity dispensed at each dispensing;
695

696 (V) initials or identification code of the dispensing pharmacist;
697

698 (VI) initials or identification code of the pharmacy technician or pharmacy technician trainee
699 preparing the prescription label, if applicable; and
700

701 (VII) total number of refills for the prescription.
702

703 (B) If refill records are maintained in accordance with subparagraph (A)(ii) of this paragraph,
704 refill records for controlled substances in Schedules III-V shall be maintained separately from
705 refill records of dangerous drugs and nonprescription drugs.
706
707

708 (3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug
709 order shall be noted on the original prescription, in addition to the documentation of dispensing
710 the refill **as specified in subsection (l) of this section.**

711

712 ~~[(4) Transfer of prescription drug order information. For the purpose of refill or initial~~
713 ~~dispensing, the transfer of original prescription drug order information is permissible between~~
714 ~~pharmacies, subject to the following requirements:~~

715

716 ~~—(A) the transfer of original prescription drug order information for controlled substances listed~~
717 ~~in Schedule III, IV, or V is permissible between pharmacies on a one-time basis;~~

718

719 ~~—(B) the transfer of original prescription drug order information for dangerous drugs is~~
720 ~~permissible between pharmacies without limitation up to the number of originally authorized~~
721 ~~refills;~~

722

723 ~~—(C) the transfer is communicated directly between pharmacists [and/or pharmacist interns];~~

724

725 ~~—(D) both the original and the transferred prescription drug order are maintained for a period of~~
726 ~~two years from the date of last refill;~~

727

728 ~~—(E) the pharmacist [or pharmacist intern] transferring the prescription drug order information~~
729 ~~shall:~~

730

731 ~~—(i) write the word "void" on the face of the invalidated prescription drug order; and~~

732

733 ~~—(ii) record on the reverse of the invalidated prescription drug order the following information:~~

734

735 ~~—(I) the name, address, and if a controlled substance, the DEA registration number of the~~
736 ~~pharmacy to which such prescription drug order is transferred;~~

737

738 ~~—(II) the name of the pharmacist [or pharmacist intern] receiving the prescription drug order~~
739 ~~information;~~

740

741 ~~—(III) the name of the pharmacist [or pharmacist intern] transferring the prescription drug~~
742 ~~order information; and~~

743

744 ~~—(IV) the date of the transfer;~~

745

746 ~~—(F) the pharmacist or pharmacist intern receiving the transferred prescription drug order~~
747 ~~information shall:~~

748

749 ~~—(i) write the word "transfer" on the face of the transferred prescription drug order; and~~

750

751 ~~—(ii) record on the transferred prescription drug order the following information:~~

752

753 ~~—(I) original date of issuance and date of dispensing or receipt, if different from date of~~
754 ~~issuance;~~

755

756 ~~—(II) original prescription number and the number of refills authorized on the original~~
757 ~~prescription drug order;~~

758

759 ———(III) number of valid refills remaining and the date of last refill, if applicable;
760
761 ———(IV) name, address, and if a controlled substance, the DEA registration number of the
762 pharmacy from which such prescription information is transferred; and
763
764 ———(V) name of the pharmacist or pharmacist intern transferring the prescription drug order
765 information.

766
767 ~~(5) A pharmacist or pharmacist intern may not refuse to transfer original prescription~~
768 ~~information to another pharmacist or pharmacist intern who is acting on behalf of a patient and~~
769 ~~who is making a request for this information as specified in paragraph (4) of this subsection.]~~
770

771 **(3)** ~~[(6)]~~ Each time a modification, change, or manipulation is made to a record of dispensing,
772 documentation of such change shall be recorded on the back of the prescription or on another
773 appropriate, uniformly maintained, readily retrievable record, such as medication records. The
774 documentation of any modification, change, or manipulation to a record of dispensing shall
775 include the identification of the individual responsible for the alteration.
776

777 (e) Prescription drug order records maintained in a data processing system.

778
779 (1) General requirements for records maintained in a data processing system.

