

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED 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 and specifying that the transfer must be confirmed.

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

The Board reviewed and voted to propose the amendments during the May 7, 2013, meeting. The proposed amendments were republished in the June 28, 2013, issue of the *Texas Register* at 38 *TexReg* 4137.

1 **PART 15. TEXAS STATE BOARD OF PHARMACY**

2 **CHAPTER 291. PHARMACIES**

3 **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**

4 **§291.34**

5 The Texas State Board of Pharmacy proposes amendments to §291.34, concerning Records. The
6 amendments, if adopted, clarify and update the section to be consistent with other sections of this
7 title and DPS and DEA laws/rules; require documentation of a consultation with a prescriber
8 regarding a prescription; add rules regarding auto-refill programs; and update the rules regarding
9 prescription transfers and specifying that the transfer must be confirmed.

10 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
11 period the rule is in effect, there will be no fiscal implications for state or local government as a
12 result of enforcing or administering the rule.

13 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
14 effect, the public benefit anticipated as a result of enforcing the rule will be to clarify and update
15 the Class A rules regarding the records of a pharmacy. There is no fiscal impact for individuals,
16 small or large businesses, or to other entities which are required to comply with this section.

17 Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S.,
18 Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite
19 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m.,
20 July 31, 2013.

21 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
22 (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as
23 authorizing the agency to protect the public through the effective control and regulation of the
24 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
25 for the proper administration and enforcement of the Act.

26 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
27 569, Texas Occupations Code.

28 **§291.34.Records.**

29 (a) Maintenance of records.

30 (1) Every inventory or other record required to be kept under the provisions of Subchapter B of
31 this chapter (relating to [§291.31 of this title (relating to Definitions), §291.32 of this title
32 (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this
33 title (relating to Records), and §291.35 of this title (relating to Official Prescription
34 Requirements), contained in] Community Pharmacy (Class A)] shall be:

35 (A) - (B) (No change.)

36 (2) - (3) (No change.)

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 processing
39 system or direct imaging system provided:

40 (A) - (B) (No change.)

41 (b) Prescriptions.

42 (1) (No change.)

43 (2) Written prescription drug orders.

44 (A) Practitioner's signature.

45 (i) Dangerous drug prescription orders. Written [~~Except as noted in clause (ii) of this~~
46 ~~subparagraph, written~~] prescription drug orders shall be:

47 (I) (No change.)

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

50 (-a-) - (-b-) (No change.)

51 (ii) Controlled substance prescription orders. Prescription drug orders for Schedule II, III, IV, or
52 V controlled substances shall be manually signed by the practitioner. Prescription drug orders for
53 Schedule II controlled substances shall be issued on an official prescription form as required by
54 the Texas Controlled Substances Act, §481.075[~~, and be manually signed by the practitioner~~].

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

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

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

60 (III) [~~(v)~~] The prescription drug order may not be signed by a practitioner's agent but may be
61 prepared by an agent for the signature of a practitioner. However, the prescribing practitioner is
62 responsible in case the prescription drug order does not conform in all essential respects to the
63 law and regulations.

- 64 (B) Prescription drug orders written by practitioners in another state.
- 65 (i) (No change.)
- 66 (ii) Controlled substance prescription drug orders.
- 67 (I) A pharmacist may dispense prescription drug order for controlled substances in Schedule II
68 issued by a practitioner in another state provided:
- 69 (-a-) - (-b-) (No change.)
- 70 (-c-) the prescription drug order is not dispensed after the end of the twenty-first ~~[seventh]~~ day
71 after the date on which the prescription is issued.
- 72 (II) A pharmacist may dispense prescription drug orders for controlled substances in Schedule
73 III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:
- 74 (-a-) the prescription drug order is a [~~written, oral, or telephonically or electronically~~
75 ~~communicated prescription, as allowed by the DEA~~] issued by a person practicing in another
76 state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a
77 current federal DEA registration number, and who may legally prescribe Schedule III, IV, or V
78 controlled substances in such other state;
- 79 (-b-) - (-c-) (No change.)
- 80 (C) (No change.)
- 81 (D) Prescription drug orders carried out or signed by an advanced practice nurse, physician
82 assistant, or pharmacist.
- 83 (i) A pharmacist may dispense a prescription drug order that ~~[which]~~ is:
- 84 (I) - (II) (No change.)
- 85 (ii) (No change.)
- 86 (E) (No change.)
- 87 (3) (No change.)
- 88 (4) Electronic prescription drug orders. ~~[For the purpose of this subsection, prescription drug~~
89 ~~orders shall be considered the same as verbal prescription drug orders.]~~
- 90 (A) Dangerous drug prescription orders.

