

RULE ANALYSIS

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

Short Title: Out-of-state plans

Rule Numbers: §291.34

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, 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, implement provisions of S.B. 195 passed during the 2015 Texas Legislative session which update the requirements regarding Class A pharmacies dispensing schedule II controlled substance prescriptions issued by prescribers licensed in a state other than Texas to require the plan be approved by the Texas State Board of 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 of
11 this chapter (relating to Community Pharmacy (Class A)) shall be:
12

13 (A) kept by the pharmacy at the pharmacy's licensed location and be available, for at least
14 two years from the date of such inventory or record, for inspecting and copying by the board or
15 its representative and to other authorized local, state, or federal law enforcement agencies; and
16

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

24 (2) Records of controlled substances listed in Schedule II shall be maintained separately from
25 all other records of the pharmacy.
26

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

33 (4) Records, except when specifically required to be maintained in original or hard copy form,
34 may be maintained in an alternative data retention system, such as a data processing system or
35 direct imaging system provided:
36

37 (A) the records maintained in the alternative system contain all of the information required on
38 the manual record; and
39

40 (B) the data processing system is capable of producing a hard copy of the record upon the
41 request of the board, its representative, or other authorized local, state, or federal law
42 enforcement or regulatory agencies.
43

44 (b) Prescriptions.
45

46 (1) Professional responsibility.
47

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

52
53 (B) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound
54 professional judgment, that the prescription is a valid prescription. A pharmacist may not
55 dispense a prescription drug unless the pharmacist complies with the requirements of §562.056
56 of the Act, and §291.29 of this title (relating to Professional Responsibility of Pharmacists).
57

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

62 (2) Written prescription drug orders.

63
64 (A) Practitioner's signature.

65
66 (i) Dangerous drug prescription orders. Written prescription drug orders shall be:

67
68 (I) manually signed by the practitioner; or

69
70 (II) electronically signed by the practitioner using a system that electronically replicates the
71 practitioner's manual signature on the written prescription, provided:

72
73 (-a-) that security features of the system require the practitioner to authorize each use;
74 and

75
76 (-b-) the prescription is printed on paper that is designed to prevent unauthorized copying
77 of a completed prescription and to prevent the erasure or modification of information written on
78 the prescription by the prescribing practitioner. (For example, the paper contains security
79 provisions against copying that results in some indication on the copy that it is a copy and
80 therefore render the prescription null and void.)

81
82 (ii) Controlled substance prescription orders. Prescription drug orders for Schedule II, III, IV,
83 or V controlled substances shall be manually signed by the practitioner. Prescription drug orders
84 for Schedule II controlled substances shall be issued on an official prescription form as required
85 by the Texas Controlled Substances Act, §481.075.

86
87 (iii) Other provisions for a practitioner's signature.

88
89 (I) A practitioner may sign a prescription drug order in the same manner as he would sign a
90 check or legal document, e.g., J.H. Smith or John H. Smith.

91
92 (II) Rubber stamped or otherwise reproduced signatures may not be used except as
93 authorized in clause (i) of this subparagraph.

94
95 (III) The prescription drug order may not be signed by a practitioner's agent but may be
96 prepared by an agent for the signature of a practitioner. However, the prescribing practitioner is
97 responsible in case the prescription drug order does not conform in all essential respects to the
98 law and regulations.

99
100 (B) Prescription drug orders written by practitioners in another state.
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102 (i) Dangerous drug prescription orders. A pharmacist may dispense a prescription drug
103 order for dangerous drugs issued by practitioners in a state other than Texas in the same
104 manner as prescription drug orders for dangerous drugs issued by practitioners in Texas are
105 dispensed.

106
107 (ii) Controlled substance prescription drug orders.

108
109 (I) A pharmacist may dispense prescription drug order for controlled substances in
110 Schedule II issued by a practitioner in another state provided:

111
112 (-a-) the prescription is **dispensed as specified in §315.9 of this title (relating to**
113 **Pharmacy Responsibility - Out-of-State Practitioner - Effective September 1, 2016)** ~~[filled in~~
114 ~~compliance with a written plan approved by the Director of the Texas Department of Public~~
115 ~~Safety in consultation with the Board, which provides the manner in which the dispensing~~
116 ~~pharmacy may fill a prescription for a Schedule II controlled substance];~~

117
118 (-b-) the prescription drug order is an original written prescription issued by a person
119 practicing in another state and licensed by another state as a physician, dentist, veterinarian, or
120 podiatrist, who has a current federal Drug Enforcement Administration (DEA) registration
121 number, and who may legally prescribe Schedule II controlled substances in such other state;
122 and

123
124 (-c-) the prescription drug order is not dispensed after the end of the twenty-first day after
125 the date on which the prescription is issued.