780
781 (A) Compliance with data processing system requirements. If a Class A ~~[(community)]~~
782 pharmacy's data processing system is not in compliance with this subsection, the pharmacy
783 must maintain a manual recordkeeping system as specified in subsection (d) of this section.
784

785 (B) Original prescriptions. Original prescriptions shall be maintained in three files as specified
786 in subsection **(b)(6)(D)** ~~[(b)(5)(D)]~~ of this section.
787

788 (C) Requirements for backup systems.

789
790 (i) The pharmacy shall maintain a backup copy of information stored in the data processing
791 system using disk, tape, or other electronic backup system and update this backup copy on a
792 regular basis, at least monthly, to assure that data is not lost due to system failure.
793

794 (ii) Data processing systems shall have a workable (electronic) data retention system **that**
795 ~~[which]~~ can produce an audit trail of drug usage for the preceding two years as specified in
796 paragraph (2)(H) of this subsection.
797

798 (D) Change or discontinuance of a data processing system.

799
800 (i) Records of dispensing. A pharmacy that changes or discontinues use of a data
801 processing system must:

802
803 (I) transfer the records of dispensing to the new data processing system; or

804
805 (II) purge the records of dispensing to a printout **that** ~~[which]~~ contains the same information
806 required on the daily printout as specified in paragraph (2)(C) of this subsection. The information
807 on this **hard copy** ~~[hard-copy]~~ printout shall be sorted and printed by prescription number and
808 list each dispensing for this prescription chronologically.
809

810 (ii) Other records. A pharmacy that changes or discontinues use of a data processing
811 system must:
812
813 (I) transfer the records to the new data processing system; or
814
815 (II) purge the records to a printout that [~~which~~] contains all of the information required on
816 the original document.
817
818 (iii) Maintenance of purged records. Information purged from a data processing system must
819 be maintained by the pharmacy for two years from the date of initial entry into the data
820 processing system.
821
822 (E) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant
823 loss of information from the data processing system within 10 days of discovery of the loss.
824
825 (2) Records of dispensing.
826
827 (A) Each time a prescription drug order is filled or refilled, a record of such dispensing shall
828 be entered into the data processing system.
829
830 (B) Each time a modification, change or manipulation is made to a record of dispensing,
831 documentation of such change shall be recorded in the data processing system. The
832 documentation of any modification, change, or manipulation to a record of dispensing shall
833 include the identification of the individual responsible for the alteration. Should the data
834 processing system not be able to record a modification, change, or manipulation to a record of
835 dispensing, the information should be clearly documented on the hard copy [~~hardcopy~~]
836 prescription.
837
838 (C) The data processing system shall have the capacity to produce a daily hard copy [~~hard-~~
839 ~~copy~~] printout of all original prescriptions dispensed and refilled. This hard copy [~~hard-copy~~]
840 printout shall contain the following information:
841
842 (i) unique identification number of the prescription;
843
844 (ii) date of dispensing;
845
846 (iii) patient name;
847
848 (iv) prescribing practitioner's name; and the supervising physician's name if the prescription
849 was issued by an advanced practice nurse, physician assistant or pharmacist;
850
851 (v) name and strength of the drug product actually dispensed; if generic name, the brand
852 name or manufacturer of drug dispensed;
853
854 (vi) quantity dispensed;
855
856 (vii) initials or an identification code of the dispensing pharmacist;
857
858 (viii) initials or an identification code of the pharmacy technician or pharmacy technician
859 trainee performing data entry of the prescription, if applicable;
860

861 (ix) if not immediately retrievable via computer [CRT] display, the following shall also be
862 included on the hard copy [~~hard-copy~~] printout:

863

864 (I) patient's address;

865

866 (II) prescribing practitioner's address;

867

868 (III) practitioner's DEA registration number, if the prescription drug order is for a controlled
869 substance;

870

871 (IV) quantity prescribed, if different from the quantity dispensed;

872

873 (V) date of issuance of the prescription drug order, if different from the date of dispensing;
874 and

875

876 (VI) total number of refills dispensed to date for that prescription drug order; and

877

878 (x) any changes made to a record of dispensing.