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

93 (I) ~~(+)~~ directly to a pharmacy; or

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

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

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

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

103 (B) ~~(C)~~ Controlled substance prescription orders. A pharmacist may only dispense an electronic
104 prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with
105 the federal and state laws and the rules of the Drug Enforcement Administration outlined in Part
106 1300 of the Code of Federal Regulations and Texas Department of Public Safety.

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

111 (5) Facsimile (faxed) prescription drug orders.

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

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

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

121 (6) ~~(5)~~ Original prescription drug order records.

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

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

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

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

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

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

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

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

137 (E) Original prescription records other than prescriptions for Schedule II controlled substances
138 may be stored in a [~~on microfilm, microfiche, or other~~] system that [~~which~~] is capable of
139 producing a direct image of the original prescription record, e.g., digitalized imaging system. If
140 original prescription records are stored in a direct imaging system, the following is applicable:

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

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

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

146 (7) [~~(6)~~] Prescription drug order information.

147 (A) All original prescriptions shall bear:

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

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

153 (iii) name, address and telephone number of the practitioner at the practitioner's usual place of
154 business, legibly printed or stamped and if for a controlled substance, the ~~[address and]~~ DEA
155 registration number of the practitioner;

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

157 (v) quantity prescribed numerically and if for a controlled substance:[;]

158 (I) numerically, followed by the number written as a word, if the prescription is written;

159 (II) numerically, if the prescription is electronic; or

160 (III) if the prescription is communicated orally or telephonically, as transcribed by the receiving
161 pharmacist;

162 (vi) directions for use;

163 (vii) intended use for the drug unless the practitioner determines the furnishing of this
164 information is not in the best interest of the patient; ~~[and]~~

165 (viii) date of issuance;[-]

166 (ix) if a faxed prescription:

167 (I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and

168 (II) if transmitted by a designated agent, the full name of the designated agent;

169 (x) if electronically transmitted:

170 (I) the date the prescription drug order was electronically transmitted to the pharmacy, if
171 different from the date of issuance of the prescription; and

172 (II) if transmitted by a designated agent, the full name of the designated agent; and

173 (xi) if issued by an advanced practice nurse or physician assistant in accordance with Subtitle B,
174 Chapter 157, Occupations Code the:

175 (I) name, address, telephone number, and if the prescription is for a controlled substance, the
176 DEA number of the supervising practitioner; and

177 (II) address and telephone number of the clinic where the prescription drug order was carried out
178 or signed.

179 ~~[(B) All original electronic prescription drug orders shall bear:]~~

180 ~~{(i) name of the patient, if such drug is for an animal, the species of such animal, and the name of~~
181 ~~the owner;}~~

182 ~~{(ii) address of the patient, provided, however, a prescription for a dangerous drug is not required~~
183 ~~to bear the address of the patient if such address is readily retrievable on another appropriate,~~
184 ~~uniformly maintained pharmacy record, such as medication records;}~~

185 ~~{(iii) name, and if for a controlled substance, the address and DEA registration number of the~~
186 ~~practitioner;}~~

187 ~~{(iv) name and strength of the drug prescribed;}~~

188 ~~{(v) quantity prescribed;}~~

189 ~~{(vi) directions for use;}~~

190 ~~{(vii) indications for use, unless the practitioner determines the furnishing of this information is~~
191 ~~not in the best interest of the patient;}~~

192 ~~{(viii) date of issuance;}~~

193 ~~{(ix) if a faxed prescription, a statement which indicates that the prescription has been faxed~~
194 ~~(e.g., Faxed to);}~~

195 ~~{(x) telephone number of the prescribing practitioner;}~~

196 ~~{(xi) date the prescription drug order was electronically transmitted to the pharmacy, if different~~
197 ~~from the date of issuance of the prescription; and}~~

198 ~~{(xii) if transmitted by a designated agent, the full name of the designated agent.}~~

199 ~~{(C) All original written prescriptions carried out or signed by an advanced practice nurse or~~
200 ~~physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code, shall bear:}~~

201 ~~{(i) name and address of the patient;}~~

202 ~~{(ii) name, address, telephone number, and if the prescription is for a controlled substance, the~~
203 ~~DEA number of the supervising practitioner;}~~