126
127 (II) A pharmacist may dispense prescription drug orders for controlled substances in
128 Schedule III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state
129 provided:

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131 (-a-) the prescription drug order is issued by a person practicing in another state and
132 licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current
133 federal DEA registration number, and who may legally prescribe Schedule III, IV, or V controlled
134 substances in such other state;

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

138
139 (-c-) if there are no refill instructions on the original prescription drug order (which shall be
140 interpreted as no refills authorized) or if all refills authorized on the original prescription drug
141 order have been dispensed, a new prescription drug order is obtained from the prescribing
142 practitioner prior to dispensing any additional quantities of controlled substances.

143
144 (C) Prescription drug orders written by practitioners in the United Mexican States or the
145 Dominion of Canada.

146
147 (i) Controlled substance prescription drug orders. A pharmacist may not dispense a
148 prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a
149 practitioner in the Dominion of Canada or the United Mexican States.

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

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

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

160 (D) Prescription drug orders issued by an advanced practice registered nurse, physician
161 assistant, or pharmacist.

162 (i) A pharmacist may dispense a prescription drug order that is:

163 (I) issued by an advanced practice registered nurse or physician assistant provided the
164 advanced practice registered nurse or physician assistant is practicing in accordance with
165 Subtitle B, Chapter 157, Occupations Code; and

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

168 (ii) Each practitioner shall designate in writing the name of each advanced practice
169 registered nurse or physician assistant authorized to issue a prescription drug order pursuant to
170 Subtitle B, Chapter 157, Occupations Code. A list of the advanced practice registered nurses or
171 physician assistants designated by the practitioner must be maintained in the practitioner's
172 usual place of business. On request by a pharmacist, a practitioner shall furnish the pharmacist
173 with a copy of the written authorization for a specific advanced practice registered nurse or
174 physician assistant.

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

178 (3) Verbal prescription drug orders.

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

182 (B) A practitioner shall designate in writing the name of each agent authorized by the
183 practitioner to communicate prescriptions verbally for the practitioner. The practitioner shall
184 maintain at the practitioner's usual place of business a list of the designated agents. The
185 practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a
186 specific agent on the pharmacist's request.

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

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(4) Electronic prescription drug orders.

(A) Dangerous drug prescription orders.

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

(I) directly to a pharmacy; or

(II) through the use of a data communication device provided:

(-a-) the confidential prescription information is not altered during transmission; and

(-b-) confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

(ii) A practitioner shall designate in writing the name of each agent authorized by the practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(B) Controlled substance prescription orders. A pharmacist may only dispense an electronic prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with the federal and state laws and the rules of the Drug Enforcement Administration outlined in Part 1300 of the Code of Federal Regulations and Texas Department of Public Safety.

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

(5) Facsimile (faxed) prescription drug orders.

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

(B) A pharmacist may dispense a prescription drug order for a Schedule III-V controlled substance transmitted to the pharmacy by facsimile provided the prescription is manually signed by the practitioner and not electronically signed using a system that electronically replicates the practitioner's manual signature on the prescription drug order.

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

(6) Original prescription drug order records.

(A) Original prescriptions may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order including clarifications to the

253 order given to the pharmacist by the practitioner or the practitioner's agent and recorded on the
254 prescription.

255

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

258

259 (C) If an original prescription drug order is changed, such prescription order shall be invalid
260 and of no further force and effect; if additional drugs are to be dispensed, a new prescription
261 drug order with a new and separate number is required. However, an original prescription drug
262 order for a dangerous drug may be changed in accordance with paragraph (10) of this
263 subsection relating to accelerated refills.

264

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

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

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

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271 (iii) prescriptions for dangerous drugs and nonprescription drugs.

272

273 (E) Original prescription records other than prescriptions for Schedule II controlled
274 substances may be stored in a system that is capable of producing a direct image of the original
275 prescription record, e.g., digitalized imaging system. If original prescription records are stored in
276 a direct imaging system, the following is applicable:

277

278 (i) the record of refills recorded on the original prescription must also be stored in this
279 system;

280

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

283

284 (iii) the pharmacy must provide immediate access to equipment necessary to render the
285 records easily readable.

286

287 (7) Prescription drug order information.

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289 (A) All original prescriptions shall bear:

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

293

294 (ii) address of the patient, provided, however, a prescription for a dangerous drug is not
295 required to bear the address of the patient if such address is readily retrievable on another
296 appropriate, uniformly maintained pharmacy record, such as medication records;

297

298 (iii) name, address and telephone number of the practitioner at the practitioner's usual place
299 of business, legibly printed or stamped and if for a controlled substance, the DEA registration
300 number of the practitioner;

301

302 (iv) name and strength of the drug prescribed;