879

880 (D) The daily hard copy [~~hard-copy~~] printout shall be produced within 72 hours of the date on
881 which the prescription drug orders were dispensed and shall be maintained in a separate file at
882 the pharmacy. Records of controlled substances shall be readily retrievable from records of
883 noncontrolled substances.

884

885 (E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify
886 that the data indicated on the daily hard copy [~~hard-copy~~] printout is correct, by dating and
887 signing such document in the same manner as signing a check or legal document (e.g., J.H.
888 Smith, or John H. Smith) within seven days from the date of dispensing.

889

890 (F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall
891 maintain a log book in which each individual pharmacist using the data processing system shall
892 sign a statement each day, attesting to the fact that the information entered into the data
893 processing system that day has been reviewed by him or her and is correct as entered. Such
894 log book shall be maintained at the pharmacy employing such a system for a period of two
895 years after the date of dispensing; provided, however, that the data processing system can
896 produce the hard copy [~~hard-copy~~] printout on demand by an authorized agent of the Texas
897 State Board of Pharmacy. If no printer is available on site, the hard copy [~~hard-copy~~] printout
898 shall be available within 72 hours with a certification by the individual providing the printout, that
899 [~~which~~] states that the printout is true and correct as of the date of entry and such information
900 has not been altered, amended, or modified.

901

902 (G) The pharmacist-in-charge is responsible for the proper maintenance of such records and
903 responsible that such data processing system can produce the records outlined in this section
904 and that such system is in compliance with this subsection.

905

906 (H) The data processing system shall be capable of producing a hard copy [~~hard-copy~~]
907 printout of an audit trail for all dispensings (original and refill) of any specified strength and
908 dosage form of a drug (by either brand or generic name or both) during a specified time period.

909

910 (i) Such audit trail shall contain all of the information required on the daily printout as set out
911 in subparagraph (C) of this paragraph.

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(ii) The audit trail required in this subparagraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

(I) Failure to provide the records set out in this subsection, either on site or within 72 hours constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(J) The data processing system shall provide on-line retrieval (via **computer** [CRT] display or **hard copy** [hard-copy] printout) of the information set out in subparagraph (C) of this paragraph of:

(i) the original controlled substance prescription drug orders currently authorized for refilling; and

(ii) the current refill history for Schedules III, IV, and V controlled substances for the immediately preceding six-month period.

(K) In the event that a pharmacy **that** [which] uses a data processing system experiences system downtime, the following is applicable:

(i) an auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or authorization from the prescribing practitioner shall be obtained prior to dispensing a refill; and

(ii) all of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

- (A) on the **hard copy** [hard-copy] prescription drug order;
- (B) on the daily **hard copy** [hard-copy] printout; or
- (C) via the **computer** [CRT] display.

~~[(4) Transfer of prescription drug order information. For the purpose of refill or initial dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements.~~

~~—(A) The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.~~

~~—(B) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.~~

~~—(C) The transfer is communicated directly between pharmacists and/or pharmacist interns orally by telephone or via facsimile or as authorized in paragraph (5) of this subsection. A~~

