

RULE ANALYSIS

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

Short Title: Centralized Prescription Dispensing.

Rule Number: §291.125

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 a Class E pharmacy may outsource prescription drug order dispensing to a central fill pharmacy and shall comply with specified requirements unless compliance with the requirements would violate the laws or rules in the state in which the pharmacy is located.

1 **TITLE 22 EXAMINING BOARDS**
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 291 PHARMACIES**
4 **SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES**

5 **§ 291.125 Centralized Prescription Dispensing.**

6 (a) Purpose. The purpose of this section is to provide standards for centralized prescription
7 dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-
8 Resident) Pharmacy.

9 (b) Definitions. The following words and terms, when used in this section, shall have the
10 following meanings, unless the context clearly indicates otherwise. Any term not defined in this
11 section shall have the definition set out in the Act.

12 (1) Central fill pharmacy--a Class A, Class A-S, Class C, Class C-S, Class E, or Class E-S
13 pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription
14 transmitted to the central fill pharmacy by an outsourcing pharmacy.

15 (2) Centralized prescription dispensing--the dispensing or refilling of a prescription drug order
16 by a Class A, Class C, or Class E pharmacy at the request of another Class A, ~~Class C,~~ **or**
17 **Class E** pharmacy and the return of the dispensed prescriptions to the outsourcing pharmacy
18 for delivery to the patient or patient's agent, or at the request of the outsourcing pharmacy for
19 direct delivery to the patient.

20 (3) Outsourcing pharmacy--a Class A, ~~Class C,~~ **or Class E** pharmacy that transmits a
21 prescription drug order via facsimile or communicates prescription information electronically to a
22 central fill pharmacy to be dispensed by the central fill pharmacy.

23 (c) Operational standards.

24 (1) General requirements.

25 (A) A Class A or Class C pharmacy may outsource prescription drug order dispensing to a
26 central fill pharmacy provided the pharmacies:

27 (i) have:

28 (I) the same owner; or

29 (II) entered into a written contract or agreement which outlines the services to be provided
30 and the responsibilities and accountabilities of each pharmacy in compliance with federal and
31 state laws and regulations; and

32 (ii) share a common electronic file or have appropriate technology to allow access to
33 sufficient information necessary or required to dispense or process a prescription drug order.

34 **(B) Unless compliance would violate the pharmacy or drug laws or rules in the state in**
35 **which the pharmacy is located, a Class E pharmacy may outsource prescription drug**
36 **order dispensing to a central fill pharmacy provided the pharmacies meet the**
37 **requirements of subparagraph (A) of this paragraph.**

38 **(C)**~~(B)~~ The pharmacist-in-charge of the central fill pharmacy shall ensure that:

39 (i) the pharmacy maintains and uses adequate storage or shipment containers and shipping
40 processes to ensure drug stability and potency. Such shipping processes shall include the use
41 of appropriate packaging material and/or devices to ensure that the drug is maintained at an
42 appropriate temperature range to maintain the integrity of the medication throughout the delivery
43 process; and

44 (ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to
45 show evidence of opening or tampering.

46 ~~(D)(C)~~ A Class A or Class C central fill pharmacy shall comply with the provisions of
47 §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards,
48 Records, and Official Prescription Requirements in Community Pharmacy (Class A) and this
49 section.

50 ~~(E)(D)~~ A Class E central fill pharmacy shall comply with §§291.101 - 291.105 of this title
51 (relating to Purpose, Definitions, Personnel, Operational Standards, and Records in Non-
52 resident Pharmacy (Class E) and this section.

53 (2) Notifications to patients.