303

304 (v) quantity prescribed numerically and if for a controlled substance:
305
306 (I) numerically, followed by the number written as a word, if the prescription is written;
307
308 (II) numerically, if the prescription is electronic; or
309
310 (III) if the prescription is communicated orally or telephonically, as transcribed by the
311 receiving pharmacist;
312
313 (vi) directions for use;
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315 (vii) intended use for the drug unless the practitioner determines the furnishing of this
316 information is not in the best interest of the patient;
317
318 (viii) date of issuance;
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320 (ix) if a faxed prescription:
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322 (I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and
323
324 (II) if transmitted by a designated agent, the name of the designated agent;
325
326 (x) if electronically transmitted:
327
328 (I) the date the prescription drug order was electronically transmitted to the pharmacy, if
329 different from the date of issuance of the prescription; and
330
331 (II) if transmitted by a designated agent, the name of the designated agent; and
332
333 (xi) if issued by an advanced practice nurse or physician assistant in accordance with
334 Subtitle B, Chapter 157, Occupations Code the:
335
336 (I) name, address, telephone number, and if the prescription is for a controlled substance,
337 the DEA number of the supervising practitioner; and
338
339 (II) address and telephone number of the clinic where the prescription drug order was
340 carried out or signed.
341
342 (B) At the time of dispensing, a pharmacist is responsible for documenting the following
343 information on either the original hard copy prescription or in the pharmacy's data processing
344 system:
345
346 (i) unique identification number of the prescription drug order;
347
348 (ii) initials or identification code of the dispensing pharmacist;
349
350 (iii) initials or identification code of the pharmacy technician or pharmacy technician trainee
351 performing data entry of the prescription, if applicable;
352
353 (iv) quantity dispensed, if different from the quantity prescribed;
354

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

356

357 (vi) brand name or manufacturer of the drug or biological product actually dispensed, if the
358 drug was prescribed by generic name or interchangeable biological name or if a drug or
359 interchangeable biological product other than the one prescribed was dispensed pursuant to the
360 provisions of the Act, Chapters 562 and 563.

361

362 (8) Refills.

363

364 (A) General information.

365

366 (i) Refills may be dispensed only in accordance with the prescriber's authorization as
367 indicated on the original prescription drug order except as authorized in paragraph (10) of this
368 subsection relating to accelerated refills.

369

370 (ii) If there are no refill instructions on the original prescription drug order (which shall be
371 interpreted as no refills authorized) or if all refills authorized on the original prescription drug
372 order have been dispensed, authorization from the prescribing practitioner shall be obtained
373 prior to dispensing any refills and documented as specified in subsection (l) of this section.

374

375 (B) Refills of prescription drug orders for dangerous drugs or nonprescription drugs.

376

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

379

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

383

384 (C) Refills of prescription drug orders for Schedules III-V controlled substances.

385

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

389

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

395

396 (D) Pharmacist unable to contact prescribing practitioner. If a pharmacist is unable to contact
397 the prescribing practitioner after a reasonable effort, a pharmacist may exercise his professional
398 judgment in refilling a prescription drug order for a drug, other than a controlled substance listed
399 in Schedule II, without the authorization of the prescribing practitioner, provided:

400

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

403

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

405

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

409
410 (iv) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable
411 time;

412
413 (v) the pharmacist maintains a record of the emergency refill containing the information
414 required to be maintained on a prescription as specified in this subsection;

415
416 (vi) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of
417 this title; and

418
419 (vii) if the prescription was initially filled at another pharmacy, the pharmacist may exercise
420 his professional judgment in refilling the prescription provided:

421
422 (I) the patient has the prescription container, label, receipt or other documentation from the
423 other pharmacy that contains the essential information;

424
425 (II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to
426 transfer the remaining prescription refills or there are no refills remaining on the prescription;

427
428 (III) the pharmacist, in his professional judgment, determines that such a request for an
429 emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph;
430 and

431
432 (IV) the pharmacist complies with the requirements of clauses (ii) - (vi) of this
433 subparagraph.

434
435 (E) Natural or manmade disasters. If a natural or manmade disaster has occurred that
436 prohibits the pharmacist from being able to contact the practitioner, a pharmacist may exercise
437 his professional judgment in refilling a prescription drug order for a drug, other than a controlled
438 substance listed in Schedule II, without the authorization of the prescribing practitioner,
439 provided:

440
441 (i) failure to refill the prescription might result in an interruption of a therapeutic regimen or
442 create patient suffering;

443
444 (ii) the quantity of prescription drug dispensed does not exceed a 30-day supply;

445
446 (iii) the governor has declared a state of disaster;

447
448 (iv) the board, through the executive director, has notified pharmacies that pharmacists may
449 dispense up to a 30-day supply of prescription drugs;

450
451 (v) the pharmacist informs the patient or the patient's agent at the time of dispensing that the
452 refill is being provided without such authorization and that authorization of the practitioner is
453 required for future refills;

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455 (vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable
456 time;

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

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

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

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

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

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

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

(F) Auto-Refill Programs. A pharmacy may use a program that automatically refills prescriptions that have existing refills available in order to improve patient compliance with and adherence to prescribed medication therapy. The following is applicable in order to enroll patients into an auto-refill program.