963 ~~transfer completed as authorized in paragraph (5) of this subsection may be initiated by a~~
964 ~~pharmacy technician or pharmacy technician trainee acting under the direct supervision of a~~
965 ~~pharmacist.~~
966
967 ~~—(D) Both the original and the transferred prescription drug orders are maintained for a period~~
968 ~~of two years from the date of last refill.~~
969
970 ~~—(E) The pharmacist or pharmacist intern transferring the prescription drug order information~~
971 ~~shall ensure the following occurs:~~
972
973 ~~—(i) the prescription is voided in the data processing system; and~~
974
975 ~~—(ii) the following information is stored with the invalidated prescription drug order in the data~~
976 ~~processing system:~~
977
978 ~~—(I) the name, address, and if a controlled substance, the DEA registration number of the~~
979 ~~pharmacy to which such prescription is transferred;~~
980
981 ~~—(II) the name of the pharmacist or pharmacist intern receiving the prescription drug order~~
982 ~~information;~~
983
984 ~~—(III) the name of the pharmacist or pharmacist intern transferring the prescription drug~~
985 ~~order information; and~~
986
987 ~~—(IV) the date of the transfer.~~
988
989 ~~—(F) The pharmacist or pharmacist intern receiving the transferred prescription drug order~~
990 ~~information shall ensure the following occurs:~~
991
992 ~~—(i) the prescription record indicates the prescription was a transfer; and~~
993
994 ~~—(ii) the following information is stored with the prescription drug order in the data processing~~
995 ~~system:~~
996
997 ~~—(I) original date of issuance and date of dispensing or receipt, if different from date of~~
998 ~~issuance;~~
999
1000 ~~—(II) original prescription number and the number of refills authorized on the original~~
1001 ~~prescription drug order;~~
1002
1003 ~~—(III) number of valid refills remaining and the date of last refill, if applicable;~~
1004
1005 ~~—(IV) name, address, and if a controlled substance, the DEA registration number of the~~
1006 ~~pharmacy from which such prescription drug order information is transferred; and~~
1007
1008 ~~—(V) name of the pharmacist or pharmacist intern transferring the prescription drug order~~
1009 ~~information.~~
1010
1011 ~~—(G) Prescription drug orders may not be transferred by non-electronic means during periods~~
1012 ~~of downtime except on consultation with and authorization by a prescribing practitioner;~~
1013 ~~provided however, during downtime, a hard copy of a prescription drug order may be made~~

1014 available for informational purposes only, to the patient, a pharmacist [or pharmacist intern], and
1015 the prescription may be read to a pharmacist or pharmacist intern by telephone.

1016
1017 ~~—(H) The original prescription drug order shall be invalidated in the data processing system for~~
1018 ~~purposes of filling or refilling, but shall be maintained in the data processing system for refill~~
1019 ~~history purposes.~~

1020
1021 ~~—(I) If the data processing system does not have the capacity to store all the information~~
1022 ~~required in subparagraphs (E) and (F) of this paragraph, the pharmacist is required to record~~
1023 ~~this information on the original or transferred prescription drug order.~~

1024
1025 ~~—(J) The data processing system shall have a mechanism to prohibit the transfer or refilling of~~
1026 ~~controlled substance prescription drug orders which have been previously transferred.]~~

1027
1028 ~~[(5) Electronic transfer of prescription drug order information between pharmacies. Pharmacies~~
1029 ~~electronically accessing the same prescription drug order records may electronically transfer~~
1030 ~~prescription information if the following requirements are met.~~

1031
1032 ~~—(A) The original prescription is voided and the following information is documented in the~~
1033 ~~records of the transferring pharmacy:~~

1034
1035 ~~—(i) the name, address, and if a controlled substance, the DEA registration number of the~~
1036 ~~pharmacy to which such prescription is transferred;~~

1037
1038 ~~—(ii) the name of the pharmacist or pharmacist intern receiving the prescription drug order~~
1039 ~~information; and~~

1040
1041 ~~—(iii) the date of the transfer.~~

1042
1043 ~~—(B) Pharmacies not owned by the same person may electronically access the same~~
1044 ~~prescription drug order records, provided the owner or chief executive officer of each pharmacy~~
1045 ~~signs an agreement allowing access to such prescription drug order records.~~

1046
1047 ~~—(C) An electronic transfer between pharmacies may be initiated by a pharmacy technician or~~
1048 ~~pharmacy technician trainee acting under the direct supervision of a pharmacist.]~~

1049
1050 ~~[(6) A pharmacist or pharmacist intern may not refuse to transfer original prescription~~
1051 ~~information to another pharmacist or pharmacist intern who is acting on behalf of a patient and~~
1052 ~~who is making a request for this information as specified in paragraphs (4) and (5) of this~~
1053 ~~subsection.]~~

1054
1055 (f) Limitation to one type of recordkeeping system. When filing prescription drug order
1056 information a pharmacy may use only one of the two systems described in subsection (d) or (e)
1057 of this section.

