

RULE ANALYSIS

Introduction: THESE NEW RULES ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS PROPOSED RULES

Short Title: Sterile Compounding

Rule Numbers: §291.133

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, clarify pharmacies compounding sterile preparations should use sterile alcohol and sterile gloves.

Background: Staff presents these amendments to clarify the requirements for compounding sterile preparations to be consistent with USP 797 guidelines.

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
6 **§291.133 Pharmacies Compounding Sterile Preparations**
7

8 (a) – (c) (No change.)
9

10 (d) Operational Standards.

11
12 (1) – (4) (No change.)
13

14 (5) Environment. Compounding facilities shall be physically designed and environmentally
15 controlled to minimize airborne contamination of critical sites.
16

17 (A) – (D) (No change.)
18

19 (E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and
20 disinfecting practices and frequencies apply to direct and contiguous compounding areas,
21 which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer
22 rooms, anterooms, and ante-areas.
23

24 (i) The pharmacist-in-charge is responsible for developing written procedures for
25 cleaning and disinfecting the direct and contiguous compounding areas and assuring the
26 procedures are followed.
27

28 (ii) These procedures shall be conducted prior to and after each work shift (at a minimum
29 of every 12 hours while the pharmacy is open) and when there are spills or environmental
30 quality breaches.
31

32 (iii) Before compounding is performed, all items are removed from the direct and
33 contiguous compounding areas and all surfaces are cleaned of loose material and residue
34 from spills, followed by an application of a residue-free **suitable** disinfecting agent (e.g.,
35 **sterile** IPA), that is left on for a time sufficient to exert its antimicrobial effect.
36

37 (iv) Work surfaces near the direct and contiguous compounding areas in the buffer or
38 clean area are cleaned of loose material and residue from spills, followed by an application
39 of a residue-free disinfecting agent that is left on for a time sufficient to exert its antimicrobial
40 effect.
41

42 (v) Floors in the buffer or clean area are cleaned by mopping at least once daily when no
43 aseptic operations are in progress preceding from the buffer or clean room area to the
44 anteroom area.
45

46 (vi) In the anteroom area, walls, ceilings, and shelving shall be cleaned monthly.
47

48 (vii) Supplies and equipment removed from shipping cartons must be wiped with a
49 **suitable** disinfecting agent, such as **sterile** IPA. However, if supplies are received in sealed
50 pouches, the pouches may be removed as the supplies are introduced into the buffer or

51 clean area without the need to disinfect the individual supply items. No shipping or other
52 external cartons may be taken into the buffer or clean area.

53
54 (viii) Storage shelving, emptied of all supplies, walls, and ceilings are cleaned and
55 disinfected at planned intervals, monthly, if not more frequently.

56
57 (F) – (G) (No change.)

58
59 (6) Equipment and supplies. Pharmacies compounding sterile preparations shall have the
60 following equipment and supplies:

61
62 (A) – (G) (No change.)

63
64 (H) all necessary supplies, including:

65
66 (i) disposable needles, syringes, and other supplies for aseptic mixing;

67
68 (ii) disinfectant cleaning solutions;

69
70 (iii) hand washing agents with bactericidal action;

71
72 (iv) disposable, lint free towels or wipes;

73
74 (v) appropriate filters and filtration equipment;

75
76 (vi) cytotoxic spill kits, if applicable; and

77
78 (vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and **sterile** gloves, as
79 applicable.

80
81 (7) – (10) (No change.)

82
83 (11) Compounding process.

84
85 (A) – (B) (No change.)

86
87 (C) Personnel Cleansing and Garbing.

88
89 (i) Any person with an apparent illness or open lesion that may adversely affect the
90 safety or quality of a drug preparation being compounded shall be excluded from direct
91 contact with components, drug preparation containers, closures, any materials involved in
92 the compounding process, and drug products until the condition is corrected.

93
94 (ii) Before entering the clean area, compounding personnel must remove the following:

95
96 (I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters,
97 vests);

98
99 (II) all cosmetics, because they shed flakes and particles; and

100
101 (III) all hand, wrist, and other body jewelry.

102
103
104
105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141
142
143
144

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment.

(iv) Personnel must don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:

(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents.

(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the anteroom/ante-area.

(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists.

(IV) **Sterile** gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins.

(V) **Sterile** gloves, either those which are sterile or have been disinfected by applying 70% **sterile** IPA or appropriate disinfectant to all contact surface areas and allowed to dry, that form a continuous barrier with the gown shall be the last item donned before compounding begins. Routine application of 70% **sterile** IPA shall occur throughout the compounding day and whenever nonsterile surfaces are touched.

(VI) When compounding personnel must temporarily exit the ISO Class 7 environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 anteroom/ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and **sterile** gloves must be replaced with new ones before re-entering the ISO Class 7 clean environment along with performing proper hand hygiene.

(D) (No change.)

(12) – (13) (No change.)

(e) - (g) (No change.)