(i) Notice of the availability of an auto-refill program shall be given to the patient or patient's agent, and the patient or patient's agent must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication.

(ii) The patients or patient's agent shall have the option to withdraw from such a program at any time.

(iii) Auto-refill programs may be used for refills of dangerous drugs, and schedule IV and V controlled substances. Schedule II and III controlled substances may not be dispensed by an auto-refill program.

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

(9) Records Relating to Dispensing Errors. If a dispensing error occurs, the following is applicable.

(A) Original prescription drug orders:

(i) shall not be destroyed and must be maintained in accordance with subsection (a) of this section; and

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509 (ii) shall not be altered. Altering includes placing a label or any other item over any of the
510 information on the prescription drug order (e.g., a dispensing tag or label that is affixed to back
511 of a prescription drug order must not be affixed on top of another dispensing tag or label in such
512 a manner as to obliterate the information relating to the error).

513
514 (B) Prescription drug order records maintained in a data processing system:

515
516 (i) shall not be deleted and must be maintained in accordance with subsection (a) of this
517 section;

518
519 (ii) may be changed only in compliance with subsection (e)(2)(B) of this section; and

520
521 (iii) if the error involved incorrect data entry into the pharmacy's data processing system, this
522 record must be either voided or cancelled in the data processing system, so that the incorrectly
523 entered prescription drug order may not be dispensed, or the data processing system must be
524 capable of maintaining an audit trail showing any changes made to the data in the system.

525
526 (10) Accelerated refills. In accordance with §562.0545 of the Act, a pharmacist may dispense
527 up to a 90-day supply of a dangerous drug pursuant to a valid prescription that specifies the
528 dispensing of a lesser amount followed by periodic refills of that amount if:

529
530 (A) the total quantity of dosage units dispensed does not exceed the total quantity of dosage
531 units authorized by the prescriber on the original prescription, including refills;

532
533 (B) the patient consents to the dispensing of up to a 90-day supply and the physician has
534 been notified electronically or by telephone;

535
536 (C) the physician has not specified on the prescription that dispensing the prescription in an
537 initial amount followed by periodic refills is medically necessary;

538
539 (D) the dangerous drug is not a psychotropic drug used to treat mental or psychiatric
540 conditions; and

541
542 (E) the patient is at least 18 years of age.

543
544 (c) Patient medication records.

545
546 (1) A patient medication record system shall be maintained by the pharmacy for patients to
547 whom prescription drug orders are dispensed.

548
549 (2) The patient medication record system shall provide for the immediate retrieval of
550 information for the previous 12 months that is necessary for the dispensing pharmacist to
551 conduct a prospective drug regimen review at the time a prescription drug order is presented for
552 dispensing.

553
554 (3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and
555 record in the patient medication record at least the following information:

556
557 (A) full name of the patient for whom the drug is prescribed;

558

559 (B) address and telephone number of the patient;
560
561 (C) patient's age or date of birth;
562
563 (D) patient's gender;
564
565 (E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease
566 states of the patient and the identity of any other drugs currently being used by the patient which
567 may relate to prospective drug regimen review;
568
569 (F) pharmacist's comments relevant to the individual's drug therapy, including any other
570 information unique to the specific patient or drug; and
571
572 (G) a list of all prescription drug orders dispensed (new and refill) to the patient by the
573 pharmacy during the last two years. Such list shall contain the following information:
574
575 (i) date dispensed;
576
577 (ii) name, strength, and quantity of the drug dispensed;
578
579 (iii) prescribing practitioner's name;
580
581 (iv) unique identification number of the prescription; and
582
583 (v) name or initials of the dispensing pharmacists.
584
585 (4) A patient medication record shall be maintained in the pharmacy for two years. If patient
586 medication records are maintained in a data processing system, all of the information specified
587 in this subsection shall be maintained in a retrievable form for two years and information for the
588 previous 12 months shall be maintained on-line. A patient medication record must contain
589 documentation of any modification, change, or manipulation to a patient profile.
590
591 (5) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record,
592 and maintain patient information other than prescription drug order information when a patient or
593 patient's agent refuses to provide the necessary information for such patient medication
594 records.
595
596 (d) Prescription drug order records maintained in a manual system.
597
598 (1) Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D)
599 of this section.
600
601 (2) Refills.
602
603 (A) Each time a prescription drug order is refilled, a record of such refill shall be made:
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605 (i) on the back of the prescription by recording the date of dispensing, the written initials or
606 identification code of the dispensing pharmacist, the initials or identification code of the
607 pharmacy technician or pharmacy technician trainee preparing the prescription label, if
608 applicable, and the amount dispensed. (If the pharmacist merely initials and dates the back of

609 the prescription drug order, he or she shall be deemed to have dispensed a refill for the full face
610 amount of the prescription drug order); or

611
612 (ii) on another appropriate, uniformly maintained, readily retrievable record, such as
613 medication records, that indicates by patient name the following information:

614 (I) unique identification number of the prescription;

615
616 (II) name and strength of the drug dispensed;

617
618 (III) date of each dispensing;

619
620 (IV) quantity dispensed at each dispensing;

621
622 (V) initials or identification code of the dispensing pharmacist;

623
624 (VI) initials or identification code of the pharmacy technician or pharmacy technician trainee
625 preparing the prescription label, if applicable; and

626
627 (VII) total number of refills for the prescription.