1058
1059 **(g) Transfer of prescription drug order information. For the purpose of initial or refill**
1060 **dispensing, the transfer of original prescription drug order information is permissible**
1061 **between pharmacies, subject to the following requirements.**

1062
1063 **(1) The transfer of original prescription drug order information for controlled**
1064 **substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-**

1065 time basis only. However, pharmacies electronically sharing a real-time, on-line database
1066 may transfer up to the maximum refills permitted by law and the prescriber's
1067 authorization.

1068
1069 (2) The transfer of original prescription drug order information for dangerous drugs is
1070 permissible between pharmacies without limitation up to the number of originally
1071 authorized refills.

1072
1073 (3) The transfer is communicated directly between pharmacists orally by telephone or
1074 via facsimile or as authorized in paragraph (9)(E) of this subsection. A transfer completed
1075 as authorized in paragraph (9)(E) of this subsection may be initiated by a pharmacy
1076 technician or pharmacy technician trainee acting under the direct supervision of a
1077 pharmacist.

1078
1079 (4) Both the original and the transferred prescription drug orders are maintained for a
1080 period of two years from the date of last refill.

1081
1082 (5) The pharmacist transferring the prescription drug order information shall ensure
1083 the following occurs:

1084
1085 (A) write the word "void" on the face of the invalidated prescription or the
1086 prescription is voided in the data processing system; and

1087
1088 (B) the following information is recorded on the reverse of the invalidated
1089 prescription drug order or stored with the invalidated prescription drug order in the data
1090 processing system:

1091
1092 (i) the name, address, and if a controlled substance, the DEA registration number of
1093 the pharmacy to which such prescription is transferred;

1094
1095 (ii) the name of the pharmacist receiving the prescription drug order information;

1096
1097 (iii) the name of the pharmacist transferring the prescription drug order information;
1098 and

1099
1100 (iv) the date of the transfer.

1101
1102 (6) The pharmacist receiving the transferred prescription drug order information shall
1103 ensure the following occurs:

1104
1105 (A) write the word "transfer" on the face of the prescription or the prescription record
1106 indicates the prescription was a transfer; and

1107
1108 (B) the following information if recorded on the prescription drug order or is stored
1109 with the prescription drug order in the data processing system:

1110
1111 (i) original date of issuance and date of dispensing or receipt, if different from date
1112 of issuance;

1113
1114 (ii) original prescription number and the number of refills authorized on the original
1115 prescription drug order;

1116
1117 (iii) number of valid refills remaining and the date of last refill, if applicable;
1118
1119 (iv) name, address, and if a controlled substance, the DEA registration number of
1120 the pharmacy from which such prescription drug order information is transferred; and
1121
1122 (v) name of the pharmacist transferring the prescription drug order information.
1123
1124 (7) Both the pharmacist transferring the prescription and the pharmacist receiving the
1125 prescription must engage in confirmation of the prescription information by such means
1126 as:
1127
1128 (A) the transferring pharmacist faxes the hard-copy prescription to the receiving
1129 pharmacist; or
1130 (B) the receiving pharmacist repeats the verbal information from the transferring
1131 pharmacist and the transferring pharmacist verbally confirms that the repeated
1132 information is correct.
1133
1134 (8) If an error is made in transferring a prescription, both the transferring and receiving
1135 pharmacist shall be responsible for the error.
1136
1137 (9) Pharmacies using a data processing system shall comply with the following:
1138
1139 (A) Prescription drug orders may not be transferred by non-electronic means during
1140 periods of downtime except on consultation with and authorization by a prescribing
1141 practitioner; provided however, during downtime, a hard copy of a prescription drug
1142 order may be made available for informational purposes only, to the patient, a
1143 pharmacist, and the prescription may be read to a pharmacist by telephone.
1144
1145 (B) The original prescription drug order shall be invalidated in the data processing
1146 system for purposes of filling or refilling, but shall be maintained in the data processing
1147 system for refill history purposes.
1148
1149 (C) If the data processing system does not have the capacity to store all the
1150 information required in paragraphs (5) and (6) of this subsection, the pharmacist is
1151 required to record this information on the original or transferred prescription drug order.
1152
1153 (D) The data processing system shall have a mechanism to prohibit the transfer or
1154 refilling of controlled substance prescription drug orders that have been previously
1155 transferred.
1156
1157 (E) Pharmacies electronically accessing the same prescription drug order records may
1158 electronically transfer prescription information if the following requirements are met.
1159
1160 (i) The original prescription is voided and the pharmacies' data processing systems
1161 shall store all the information required in paragraphs (5) and (6) of this subsection,
1162
1163 (ii) Pharmacies not owned by the same person may electronically access the same
1164 prescription drug order records, provided the owner or chief executive officer of each
1165 pharmacy signs an agreement allowing access to such prescription drug order records.
1166

