

RULE ANALYSIS

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

Short Title: Emergency Medication Kits

Rule Numbers: §291.121

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;
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act; and
- (3) Section 562.108 give the Board the authority to adopt rules relating to emergency medication kits including procedures regarding the use of drugs from an emergency medication kit.

Purpose: The amendments, if adopted, clarify the requirements for emergency kits using automated systems and bar-code type technology.

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 7711.

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

2 **CHAPTER 291. PHARMACIES**

3 **SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES**

4 **22 TAC §291.121**

5 The Texas State Board of Pharmacy proposes amendments to §291.121, concerning Remote
6 Pharmacy Services. The amendments, if adopted, clarify the requirements for emergency kits
7 using automated systems and bar-code type technology.

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 amendment will be to ensure
13 pharmacies are using technologies that limit the risk of errors when stocking emergency kits
14 using automated systems and bar-code type technology. 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 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, 554.051, and 562.108 of the Texas Pharmacy
21 Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets
22 §551.002 as authorizing the agency to protect the public through the effective control and
23 regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the
24 agency to adopt rules for the proper administration and enforcement of the Act. The Board
25 interprets §562.108 as authorizing the agency to relating to emergency kits including the
26 procedures regarding the use of drugs from an emergency medication kit and security
27 requirements for emergency kits.

28 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 -
29 569, Texas Occupations Code.

30 ***§291.121.Remote Pharmacy Services.***

31 (a) (No change.)

32 (b) Remote pharmacy services using emergency medication kits.

33 (1) - (3) (No change.)

34 (4) Operational standards.

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

36 (F) Stocking emergency medication kits.

37 (i) Stocking of drugs in an emergency medication kit shall be completed at the provider
38 pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee
39 under the direct supervision of a pharmacist, except as provided in clause (ii) of this
40 subparagraph.

41 (ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding,
42 microchip, or other technologies to ensure that the containers or unit dose drugs are accurately
43 loaded [~~removable cartridges or containers to hold drugs~~], the prepackaging of the [~~cartridges or~~]
44 containers or unit dose drugs shall occur at the provider pharmacy unless provided by a [and]
45 FDA approved repackager. The prepackaged [~~cartridges or~~] containers or unit dose drugs may be
46 sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-
47 in-charge provided:

48 (I) a pharmacist verifies the [~~cartridge or~~] container or unit dose drug has been properly filled
49 and labeled;

50 (II) the individual [~~cartridges or~~] containers or unit dose drugs are transported to the remote site
51 in a secure, tamper-evident container; and

52 (III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure
53 that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

54 (iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site
55 by the provider pharmacy.

56 (G) (No change.)

57 (5) (No change.)

58 (c) (No change.)

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

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

62 TRD-201404389

63 Gay Dodson, R.Ph.

64 Executive Director

65 Texas State Board of Pharmacy

66 Earliest possible date of adoption: October 26, 2014

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

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