54 (A) A pharmacy that outsources prescription dispensing to a central fill pharmacy shall:

55 (i) prior to outsourcing the prescription:

56 (I) notify patients that their prescription may be outsourced to a central fill pharmacy; and

57 (II) give the name of the central fill pharmacy or if the pharmacy is part of a network of
58 pharmacies under common ownership and any of the network pharmacies may dispense the
59 prescription, the patient shall be notified of this fact. Such notification may be provided through a
60 one-time written notice to the patient or through use of a sign in the pharmacy; and

61 (ii) if a prescription that is not for a controlled substance is delivered directly to the patient by
62 the central fill pharmacy and not returned to the outsourcing pharmacy, place on the prescription
63 container or on a separate sheet delivered with the prescription container, in both English and
64 Spanish, the local, and if applicable, the toll-free telephone number of the pharmacy and the
65 statement: "Written information about this prescription has been provided for you. Please read
66 this information before you take the medication. If you have questions concerning this
67 prescription, a pharmacist is available during normal business hours to answer these questions
68 at (insert the pharmacy's local and toll-free telephone numbers)." A prescription for a controlled
69 substance may not be delivered directly to the patient by the central fill pharmacy.

70 (B) The provisions of this paragraph do not apply to patients in facilities where drugs are
71 administered to patients by a person required to do so by the laws of the state (e.g., hospitals or
72 nursing homes).

73 (3) Prescription Labeling. The central fill pharmacy shall place on the prescription label, the
74 name and address of the outsourcing pharmacy and a unique identifier (i.e., the central fill
75 pharmacy's DEA registration number or, if the pharmacy does not have a DEA registration
76 number, the central fill pharmacy's Texas license number) indicating that the prescription was
77 dispensed by the central fill pharmacy; and comply with all other labeling requirements in
78 §291.33 of this title.

79 (4) Policies and Procedures. A policy and procedure manual as it relates to centralized
80 dispensing shall be maintained at both pharmacies and be available for inspection. Each
81 pharmacy is required to maintain only those portions of the policy and procedure manual that
82 relate to that pharmacy's operations. The manual shall:

83 (A) outline the responsibilities of each of the pharmacies;

84 (B) include a list of the name, address, telephone numbers, and all license/registration
85 numbers of the pharmacies involved in centralized prescription dispensing; and

86 (C) include policies and procedures for:

87 (i) notifying patients that their prescription may be outsourced to a central fill pharmacy for
88 dispensing and providing the name of that pharmacy;

89 (ii) protecting the confidentiality and integrity of patient information;

90 (iii) dispensing prescription drug orders when the dispensed order is not received or the
91 patient comes in before the order is received;

92 (iv) complying with federal and state laws and regulations;

93 (v) operating a continuous quality improvement program for pharmacy services designed to
94 objectively and systematically monitor and evaluate the quality and appropriateness of patient
95 care, pursue opportunities to improve patient care, and resolve identified problems; and

96 (vi) annually reviewing the written policies and procedures and documenting such review.

97 (d) Records.

98 (1) Records may be maintained in an alternative data retention system, such as a data
99 processing system or direct imaging system provided:

100 (A) the records maintained in the alternative system contain all of the information required on
101 the manual record; and

102 (B) the data processing system is capable of producing a hard copy of the record upon the
103 request of the board, its representative, or other authorized local, state, or federal law
104 enforcement or regulatory agencies.

105 (2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of
106 records and be able to produce an audit trail showing all prescriptions dispensed by the
107 pharmacy.

108 (3) The outsourcing pharmacy shall maintain records, in addition to the prescription drug order,
109 which indicate the:

110 (A) date:

111 (i) the request for dispensing was transmitted to the central fill pharmacy; and

112 (ii) the dispensed prescription was received by the outsourcing pharmacy, including the
113 method of delivery (e.g., private, common, or contract carrier) and the name of the person
114 accepting delivery; and

115 (B) name, address, license number, and the unique identifier of the central fill pharmacy.

116 (4) The central fill pharmacy shall maintain records, in addition to the prescription drug order,
117 which indicate the:

118 (A) date the prescription was shipped to the outsourcing pharmacy or the patient;

119 (B) name and address where the prescription was shipped;

120 (C) method of delivery (e.g., private, common, or contract carrier); and

121 (D) name, address, and license number of the outsourcing pharmacy.

122 **(e) Nothing in this section shall be construed as requiring a nonresident pharmacy that**
123 **outsources drug order dispensing to a central fill pharmacy to be licensed as a Class E**
124 **pharmacy in accordance with §291.101 of this title, provided that the nonresident**
125 **pharmacy does not physically ship, mail, or deliver prescription drugs or devices directly**
126 **to a patient or patient's agent in this state.**