1167 (iii) An electronic transfer between pharmacies may be initiated by a pharmacy
1168 technician or pharmacy technician trainee acting under the direct supervision of a
1169 pharmacist.

1170
1171 (10) A pharmacist may not refuse to transfer original prescription information to another
1172 pharmacist who is acting on behalf of a patient and who is making a request for this
1173 information as specified in this subsection.

1174
1175 **(h)** ~~(g)~~ Distribution of controlled substances to another registrant. A pharmacy may distribute
1176 controlled substances to a practitioner, another pharmacy, or other registrant, without being
1177 registered to distribute, under the following conditions.

1178
1179 (1) The registrant to whom the controlled substance is to be distributed is registered under the
1180 Controlled Substances Act to dispense that controlled substance.

1181
1182 (2) The total number of dosage units of controlled substances distributed by a pharmacy may
1183 not exceed 5.0% of all controlled substances dispensed and distributed by the pharmacy during
1184 the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the
1185 pharmacy is required to obtain an additional registration to distribute controlled substances.

1186
1187 (3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
1188 maintained **that** ~~which~~ indicates:

1189 (A) the actual date of distribution;

1190 (B) the name, strength, and quantity of controlled substances distributed;

1191 (C) the name, address, and DEA registration number of the distributing pharmacy; and

1192 (D) the name, address, and DEA registration number of the pharmacy, practitioner, or other
1193 registrant to whom the controlled substances are distributed.

1194 (4) If the distribution is for a Schedule ~~I-IV~~ II controlled substance, the following is applicable.

1195 (A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
1196 shall issue Copy 1 and Copy 2 of a DEA order form **(DEA 222)** ~~((DEA-222C))~~ to the distributing
1197 pharmacy.

1198 (B) The distributing pharmacy shall:

1199 (i) complete the area on the DEA order form **(DEA 222)** ~~((DEA-222C))~~ titled "To Be Filled in
1200 by Supplier";

1201 (ii) maintain Copy 1 of the DEA order form **(DEA 222)** ~~((DEA-222C))~~ at the pharmacy for two
1202 years; and

1203 (iii) forward Copy 2 of the DEA order form **(DEA 222)** ~~((DEA-222C))~~ to the Divisional Office
1204 of the Drug Enforcement Administration.

1205 **(i)** ~~(h)~~ Other records. Other records to be maintained by a pharmacy:

1206
1207
1208
1209
1210
1211
1212
1213
1214
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1216
1217

1218 (1) a permanent log of the initials or identification codes that ~~[which]~~ will identify each
1219 pharmacist, pharmacy technician, and pharmacy technician trainee by name performing data
1220 entry of prescription information (the initials or identification code shall be unique to ensure that
1221 each individual can be identified, i.e., identical initials or identification codes shall not be used);
1222

