

RULE ANALYSIS

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

Short Title: Hospital Bed Size

Rule Numbers: §291.72

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, add a new definition regarding hospital bed size and how bed size is determined.

The Board reviewed and voted to propose the amendments during the August 5, 2014, meeting. The proposed amendments were published in the September 26, 2014, issue of the *Texas Register* at 39 TexReg 7709.

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

2 **CHAPTER 291. PHARMACIES**

3 **SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)**

4 **22 TAC §291.72**

5 The Texas State Board of Pharmacy proposes amendments to §291.72, concerning Definitions.
6 The amendments, if adopted, add a new definition regarding hospital bed size and how bed size
7 is determined.

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

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
12 effect, the public benefit anticipated as a result of enforcing the amendments will ensure hospital
13 pharmacies comply with appropriate rules according to the size of the hospital. There is no fiscal
14 impact for individuals, small or large businesses, or to other entities which are required to
15 comply with this section.

16 Comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of
17 Professional Services, Texas State Board of Pharmacy, by mail at 333 Guadalupe Street, Suite 3-
18 600, Austin, Texas 78701 or by fax at (512) 305-8008. Comments must be received by 5:00
19 p.m., October 31, 2014.

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

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

27 **§291.72. Definitions.**

28 The following words and terms, when used in this subchapter, shall have the following
29 meanings, unless the context clearly indicates otherwise.

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

31 (31) Number of beds--The total number of inpatients admitted during the previous calendar year
32 divided by 365 (or 366 if the previous calendar year is a leap year).

33 (32) [~~(31)~~] Part-time pharmacist--A pharmacist either employed or under contract, who routinely
34 works less than full-time.

35 (33) [~~(32)~~] Patient--A person who is receiving services at the facility (including patients
36 receiving ambulatory procedures and patients conditionally admitted as observation patients), or
37 who is receiving long term care services or Medicare extended care services in a swing bed on
38 the hospital premise or an adjacent, readily accessible facility that is under the authority of the
39 hospital's governing body. For the purposes of this definition, the term "long term care services"
40 means those services received in a skilled nursing facility which is a distinct part of the hospital
41 and the distinct part is not licensed separately or formally approved as a nursing home by the
42 state, even though it is designated or certified as a skilled nursing facility. A patient includes a
43 person confined in any correctional institution operated by the state of Texas.

44 (34) [~~(33)~~] Perpetual inventory--An inventory which documents all receipts and distributions of a
45 drug product, such that an accurate, current balance of the amount of the drug product present in
46 the pharmacy is indicated.

47 (35) [~~(34)~~] Pharmaceutical care--The provision of drug therapy and other pharmaceutical
48 services intended to assist in the cure or prevention of a disease, elimination or reduction of a
49 patient's symptoms, or arresting or slowing of a disease process.

50 (36) [~~(35)~~] Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the
51 pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and
52 rules pertaining to the practice of pharmacy.

53 (37) [~~(36)~~] Pharmacy and therapeutics function--Committee of the medical staff in the facility
54 which assists in the formulation of broad professional policies regarding the evaluation,
55 selection, distribution, handling, use, and administration, and all other matters relating to the use
56 of drugs and devices in the facility.

57 (38) [~~(37)~~] Pharmacy technician--An individual who is registered with the board as a pharmacy
58 technician and whose responsibility in a pharmacy is to provide technical services that do not
59 require professional judgment regarding preparing and distributing drugs and who works under
60 the direct supervision of and is responsible to a pharmacist.

61 (39) [~~(38)~~] Pharmacy technician trainee--An individual who is registered with the board as a
62 pharmacy technician trainee and is authorized to participate in a pharmacy's technician training
63 program.

64 (40) [~~(39)~~] Pre-packaging--The act of re-packaging and re-labeling quantities of drug products
65 from a manufacturer's original container into unit-dose packaging or a multiple dose container
66 for distribution within the facility except as specified in §291.74(f)(3)(B) of this title (relating to
67 Operational Standards).