204 ~~{(iii) name, original signature, and if the prescription is for a controlled substance, the DEA~~
205 ~~number of the advanced practice nurse or physician assistant;}~~

206 ~~{(iv) address and telephone number of the clinic at which the prescription drug order was carried~~
207 ~~out or signed;}~~

208 ~~{(v) name, strength, and quantity of the drug;}~~

209 ~~[(vi) directions for use;]~~

210 ~~[(vii) indications for use, if appropriate;]~~

211 ~~[(viii) date of issuance; and]~~

212 ~~[(ix) number of refills authorized.]~~

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

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

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

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

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

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

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

225 (8) ~~[(7)]~~ Refills.

226 (A) General information.

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

230 (ii) ~~[(B)]~~ If there are no refill instructions on the original prescription drug order (which shall be
231 interpreted as no refills authorized) or if all refills authorized on the original prescription drug
232 order have been dispensed, authorization from the prescribing practitioner shall be obtained prior
233 to dispensing any refills and documented as specified in subsection (1) of this section.

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

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

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

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

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

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

249 (D) [~~(E)~~] Pharmacist unable to contact prescribing practitioner. If a pharmacist is unable to
250 contact the prescribing practitioner after a reasonable effort, a pharmacist may exercise his
251 professional judgment in refilling a prescription drug order for a drug, other than a controlled
252 substance listed in Schedule II, without the authorization of the prescribing practitioner,
253 provided:

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

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

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

260 (iv) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable
261 time;

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

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

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

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

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

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

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

275 (E) [(F)] Natural or manmade disasters. If a natural or manmade disaster has occurred that
276 prohibits the pharmacist from being able to contact the practitioner, a pharmacist may exercise
277 his professional judgment in refilling a prescription drug order for a drug, other than a controlled
278 substance listed in Schedule II, without the authorization of the prescribing practitioner,
279 provided:

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

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

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

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

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

289 (vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable
290 time;

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

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

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

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

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

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

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

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

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

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

313 (iii) Auto-refill programs may be used for refills of dangerous drugs, and schedule IV and V
314 controlled substances at the discretion of the pharmacist-in-charge. Schedule II and III controlled
315 substances may not be dispensed by an auto-refill program.

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

320 (9) [(8)] Records Relating to Dispensing Errors.

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

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

327 (A) [(+)] Original prescription drug orders:

328 (i) [(+)] shall not be destroyed and must be maintained in accordance with subsection (a) of this
329 section; and

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

334 (B) [~~(H)~~] Prescription drug order records maintained in a data processing system:

335 (i) [~~(I)~~] shall not be deleted and must be maintained in accordance with subsection (a) of this
336 section;

337 (ii) [~~(H)~~] may be changed only in compliance with subsection (e)(2)(B) of this section; and

338 (iii) [~~(H)~~] if the error involved incorrect data entry into the pharmacy's data processing system,
339 this record must be either voided or cancelled in the data processing system, so that the
340 incorrectly entered prescription drug order may not be dispensed, or the data processing system
341 must be capable of maintaining an audit trail showing any changes made to the data in the
342 system.

343 (10) [~~(9)~~] Accelerated refills. In accordance with §562.0545 of the Act, a pharmacist may
344 dispense up to a 90-day supply of a dangerous drug pursuant to a valid prescription that specifies
345 the dispensing of a lesser amount followed by periodic refills of that amount if:

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

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

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

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

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

355 (c) Patient medication records.

356 (1) (No change.)

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

361 (3) - (5) (No change.)

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

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

365 (2) Refills.

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

367 (i) (No change.)

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

370 (I) - (VII) (No change.)

371 (B) (No change.)

372 (3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug
373 order shall be noted on the original prescription, in addition to the documentation of dispensing
374 the refill as specified in subsection (1) of this section.