628
629 (B) If refill records are maintained in accordance with subparagraph (A)(ii) of this paragraph,
630 refill records for controlled substances in Schedules III-V shall be maintained separately from
631 refill records of dangerous drugs and nonprescription drugs.

632
633 (3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug
634 order shall be noted on the original prescription, in addition to the documentation of dispensing
635 the refill as specified in subsection (l) of this section.

636
637 (4) Each time a modification, change, or manipulation is made to a record of dispensing,
638 documentation of such change shall be recorded on the back of the prescription or on another
639 appropriate, uniformly maintained, readily retrievable record, such as medication records. The
640 documentation of any modification, change, or manipulation to a record of dispensing shall
641 include the identification of the individual responsible for the alteration.

642
643 (e) Prescription drug order records maintained in a data processing system.

644
645 (1) General requirements for records maintained in a data processing system.

646
647 (A) Compliance with data processing system requirements. If a Class A pharmacy's data
648 processing system is not in compliance with this subsection, the pharmacy must maintain a
649 manual recordkeeping system as specified in subsection (d) of this section.

650
651 (B) Original prescriptions. Original prescriptions shall be maintained in three files as specified
652 in subsection (b)(6)(D) of this section.

653
654 (C) Requirements for backup systems.

655
656 (i) The pharmacy shall maintain a backup copy of information stored in the data processing
657 system using disk, tape, or other electronic backup system and update this backup copy on a
658 regular basis, at least monthly, to assure that data is not lost due to system failure.

660
661 (ii) Data processing systems shall have a workable (electronic) data retention system that
662 can produce an audit trail of drug usage for the preceding two years as specified in paragraph
663 (2)(H) of this subsection.

664
665 (D) Change or discontinuance of a data processing system.

666
667 (i) Records of dispensing. A pharmacy that changes or discontinues use of a data
668 processing system must:

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

670
671
672 (II) purge the records of dispensing to a printout that contains the same information
673 required on the daily printout as specified in paragraph (2)(C) of this subsection. The information
674 on this hard copy printout shall be sorted and printed by prescription number and list each
675 dispensing for this prescription chronologically.

676
677 (ii) Other records. A pharmacy that changes or discontinues use of a data processing
678 system must:

679 (I) transfer the records to the new data processing system; or

680
681 (II) purge the records to a printout that contains all of the information required on the
682 original document.

683
684 (iii) Maintenance of purged records. Information purged from a data processing system must
685 be maintained by the pharmacy for two years from the date of initial entry into the data
686 processing system.

687
688 (E) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant
689 loss of information from the data processing system within 10 days of discovery of the loss.

690
691 (2) Records of dispensing.

692
693 (A) Each time a prescription drug order is filled or refilled, a record of such dispensing shall
694 be entered into the data processing system.

695
696 (B) Each time a modification, change or manipulation is made to a record of dispensing,
697 documentation of such change shall be recorded in the data processing system. The
698 documentation of any modification, change, or manipulation to a record of dispensing shall
699 include the identification of the individual responsible for the alteration. Should the data
700 processing system not be able to record a modification, change, or manipulation to a record of
701 dispensing, the information should be clearly documented on the hard copy prescription.

702
703 (C) The data processing system shall have the capacity to produce a daily hard copy printout
704 of all original prescriptions dispensed and refilled. This hard copy printout shall contain the
705 following information:

706
707 (i) unique identification number of the prescription;

708
709 (ii) date of dispensing;

