

## **RULE ANALYSIS**

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

**Short Title:** Records

**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, allow the utilization of and specify recordkeeping requirements for prescription drug orders dispensed for patients institutionalized in licensed health care institutions, as authorized in Title 40, Part 1, Chapter 19 of the Texas Administrative Code, and correct grammatical errors.

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

**§291.34.      Records.**

(a) (No change.)

(b) Prescriptions.

(1) Professional responsibility.

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

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

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

(2) Written prescription drug orders.

(A) Practitioner's signature.

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

(I) manually signed by the practitioner; or

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

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

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

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

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

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

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

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

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

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

(ii) Controlled substance prescription drug orders.

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

(-a-) the prescription is dispensed as specified in §315.9 of this title (relating to Pharmacy Responsibility - Out-of-State Practitioner - Effective September 1, 2016);

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

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

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

(-a-) the prescription drug order is issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current

federal DEA registration number, and who may legally prescribe ~~Schedules~~~~[Schedule]~~ III, IV, or V controlled substances in such other state;

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

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

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

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

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

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

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

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

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

(I) issued 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; and

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

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

with a copy of the written authorization for a specific advanced practice registered nurse or physician assistant.

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

(3) Verbal prescription drug orders.

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

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to communicate prescriptions verbally 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.

(C) A pharmacist may not dispense a verbal prescription drug order for a dangerous drug or a 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.

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

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

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

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

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

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

(iii) prescriptions for dangerous drugs and nonprescription drugs.

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

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

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

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

180 (7) Prescription drug order information.

181 (A) All original prescriptions shall bear:

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

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

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

190 (iv) **the** name and strength of the drug prescribed;

191 (v) **the** quantity prescribed numerically, and if for a controlled substance:

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

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

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

196 (vi) directions for use;

197 (vii) **the** intended use for the drug unless the practitioner determines the furnishing of this  
198 information is not in the best interest of the patient;

199 (viii) **the** date of issuance;

200 (ix) if a faxed prescription:

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

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

203 (x) if electronically transmitted:

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

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

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

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

(II) ~~the~~ address and telephone number of the clinic where the prescription drug order was carried out or signed; and

(xii) if communicated orally or telephonically:

(I) the initials or identification code of the transcribing pharmacist; and

(II) the name of the prescriber or prescriber's agent communicating the prescription information.

(B) At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hardcopy prescription or in the pharmacy's data processing system:

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

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

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

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

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

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

**(C) Prescription drug orders may be utilized as authorized in Title 40, Part 1, Chapter 19 of the Texas Administrative Code.**

**(i) A prescription drug order is not required to bear the information specified in subparagraph (A) of this paragraph if the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital). Such prescription drug orders must contain the following information:**



237 (I) the full name of the patient;

238 (II) the date of issuance;

239 (III) the name, strength, and dosage form of the drug prescribed;

240 (IV) directions for use; and

241 (V) the signature(s) required by §19.1506, Texas Administrative Code.

242 (ii) Prescription drug orders for dangerous drugs shall not be dispensed following  
243 one year after the date of issuance unless the authorized prescriber renews the  
244 prescription drug order.

245 (iii) Controlled substances shall not be dispensed pursuant to a prescription drug  
246 order under this subparagraph.

247 (8) Refills.

248 (A) General information.

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

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

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

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

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

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

263 (i) Prescription drug orders for Schedules III-V controlled substances may not be refilled  
264 more than five times or after six months from the date of issuance of the original prescription  
265 drug order, **whichever**~~[which ever]~~ occurs first.

266 (ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been  
267 refilled a total of five times or if six **months have**~~[month shave]~~ expired from the date of  
268 issuance of the original prescription drug order, whichever occurs first, a new and separate

prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

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

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

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

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

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

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

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

(vii) 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) - (vi) of this subparagraph.

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

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

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

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

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

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

313 (vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable  
314 time;

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

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

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

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

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

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

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

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

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

(ii) The ~~patient~~~~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 ~~Schedules~~~~schedule~~ IV and V controlled substances. ~~Schedules~~~~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

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

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

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

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

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

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

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

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

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

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

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

376 (c) – (l) (No change.)