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

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

380 ~~[(B) the transfer of original prescription drug order information for dangerous drugs is
381 permissible between pharmacies without limitation up to the number of originally authorized
382 refills;]~~

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

384 ~~[(D) both the original and the transferred prescription drug order are maintained for a period of
385 two years from the date of last refill;]~~

386 ~~[(E) the pharmacist or pharmacist intern transferring the prescription drug order information
387 shall:]~~

388 ~~[(i) write the word "void" on the face of the invalidated prescription drug order; and]~~

389 ~~[(ii) record on the reverse of the invalidated prescription drug order the following information:]~~

390 ~~[(F) the name, address, and if a controlled substance, the DEA registration number of the
391 pharmacy to which such prescription drug order is transferred;]~~

392 ~~[(H) the name of the pharmacist or pharmacist intern receiving the prescription drug order
393 information;]~~

394 ~~[(III) the name of the pharmacist or pharmacist intern transferring the prescription drug order~~
395 ~~information; and]~~

396 ~~[(IV) the date of the transfer;]~~

397 ~~[(F) the pharmacist or pharmacist intern receiving the transferred prescription drug order~~
398 ~~information shall:]~~

399 ~~[(i) write the word "transfer" on the face of the transferred prescription drug order; and]~~

400 ~~[(ii) record on the transferred prescription drug order the following information:]~~

401 ~~[(I) original date of issuance and date of dispensing or receipt, if different from date of issuance;]~~

402 ~~[(II) original prescription number and the number of refills authorized on the original~~
403 ~~prescription drug order;]~~

404 ~~[(III) number of valid refills remaining and the date of last refill, if applicable;]~~

405 ~~[(IV) name, address, and if a controlled substance, the DEA registration number of the pharmacy~~
406 ~~from which such prescription information is transferred; and]~~

407 ~~[(V) name of the pharmacist or pharmacist intern transferring the prescription drug order~~
408 ~~information.]~~

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

412 (4) ~~[(6)]~~ Each time a modification, change, or manipulation is made to a record of dispensing,
413 documentation of such change shall be recorded on the back of the prescription or on another
414 appropriate, uniformly maintained, readily retrievable record, such as medication records. The
415 documentation of any modification, change, or manipulation to a record of dispensing shall
416 include the identification of the individual responsible for the alteration.

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

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

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

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

424 (C) Requirements for backup systems.

425 (i) (No change.)

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

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

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

432 (I) (No change.)

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

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

439 (I) (No change.)

440 (II) purge the records to a printout that [~~which~~] contains all of the information required on the
441 original document.

442 (iii) (No change.)

443 (E) (No change.)

444 (2) Records of dispensing.

445 (A) (No change.)

446 (B) Each time a modification, change or manipulation is made to a record of dispensing,
447 documentation of such change shall be recorded in the data processing system. The
448 documentation of any modification, change, or manipulation to a record of dispensing shall
449 include the identification of the individual responsible for the alteration. Should the data
450 processing system not be able to record a modification, change, or manipulation to a record of
451 dispensing, the information should be clearly documented on the hard copy [~~hardcopy~~]
452 prescription.

453 (C) The data processing system shall have the capacity to produce a daily hard copy [~~hard copy~~]
454 printout of all original prescriptions dispensed and refilled. This hard copy [~~hard copy~~] printout
455 shall contain the following information:

456 (i) - (viii) (No change.)

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

459 (I) - (VI) (No change.)

460 (x) (No change.)

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

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

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

480 (G) (No change.)

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

484 (i) - (ii) (No change.)

485 (I) (No change.)

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

489 (i) - (ii) (No change.)

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

492 (i) - (ii) (No change.)

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

495 (A) on the hard copy [hard-copy] prescription drug order;

496 (B) on the daily hard copy [hard-copy] printout; or

497 (C) via the computer [CRT] display.

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

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

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

508 ~~[(C) The transfer is communicated directly between pharmacists and/or pharmacist interns orally~~
509 ~~by telephone or via facsimile or as authorized in paragraph (5) of this subsection. A transfer~~
510 ~~completed as authorized in paragraph (5) of this subsection may be initiated by a pharmacy~~
511 ~~technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.]~~

512 ~~[(D) Both the original and the transferred prescription drug orders are maintained for a period of~~
513 ~~two years from the date of last refill.]~~

514 ~~[(E) The pharmacist or pharmacist intern transferring the prescription drug order information~~
515 ~~shall ensure the following occurs:]~~

516 ~~[(i) the prescription is voided in the data processing system; and]~~

517 ~~{(i) the following information is stored with the invalidated prescription drug order in the data~~
518 ~~processing system:}~~

519 ~~{(I) the name, address, and if a controlled substance, the DEA registration number of the~~
520 ~~pharmacy to which such prescription is transferred;}~~

521 ~~{(II) the name of the pharmacist or pharmacist intern receiving the prescription drug order~~
522 ~~information;}~~