711
712 (iii) patient name;
713
714 (iv) prescribing practitioner's name; and the supervising physician's name if the prescription
715 was issued by an advanced practice registered nurse, physician assistant or pharmacist;
716
717 (v) name and strength of the drug product actually dispensed; if generic name, the brand
718 name or manufacturer of drug dispensed;
719
720 (vi) quantity dispensed;
721
722 (vii) initials or an identification code of the dispensing pharmacist;
723
724 (viii) initials or an identification code of the pharmacy technician or pharmacy technician
725 trainee performing data entry of the prescription, if applicable;
726
727 (ix) if not immediately retrievable via computer display, the following shall also be included
728 on the hard copy printout:
729
730 (I) patient's address;
731
732 (II) prescribing practitioner's address;
733
734 (III) practitioner's DEA registration number, if the prescription drug order is for a controlled
735 substance;
736
737 (IV) quantity prescribed, if different from the quantity dispensed;
738
739 (V) date of issuance of the prescription drug order, if different from the date of dispensing;
740 and
741
742 (VI) total number of refills dispensed to date for that prescription drug order; and
743
744 (x) any changes made to a record of dispensing.
745
746 (D) The daily hard copy printout shall be produced within 72 hours of the date on which the
747 prescription drug orders were dispensed and shall be maintained in a separate file at the
748 pharmacy. Records of controlled substances shall be readily retrievable from records of
749 noncontrolled substances.
750
751 (E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify
752 that the data indicated on the daily hard copy printout is correct, by dating and signing such
753 document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John
754 H. Smith) within seven days from the date of dispensing.
755
756 (F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall
757 maintain a log book in which each individual pharmacist using the data processing system shall
758 sign a statement each day, attesting to the fact that the information entered into the data
759 processing system that day has been reviewed by him or her and is correct as entered. Such
760 log book shall be maintained at the pharmacy employing such a system for a period of two
761 years after the date of dispensing; provided, however, that the data processing system can

762 produce the hard copy printout on demand by an authorized agent of the Texas State Board of
763 Pharmacy. If no printer is available on site, the hard copy printout shall be available within 72
764 hours with a certification by the individual providing the printout, that states that the printout is
765 true and correct as of the date of entry and such information has not been altered, amended, or
766 modified.

767
768 (G) The pharmacist-in-charge is responsible for the proper maintenance of such records and
769 responsible that such data processing system can produce the records outlined in this section
770 and that such system is in compliance with this subsection.

771
772 (H) The data processing system shall be capable of producing a hard copy printout of an
773 audit trail for all dispensings (original and refill) of any specified strength and dosage form of a
774 drug (by either brand or generic name or both) during a specified time period.

775
776 (i) Such audit trail shall contain all of the information required on the daily printout as set out
777 in subparagraph (C) of this paragraph.

778
779 (ii) The audit trail required in this subparagraph shall be supplied by the pharmacy within 72
780 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

781
782 (I) Failure to provide the records set out in this subsection, either on site or within 72 hours
783 constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

784
785 (J) The data processing system shall provide on-line retrieval (via computer display or hard
786 copy printout) of the information set out in subparagraph (C) of this paragraph of:

787
788 (i) the original controlled substance prescription drug orders currently authorized for refilling;
789 and

790
791 (ii) the current refill history for Schedules III, IV, and V controlled substances for the
792 immediately preceding six-month period.

793
794 (K) In the event that a pharmacy that uses a data processing system experiences system
795 downtime, the following is applicable:

796
797 (i) an auxiliary procedure shall ensure that refills are authorized by the original prescription
798 drug order and that the maximum number of refills has not been exceeded or authorization from
799 the prescribing practitioner shall be obtained prior to dispensing a refill; and

800
801 (ii) all of the appropriate data shall be retained for on-line data entry as soon as the system
802 is available for use again.

803
804 (3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug
805 order shall be noted as follows:

806
807 (A) on the hard copy prescription drug order;

808
809 (B) on the daily hard copy printout; or

810
811 (C) via the computer display.

812

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

816

817 (g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing,
818 the transfer of original prescription drug order information is permissible between pharmacies,
819 subject to the following requirements.

820

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

825

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

829

830 (3) The transfer is communicated orally by telephone or via facsimile directly by a pharmacist
831 to another pharmacist; by a pharmacist to a student-intern, extended-intern, or resident-intern;
832 or by a student-intern, extended-intern, or resident-intern to another pharmacist.

833

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

836

837 (5) The individual transferring the prescription drug order information shall ensure the following
838 occurs:

839

840 (A) write the word "void" on the face of the invalidated prescription or the prescription is
841 voided in the data processing system;

842

843 (B) record the name, address, if for a controlled substance, the DEA registration number of
844 the pharmacy to which it was transferred, and the name of the receiving individual on the
845 reverse of the invalidated prescription or stored with the invalidated prescription drug order in
846 the data processing system;

847

848 (C) record the date of the transfer and the name of the individual transferring the information;
849 and

850

851 (D) if the prescription is transferred electronically, provide the following information:

852

853 (i) date of original dispensing and prescription number;

854

855 (ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of
856 previous refills;

857

858 (iii) name, address, and if a controlled substance, the DEA registration number of the
859 transferring pharmacy;

860

861 (iv) name of the individual transferring the prescription; and

862

863 (v) if a controlled substance, name, address and DEA registration number, and prescription
864 number from the pharmacy that originally dispensed the prescription, if different.