68 (41) [~~(40)~~] Prescription drug--

- 69 (A) A substance for which federal or state law requires a prescription before it may be legally
70 dispensed to the public;
- 71 (B) A drug or device that under federal law is required, prior to being dispensed or delivered, to
72 be labeled with either of the following statements:
- 73 (i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend
74 that complies with federal law; or
- 75 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or
- 76 (C) A drug or device that is required by any applicable federal or state law or regulation to be
77 dispensed on prescription only or is restricted to use by a practitioner only.
- 78 (42) [~~(41)~~] Prescription drug order--
- 79 (A) a written order from a practitioner or a verbal order from a practitioner or his authorized
80 agent to a pharmacist for a drug or device to be dispensed; or
- 81 (B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.
- 82 (43) [~~(42)~~] Rural hospital--A licensed hospital with 75 beds or fewer that:
- 83 (A) is located in a county with a population of 50,000 or less as defined by the United States
84 Census Bureau in the most recent U.S. census; or
- 85 (B) has been designated by the Centers for Medicare and Medicaid Services as a critical access
86 hospital, rural referral center, or sole community hospital.
- 87 (44) [~~(43)~~] Sample--A prescription drug which is not intended to be sold and is intended to
88 promote the sale of the drug.
- 89 (45) [~~(44)~~] Supervision--
- 90 (A) Physically present supervision--In a Class C pharmacy, a pharmacist shall be physically
91 present to directly supervise pharmacy technicians or pharmacy technician trainees.
- 92 (B) Electronic supervision--In a Class C pharmacy in a facility with 100 beds or less, a
93 pharmacist licensed in Texas may electronically supervise pharmacy technicians or pharmacy
94 technician trainees to perform the duties specified in §291.73(e)(2) of this title (relating to
95 Personnel) provided:
- 96 (i) the pharmacy uses a system that monitors the data entry of medication orders and the filling
97 of such orders by an electronic method that shall include the use of one or more the following
98 types of technology:

99 (I) digital interactive video, audio, or data transmission;

100 (II) data transmission using computer imaging by way of still-image capture and store and
101 forward; and

102 (III) other technology that facilitates access to pharmacy services;

103 (ii) the pharmacy establishes controls to protect the privacy and security of confidential records;

104 (iii) the pharmacist responsible for the duties performed by a pharmacy technician or pharmacy
105 technician trainee verifies:

106 (I) the data entry; and

107 (II) the accuracy of the filled orders prior to release of the order; and

108 (iv) the pharmacy keeps permanent digital records of duties electronically supervised and data
109 transmissions associated with electronically supervised duties for a period of two years.

110 (C) If the conditions of subparagraph (B) of this paragraph are met, electronic supervision shall
111 be considered the equivalent of direct supervision for the purposes of the Act.

112 (46) [~~(45)~~] Tech-Check-Tech--Allowing a pharmacy technician to verify the accuracy of work
113 performed by another pharmacy technician relating to the filling of floor stock and unit dose
114 distribution systems for a patient admitted to the hospital if the patient's orders have previously
115 been reviewed and approved by a pharmacist.

116 (47) [~~(46)~~] Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health
117 and Safety Code, Chapter 481, as amended.

118 (48) [~~(47)~~] Unit-dose packaging--The ordered amount of drug in a dosage form ready for
119 administration to a particular patient, by the prescribed route at the prescribed time, and properly
120 labeled with name, strength, and expiration date of the drug.

121 (49) [~~(48)~~] Unusable drugs--Drugs or devices that are unusable for reasons, such as they are
122 adulterated, misbranded, expired, defective, or recalled.

123 (50) [~~(49)~~] Written protocol--A physician's order, standing medical order, standing delegation
124 order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas
125 Medical Practice Act Subtitle B, Chapter 157, Occupations Code.

126 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
127 state agency's legal authority to adopt.

128 Filed with the Office of the Secretary of State on September 15, 2014.

129 TRD-201404387
130 Gay Dodson, R.Ph.
131 Executive Director
132 Texas State Board of Pharmacy
133 Earliest possible date of adoption: October 26, 2014
134 For further information, please call: (512) 305-8028
135

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)

5
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9 meanings, unless the context clearly indicates otherwise.

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11 (1) – (30) (No change.)
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14 **(A) beds that the hospital is licensed for by the Texas Department of State Health**
15 **Services; or**
16 **(B) inpatients admitted during the previous calendar year divided by 365 (or 366 if the**
17 **previous calendar year is a leap year).**
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19 **(32) [(31)] Part-time pharmacist--**A pharmacist either employed or under contract, who
20 routinely works less than full-time.
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25 the hospital premise or an adjacent, readily accessible facility that is under the authority of the
26 hospital's governing body. For the purposes of this definition, the term "long term care services"
27 means those services received in a skilled nursing facility which is a distinct part of the hospital
28 and the distinct part is not licensed separately or formally approved as a nursing home by the
29 state, even though it is designated or certified as a skilled nursing facility. A patient includes a
30 person confined in any correctional institution operated by the state of Texas.
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32 **(34) [(33)] Perpetual inventory--**An inventory which documents all receipts and distributions of
33 a drug product, such that an accurate, current balance of the amount of the drug product
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72 legend that complies with federal law; or

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74 (ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

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76 (C) A drug or device that is required by any applicable federal or state law or regulation to be
77 dispensed on prescription only or is restricted to use by a practitioner only.

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89 Census Bureau in the most recent U.S. census; or

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92 access hospital, rural referral center, or sole community hospital.

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