523 ~~{(III) the name of the pharmacist or pharmacist intern transferring the prescription drug order~~
524 ~~information; and}~~

525 ~~{(IV) the date of the transfer.}~~

526 ~~{(F) The pharmacist or pharmacist intern receiving the transferred prescription drug order~~
527 ~~information shall ensure the following occurs:}~~

528 ~~{(i) the prescription record indicates the prescription was a transfer; and}~~

529 ~~{(ii) the following information is stored with the prescription drug order in the data processing~~
530 ~~system:}~~

531 ~~{(I) original date of issuance and date of dispensing or receipt, if different from date of issuance;}~~

532 ~~{(II) original prescription number and the number of refills authorized on the original~~
533 ~~prescription drug order;}~~

534 ~~{(III) number of valid refills remaining and the date of last refill, if applicable;}~~

535 ~~{(IV) name, address, and if a controlled substance, the DEA registration number of the pharmacy~~
536 ~~from which such prescription drug order information is transferred; and}~~

537 ~~{(V) name of the pharmacist or pharmacist intern transferring the prescription drug order~~
538 ~~information.}~~

539 ~~{(G) Prescription drug orders may not be transferred by non-electronic means during periods of~~
540 ~~downtime except on consultation with and authorization by a prescribing practitioner; provided~~
541 ~~however, during downtime, a hard copy of a prescription drug order may be made available for~~
542 ~~informational purposes only, to the patient, a pharmacist or pharmacist intern, and the~~
543 ~~prescription may be read to a pharmacist or pharmacist intern by telephone.}~~

544 ~~{(H) The original prescription drug order shall be invalidated in the data processing system for~~
545 ~~purposes of filling or refilling, but shall be maintained in the data processing system for refill~~
546 ~~history purposes.}~~

547 ~~{(I) If the data processing system does not have the capacity to store all the information required~~
548 ~~in subparagraphs (E) and (F) of this paragraph, the pharmacist is required to record this~~
549 ~~information on the original or transferred prescription drug order.}~~

550 ~~{(J) The data processing system shall have a mechanism to prohibit the transfer or refilling of~~
551 ~~controlled substance prescription drug orders which have been previously transferred.}~~

552 ~~{(5) Electronic transfer of prescription drug order information between pharmacies. Pharmacies~~
553 ~~electronically accessing the same prescription drug order records may electronically transfer~~
554 ~~prescription information if the following requirements are met.}~~

555 ~~{(A) The original prescription is voided and the following information is documented in the~~
556 ~~records of the transferring pharmacy:}~~

557 ~~{(i) the name, address, and if a controlled substance, the DEA registration number of the~~
558 ~~pharmacy to which such prescription is transferred;}~~

559 ~~{(ii) the name of the pharmacist or pharmacist intern receiving the prescription drug order~~
560 ~~information; and}~~

561 ~~{(iii) the date of the transfer.}~~

562 ~~{(B) Pharmacies not owned by the same person may electronically access the same prescription~~
563 ~~drug order records, provided the owner or chief executive officer of each pharmacy signs an~~
564 ~~agreement allowing access to such prescription drug order records.}~~

565 ~~{(C) An electronic transfer between pharmacies may be initiated by a pharmacy technician or~~
566 ~~pharmacy technician trainee acting under the direct supervision of a pharmacist.}~~

567 ~~{(6) A pharmacist or pharmacist intern may not refuse to transfer original prescription~~
568 ~~information to another pharmacist or pharmacist intern who is acting on behalf of a patient and~~
569 ~~who is making a request for this information as specified in paragraphs (4) and (5) of this~~
570 ~~subsection.}~~

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

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

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

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

584 (3) The transfer is communicated orally by telephone or via facsimile directly by a pharmacist to
585 another pharmacist; by a pharmacist to a student intern, extended intern, or resident intern; or by
586 a student intern, extended intern, or resident intern to another pharmacist.

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

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

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

593 (B) the following information is recorded on the reverse of the invalidated prescription drug
594 order or stored with the invalidated prescription drug order in the data processing system:

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

597 (ii) the name of the individual receiving the prescription drug order information;

598 (iii) the name of the individual transferring the prescription drug order information; and

599 (iv) the date of the transfer.