865
866 (6) The individual receiving the transferred prescription drug order information shall:
867

868 (A) write the word "transfer" on the face of the prescription or the prescription record indicates
869 the prescription was a transfer; and

870
871 (B) reduce to writing all of the information required to be on a prescription as specified in
872 subsection (b)(7) of this section (relating to Prescriptions) and including the following
873 information;

874
875 (i) date of issuance and prescription number;

876
877 (ii) original number of refills authorized on the original prescription drug order;

878
879 (iii) date of original dispensing;

880
881 (iv) number of valid refills remaining and if a controlled substance, date(s) and location(s) of
882 previous refills;

883
884 (v) name, address, and if for a controlled substance, the DEA registration number of the
885 transferring pharmacy;

886
887 (vi) name of the individual transferring the prescription; and

888
889 (vii) name, address, and if for a controlled substance, the DEA registration number, of the
890 pharmacy that originally dispensed the prescription, if different; or

891
892 (C) if the prescription is transferred electronically, create an electronic record for the
893 prescription that includes the receiving pharmacist's name and all of the information transferred
894 with the prescription including all of the information required to be on a prescription as specified
895 in subsection (b)(7) of this section (relating to Prescriptions) and the following:

896
897 (i) date of original dispensing;

898
899 (ii) number of refills remaining and if a controlled substance, the prescription number(s),
900 date(s) and location(s) of previous refills;

901
902 (iii) name, address, and if for a controlled substance, the DEA registration number;

903
904 (iv) name of the individual transferring the prescription; and

905
906 (v) name, address, and if for a controlled substance, the DEA registration number, of the
907 pharmacy that originally filled the prescription.

908
909 (7) Both the individual transferring the prescription and the individual receiving the prescription
910 must engage in confirmation of the prescription information by such means as:

911
912 (A) the transferring individual faxes the hard copy prescription to the receiving individual; or

913

914 (B) the receiving individual repeats the verbal information from the transferring individual and
915 the transferring individual verbally confirms that the repeated information is correct.

916
917 (8) Pharmacies transferring prescriptions electronically shall comply with the following:
918

919 (A) Prescription drug orders may not be transferred by non-electronic means during periods
920 of downtime except on consultation with and authorization by a prescribing practitioner;
921 provided however, during downtime, a hard copy of a prescription drug order may be made
922 available for informational purposes only, to the patient or a pharmacist, and the prescription
923 may be read to a pharmacist by telephone.

924
925 (B) The original prescription drug order shall be invalidated in the data processing system for
926 purposes of filling or refilling, but shall be maintained in the data processing system for refill
927 history purposes.

928
929 (C) If the data processing system does not have the capacity to store all the information as
930 specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this
931 information on the original or transferred prescription drug order.

932
933 (D) The data processing system shall have a mechanism to prohibit the transfer or refilling of
934 controlled substance prescription drug orders that have been previously transferred.

935
936 (E) Pharmacies electronically accessing the same prescription drug order records may
937 electronically transfer prescription information if the following requirements are met.

938
939 (i) The original prescription is voided and the pharmacies' data processing systems shall
940 store all the information as specified in paragraphs (5) and (6) of this subsection.

941
942 (ii) Pharmacies not owned by the same entity may electronically access the same
943 prescription drug order records, provided the owner, chief executive officer, or designee of each
944 pharmacy signs an agreement allowing access to such prescription drug order records.

945
946 (iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern,
947 pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a
948 pharmacist.

949
950 (9) An individual may not refuse to transfer original prescription information to another
951 individual who is acting on behalf of a patient and who is making a request for this information
952 as specified in this subsection. The transfer of original prescription information must be
953 completed within four business hours of the request.

954
955 (10) When transferring a compounded prescription, a pharmacy is required to provide all of the
956 information regarding the compounded preparation including the formula unless the formula is
957 patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum,
958 provide the quantity or strength of all of the active ingredients of the compounded preparation.

959
960 (11) The electronic transfer of multiple or bulk prescription records between two pharmacies is
961 permitted provided:

962
963 (A) a record of the transfer as specified in paragraph (5) of this subsection is maintained by
964 the transferring pharmacy;

965
966 (B) the information specified in paragraph (6) of this subsection is maintained by the receiving
967 pharmacy; and

968
969 (C) in the event that the patient or patient's agent is unaware of the transfer of the
970 prescription drug order record, the transferring pharmacy must notify the patient or patient's
971 agent of the transfer and must provide the patient or patient's agent with the telephone number
972 of the pharmacy receiving the multiple or bulk prescription drug order records.

973
974 (h) Distribution of controlled substances to another registrant. A pharmacy may distribute
975 controlled substances to a practitioner, another pharmacy, or other registrant, without being
976 registered to distribute, under the following conditions.

977
978 (1) The registrant to whom the controlled substance is to be distributed is registered under the
979 Controlled Substances Act to dispense that controlled substance.