1223 (2) Copy 3 of DEA order form **(DEA 222)** ~~[(DEA-222C)]~~ that ~~[which]~~ has been properly dated,
1224 initialed, and filed, and all copies of each unaccepted or defective order form and any attached
1225 statements or other documents **and/or for each order filled using the DEA Controlled**
1226 **Substance Ordering System (CSOS) the original signed order and all linked records for**
1227 **that order**;

1228
1229 (3) a hard copy of the power of attorney to sign **(DEA 222)** ~~[(DEA-222C)]~~ order forms (if
1230 applicable);

1231
1232 (4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify
1233 that the controlled drugs listed on the invoices were actually received by clearly recording
1234 his/her initials and the actual date of receipt of the controlled substances;

1235
1236 (5) suppliers' credit memos for controlled substances and dangerous drugs;

1237
1238 (6) a hard copy of inventories required by §291.17 of this title (relating to Inventory
1239 Requirements);

1240
1241 (7) **hard copy** ~~[hard-copy]~~ reports of surrender or destruction of controlled substances and/or
1242 dangerous drugs to an appropriate state or federal agency;

1243
1244 (8) a hard copy of the Schedule V nonprescription register book;

1245
1246 (9) records of distribution of controlled substances and/or dangerous drugs to other
1247 pharmacies, practitioners, or registrants; and

1248
1249 (10) a hard copy of any notification required by the Texas Pharmacy Act or the sections in this
1250 chapter, including, but not limited to, the following:

1251
1252 (A) reports of theft or significant loss of controlled substances to DEA, Department of Public
1253 Safety, and the board;

1254
1255 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and

1256
1257 (C) reports of a fire or other disaster that ~~[which]~~ may affect the strength, purity, or labeling of
1258 drugs, medications, devices, or other materials used in the diagnosis or treatment of injury,
1259 illness, and disease.

1260 **(i)** ~~[(i)]~~ Permission to maintain central records. Any pharmacy that uses a centralized
1262 recordkeeping system for invoices and financial data shall comply with the following procedures.

1263
1264 (1) Controlled substance records. Invoices and financial data for controlled substances may be
1265 maintained at a central location provided the following conditions are met.

1266
1267 (A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by
1268 registered or certified mail to the divisional director of the Drug Enforcement Administration as

1269 required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this
1270 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by
1271 the divisional director of the Drug Enforcement Administration that permission to keep central
1272 records is denied, the pharmacy may maintain central records commencing 14 days after
1273 receipt of notification by the divisional director.

1274
1275 (B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this
1276 paragraph.

1277
1278 (C) The records to be maintained at the central record location shall not include executed
1279 DEA order forms, prescription drug orders, or controlled substance inventories, **that** [which]
1280 shall be maintained at the pharmacy.

1281
1282 (2) Dangerous drug records. Invoices and financial data for dangerous drugs may be
1283 maintained at a central location.

1284
1285 (3) Access to records. If the records are kept on microfilm, computer media, or in any form
1286 requiring special equipment to render the records easily readable, the pharmacy shall provide
1287 access to such equipment with the records.

1288
1289 (4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the
1290 pharmacy location within two business days of written request of a board agent or any other
1291 authorized official.

1292
1293 **(k)** [~~(j)~~] Ownership of pharmacy records. For the purposes of these sections, a pharmacy
1294 licensed under the Act is the only entity **that** [which] may legally own and maintain prescription
1295 drug records.

1296
1297 **(l) Documentation of consultation. When a pharmacist consults a prescriber as**
1298 **described in this section, the pharmacist shall document on the hard copy or in the**
1299 **pharmacy's data processing system associated with the prescription such occurrences**
1300 **and shall include the following information**

1301
1302 **(i) date the prescriber was consulted;**

1303
1304 **(ii) name of the person communicating the prescriber's instructions;**

1305
1306 **(iii) any applicable information pertaining to the consultation; and**

1307
1308 **(iv) initials or identification code of the pharmacist performing the consultation**
1309 **clearly recorded for the purpose of identifying the pharmacist who performed the**
1310 **consultation if on the information is recorded on the hard copy prescription.**

1311