600 (6) The individual receiving the transferred prescription drug order information shall ensure the
601 following occurs:

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

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

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

607 (ii) original prescription number and the number of refills authorized on the original prescription
608 drug order;

609 (iii) number of valid refills remaining and the date of last refill, if applicable;

610 (iv) name, address, and if a controlled substance, the DEA registration number of the pharmacy
611 from which such prescription drug order information is transferred; and

612 (v) name of the individual transferring the prescription drug order information.

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

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

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

618 (8) Pharmacies using a data processing system shall comply with the following:

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

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

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

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

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

634 (i) The original prescription is voided and the pharmacies' data processing systems shall store all
635 the information required in paragraphs (5) and (6) of this subsection.

636 (ii) Pharmacies not owned by the same person may electronically access the same prescription
637 drug order records, provided the owner, chief executive officer, or designee of each pharmacy
638 signs an agreement allowing access to such prescription drug order records.

639 (iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern,
640 pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a
641 pharmacist.

642 (9) An individual may not refuse to transfer original prescription information to another
643 individual who is acting on behalf of a patient and who is making a request for this information
644 as specified in this subsection.

645 (h) [(g)] Distribution of controlled substances to another registrant. A pharmacy may distribute
646 controlled substances to a practitioner, another pharmacy, or other registrant, without being
647 registered to distribute, under the following conditions.

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

650 (2) The total number of dosage units of controlled substances distributed by a pharmacy may not
651 exceed 5.0% of all controlled substances dispensed and distributed by the pharmacy during the
652 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the
653 pharmacy is required to obtain an additional registration to distribute controlled substances.

654 (3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be
655 maintained that [~~which~~] indicates:

656 (A) the actual date of distribution;

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

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

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

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

662 (A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances
663 shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) [~~(DEA 222C)~~] to the distributing
664 pharmacy.

665 (B) The distributing pharmacy shall:

666 (i) complete the area on the DEA order form (DEA 222) [~~(DEA 222C)~~] titled "To Be Filled in
667 by Supplier";

668 (ii) maintain Copy 1 of the DEA order form (DEA 222) [~~(DEA 222C)~~] at the pharmacy for two
669 years; and

670 (iii) forward Copy 2 of the DEA order form (DEA 222) [~~(DEA 222C)~~] to the Divisional Office
671 of the Drug Enforcement Administration.

672 (i) [(h)] Other records. Other records to be maintained by a pharmacy:

- 673 (1) a permanent log of the initials or identification codes that [~~which~~] will identify each
674 pharmacist, pharmacy technician, and pharmacy technician trainee by name performing data
675 entry of prescription information (the initials or identification code shall be unique to ensure that
676 each individual can be identified, i.e., identical initials or identification codes shall not be used);
- 677 (2) Copy 3 of DEA order form (DEA 222) that [~~(DEA 222C) which~~] has been properly dated,
678 initialed, and filed, and all copies of each unaccepted or defective order form and any attached
679 statements or other documents and/or for each order filled using the DEA Controlled Substance
680 Ordering System (CSOS) the original signed order and all linked records for that order;
- 681 (3) a hard copy of the power of attorney to sign DEA 222 [~~(DEA 222C)~~] order forms (if
682 applicable);
- 683 (4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify
684 that the controlled drugs listed on the invoices were actually received by clearly recording his/her
685 initials and the actual date of receipt of the controlled substances;
- 686 (5) suppliers' credit memos for controlled substances and dangerous drugs;
- 687 (6) a hard copy of inventories required by §291.17 of this title (relating to Inventory
688 Requirements);
- 689 (7) hard copy [~~hard copy~~] reports of surrender or destruction of controlled substances and/or
690 dangerous drugs to an appropriate state or federal agency;
- 691 (8) a hard copy of the Schedule V nonprescription register book;
- 692 (9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies,
693 practitioners, or registrants; and
- 694 (10) a hard copy of any notification required by the Texas Pharmacy Act or the sections in this
695 chapter, including, but not limited to, the following:
- 696 (A) reports of theft or significant loss of controlled substances to DEA, Department of Public
697 Safety, and the board;
- 698 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and
- 699 (C) reports of a fire or other disaster that [~~which~~] may affect the strength, purity, or labeling of
700 drugs, medications, devices, or other materials used in the diagnosis or treatment of injury,
701 illness, and disease.
- 702 (j) [(i)] Permission to maintain central records. Any pharmacy that uses a centralized
703 recordkeeping system for invoices and financial data shall comply with the following
704 procedures.