980
981 (2) The total number of dosage units of controlled substances distributed by a pharmacy may
982 not exceed 5.0% of all controlled substances dispensed and distributed by the pharmacy during
983 the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the
984 pharmacy is required to obtain an additional registration to distribute controlled substances.

985
986 (3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
987 maintained that indicates:

988
989 (A) the actual date of distribution;

990
991 (B) the name, strength, and quantity of controlled substances distributed;

992
993 (C) the name, address, and DEA registration number of the distributing pharmacy; and

994
995 (D) the name, address, and DEA registration number of the pharmacy, practitioner, or other
996 registrant to whom the controlled substances are distributed.

997
998 (4) If the distribution is for a Schedule II controlled substance, the following is applicable.

999
1000 (A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
1001 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

1002
1003 (B) The distributing pharmacy shall:

1004
1005 (i) complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";

1006
1007 (ii) maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

1008
1009 (iii) forward Copy 2 of the DEA order form (DEA 222) to the Divisional Office of the Drug
1010 Enforcement Administration.

1011
1012 (i) Other records. Other records to be maintained by a pharmacy:

1013
1014 (1) a log of the initials or identification codes that will identify each pharmacist, pharmacy
1015 technician, and pharmacy technician trainee, who is involved in the dispensing process, in the

1016 pharmacy's data processing system, (the initials or identification code shall be unique to ensure
1017 that each individual can be identified, i.e., identical initials or identification codes shall not be
1018 used). Such log shall be maintained at the pharmacy for at least seven years from the date of
1019 the transaction;

1020

1021 (2) Copy 3 of DEA order form (DEA 222) that has been properly dated, initialed, and filed, and
1022 all copies of each unaccepted or defective order form and any attached statements or other
1023 documents and/or for each order filled using the DEA Controlled Substance Ordering System
1024 (CSOS) the original signed order and all linked records for that order;

1025

1026 (3) a copy of the power of attorney to sign DEA 222 order forms (if applicable);

1027

1028 (4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify
1029 that the controlled drugs listed on the invoices were actually received by clearly recording
1030 his/her initials and the actual date of receipt of the controlled substances;

1031

1032 (5) suppliers' credit memos for controlled substances and dangerous drugs;

1033

1034 (6) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

1035

1036 (7) reports of surrender or destruction of controlled substances and/or dangerous drugs to an
1037 appropriate state or federal agency;

1038

1039 (8) the Schedule V nonprescription register book;

1040

1041 (9) records of distribution of controlled substances and/or dangerous drugs to other
1042 pharmacies, practitioners, or registrants; and

1043

1044 (10) a copy of any notification required by the Texas Pharmacy Act or the sections in this
1045 chapter, including, but not limited to, the following:

1046

1047 (A) reports of theft or significant loss of controlled substances to DEA, Department of Public
1048 Safety, and the board;

1049

1050 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and

1051

1052 (C) reports of a fire or other disaster that may affect the strength, purity, or labeling of drugs,
1053 medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and
1054 disease.

1055

1056 (j) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping
1057 system for invoices and financial data shall comply with the following procedures.

1058

1059 (1) Controlled substance records. Invoices and financial data for controlled substances may be
1060 maintained at a central location provided the following conditions are met.

1061

1062 (A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by
1063 registered or certified mail to the divisional director of the Drug Enforcement Administration as
1064 required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this
1065 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by
1066 the divisional director of the Drug Enforcement Administration that permission to keep central

1067 records is denied, the pharmacy may maintain central records commencing 14 days after
1068 receipt of notification by the divisional director.

1069
1070 (B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this
1071 paragraph.

1072
1073 (C) The records to be maintained at the central record location shall not include executed
1074 DEA order forms, prescription drug orders, or controlled substance inventories, that shall be
1075 maintained at the pharmacy.

1076
1077 (2) Dangerous drug records. Invoices and financial data for dangerous drugs may be
1078 maintained at a central location.

1079
1080 (3) Access to records. If the records are kept on microfilm, computer media, or in any form
1081 requiring special equipment to render the records easily readable, the pharmacy shall provide
1082 access to such equipment with the records.

1083
1084 (4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the
1085 pharmacy location within two business days of written request of a board agent or any other
1086 authorized official.

1087
1088 (k) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed
1089 under the Act is the only entity that may legally own and maintain prescription drug records.

1090
1091 (l) Documentation of consultation. When a pharmacist consults a prescriber as described in this
1092 section, the pharmacist shall document on the hard copy or in the pharmacy's data processing
1093 system associated with the prescription such occurrences and shall include the following
1094 information:

1095
1096 (1) date the prescriber was consulted;

1097
1098 (2) name of the person communicating the prescriber's instructions;

1099
1100 (3) any applicable information pertaining to the consultation; and

1101
1102 (4) initials or identification code of the pharmacist performing the consultation clearly recorded
1103 for the purpose of identifying the pharmacist who performed the consultation if the information is
1104 recorded on the hard copy prescription.