

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

Short Title: Prescription 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, clarify that prescriptions must be transferred by the close of the following business day; update the rules regarding distribution to include dangerous drugs; and implement provisions of HB 751 regarding interchangeable biological products.

The Board reviewed and voted to propose the amendments during the February 2, 2016, meeting. The proposed amendments were published in the March 11, 2016, issue of the *Texas Register* at 41 TexReg 1796.

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

2 **22 TAC §291.34**

3 The Texas State Board of Pharmacy proposes amendments to §291.34, concerning Records. The
4 amendments, if adopted, clarify that prescriptions must be transferred within four business hours;
5 clarify the requirements regarding identification records for individuals involved in dispensing;
6 and implement provisions of HB 751 regarding interchangeable biological products.

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

10 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
11 effect, the public benefit anticipated as a result of enforcing the amendments to §291.5 will
12 ensure that pharmacies provide transfer information in a timely manner; ensure that records of
13 individuals involved in dispensing are accurate; and ensure prescription drug order information
14 for interchangeable biological products is maintained. There is no fiscal impact for individuals,
15 small or large businesses, or to other entities which are required to comply with this section.

16 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,
17 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
18 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5 p.m.,
19 April 25, 2016.

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

25 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas
26 Occupations Code.

27 **§291.34.Records.**

28 (a) (No change.)

29 (b) Prescriptions.

30 (1) - (6) (No change.)

31 (7) Prescription drug order information.

32 (A) (No change.)

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

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

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

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

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

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

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

46 (8) - (10) (No change.)

47 (c) - (f) (No change.)

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

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

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

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

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

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

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

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

71 (C) record the date of the transfer and the name of the individual transferring the information;
72 and

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

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

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

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

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

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

82 (6) The individual receiving the transferred prescription drug order information shall:

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

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

88 (i) date of issuance and prescription number;

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

90 (iii) date of original dispensing;

91 (iv) number of valid refills remaining and if a controlled substance, date(s) and location(s) of
92 previous refills;

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

95 (vi) name of the individual transferring the prescription; and

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

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

102 (i) date of original dispensing;

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

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

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

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

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

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

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

114 (8) Pharmacies transferring prescriptions electronically shall comply with the following:

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

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

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

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

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

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

132 (ii) Pharmacies not owned by the same entity [~~person~~] may electronically access the same
133 prescription drug order records, provided the owner, chief executive officer, or designee of each
134 pharmacy signs an agreement allowing access to such prescription drug order records.

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

138 (9) An individual may not refuse to transfer original prescription information to another
139 individual who is acting on behalf of a patient and who is making a request for this information
140 as specified in this subsection. The transfer of original prescription information must be
141 completed within four business hours of the request. [~~done in a timely manner.~~]

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

146 (11) [~~(10)~~] The electronic transfer of multiple or bulk prescription records between two
147 pharmacies is permitted provided:

148 (A) a record of the transfer as specified in paragraph (5) of this subsection [~~section~~] is maintained
149 by the transferring pharmacy;

150 (B) the information specified in paragraph (6) of this subsection is maintained by the receiving
151 pharmacy; and

152 (C) in the event that the patient or patient's agent is unaware of the transfer of the prescription
153 drug order record, the transferring pharmacy must notify the patient or patient's agent of the
154 transfer and must provide the patient or patient's agent with the telephone number of the
155 pharmacy receiving the multiple or bulk prescription drug order records.

156 (h) (No change.)

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

- 158 (1) a ~~[permanent]~~ log of the initials or identification codes that will identify each pharmacist,
159 pharmacist technician, and pharmacist technician trainee, who is involved in the dispensing
160 process, in the pharmacy's data processing system, [by name performing data entry of
161 prescription information] (the initials or identification code shall be unique to ensure that each
162 individual can be identified, i.e., identical initials or identification codes shall not be used). Such
163 log shall be maintained at the pharmacy for at least seven years from the date of the transaction;
- 164 (2) Copy 3 of DEA order form (DEA 222) that has been properly dated, initialed, and filed, and
165 all copies of each unaccepted or defective order form and any attached statements or other
166 documents and/or for each order filled using the DEA Controlled Substance Ordering System
167 (CSOS) the original signed order and all linked records for that order;
- 168 (3) a ~~[hard]~~ copy of the power of attorney to sign DEA 222 order forms (if applicable);
- 169 (4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify
170 that the controlled drugs listed on the invoices were actually received by clearly recording his/her
171 initials and the actual date of receipt of the controlled substances;
- 172 (5) suppliers' credit memos for controlled substances and dangerous drugs;
- 173 (6) a ~~[hard]~~ copy of inventories required by §291.17 of this title (relating to Inventory
174 Requirements);
- 175 (7) ~~[hard copy]~~ reports of surrender or destruction of controlled substances and/or dangerous
176 drugs to an appropriate state or federal agency;
- 177 (8) ~~[a hard copy of]~~ the Schedule V nonprescription register book;
- 178 (9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies,
179 practitioners, or registrants; and
- 180 (10) a ~~[hard]~~ copy of any notification required by the Texas Pharmacy Act or the sections in this
181 chapter, including, but not limited to, the following:
- 182 (A) reports of theft or significant loss of controlled substances to DEA, Department of Public
183 Safety, and the board;
- 184 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and
- 185 (C) reports of a fire or other disaster that may affect the strength, purity, or labeling of drugs,
186 medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and
187 disease
- 188 (j) - (l) (No change.)