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

707 (A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by
708 registered or certified mail to the divisional director of the Drug Enforcement Administration as
709 required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this
710 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by
711 the divisional director of the Drug Enforcement Administration that permission to keep central
712 records is denied, the pharmacy may maintain central records commencing 14 days after receipt
713 of notification by the divisional director.

714 (B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this
715 paragraph.

716 (C) The records to be maintained at the central record location shall not include executed DEA
717 order forms, prescription drug orders, or controlled substance inventories, that [~~which~~] shall be
718 maintained at the pharmacy.

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

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

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

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

730 (1) Documentation of consultation. When a pharmacist consults a prescriber as described in this
731 section, the pharmacist shall document on the hard copy or in the pharmacy's data processing
732 system associated with the prescription such occurrences and shall include the following
733 information:

734 (1) date the prescriber was consulted;

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

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

737 (4) initials or identification code of the pharmacist performing the consultation clearly recorded
738 for the purpose of identifying the pharmacist who performed the consultation if on the
739 information is recorded on the hard copy prescription.

740 This agency hereby certifies that the proposal has been reviewed by legal counsel and found to
741 be within the agency's legal authority to adopt.

742 Filed with the Office of the Secretary of State on June 17, 2013.

743 TRD-201302509

744 Gay Dodson, R.Ph.

745 Executive Director/Secretary

746 Texas State Board of Pharmacy

747 Earliest possible date of adoption: July 28, 2013

748 For further information, please call: (512) 305-8028



COALITION FOR NURSES IN ADVANCED PRACTICE

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July 27, 2013

Ms. Allison Benz, R. Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701

RE: Comments on proposed rules published
on June 28, 2013 in the *Texas Register*

(FAX (512) 305-8008)

Dear Ms. Benz:

The Coalition for Nurses in Advanced Practice (CNAP) consists of organizations of practitioners who are advanced practice registered nurses (APRNs) including nurse practitioners, certified nurse midwives, certified registered nurse anesthetists and clinical nurse specialists. CNAP wishes to offer comments, highlighted in red, on items related to the proposed rules published in the *Texas Register* on June 28, 2013, as follows.

Community Pharmacy (Class A)

Though the sections noted below were not originally posted for any changes, CNAP would like to point out that APRNs in 41 states have the authority to prescribe Schedule II, Controlled Substances and should be added to the list of other states' providers. In addition, Senate Bill 406 was signed into law by the governor on June 14, 2013, and it will permit certain APRNs licensed in Texas to prescribe Schedule II drugs after it is implemented on November 1, 2013. CNAP also proposes that the TSPB update its terminology regarding APRNs since it is already proposing changes to its rules. Finally, CNAP proposes that the term "controlled substances" be added to §291.34 (b)(2)(D)(i)(II) to reflect that this term is used throughout rule §291.34.

- At §291.34 (b)(2)(B)(ii)(I)(-b-), CNAP suggests that advanced practice registered nurses be added so that it now reads: "(-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, podiatrist or advanced practice registered nurse, who has a current federal Drug Enforcement Administration (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state;"
- CNAP proposes that §291.34 (b)(2)(B)(ii)(II) also be changed to add APRNs to the list of providers as suggested above, so that it now reads: "(II) A pharmacist may dispense prescription drug orders for controlled substances in Schedule III, IV, or V issued by a physician, dentist, veterinarian, podiatrist or advanced practice registered nurse in another state provided."

- CNAP proposes that §291.34 (b)(2)(D), §(i) and §(i) (I) be revised with more current terminology relating to APRNs so that these sections now read:
“(D) Prescription drug orders carried out or signed by an advanced practice registered nurse, physician assistant, or pharmacist.

(i) A pharmacist may dispense a prescription drug order which is:
(I) carried out or signed by an advanced practice registered nurse or physician assistant provided the advanced practice registered nurse or physician assistant is practicing in accordance with Subtitle B, Chapter 157, Occupations Code;”

Thank you for considering these comments. Please do not hesitate to contact me at 512-917-8782 if you have any questions. If you have any questions about an APRN's scope of practice, you can contact the Texas Board of Nursing's Advanced Practice Consultant, Jolene Zych. Jolene's phone number is (512) 305-6845 and her email address is jolene.zych@bon.texas.gov.

Sincerely,



Trish Conradt
Public Policy Director
CNAP

Cc: Jolene Zych
Kathy Hutto
Jennifer Fontana
CNAP Board