

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 **§291.131 Pharmacies Compounding Non-Sterile Preparations**

7
8 (a) – (f) (No change.)

9
10 (g) Recall Procedures.

11
12 **(1) The pharmacy shall have written procedures for the recall of any compounded non-**
13 **sterile preparations provided to a patient, to a practitioner for office use, or a pharmacy**
14 **for administration. Written procedures shall include, but not be limited to the**
15 **requirements as specified in paragraph (3) of this subsection.**

16
17 **(2) The pharmacy shall immediately initiate a recall of any non-sterile preparation**
18 **compounded by the pharmacy upon identification of a potential or confirmed harm to a**
19 **patient.**

20
21 **(3) If the pharmacy identifies a potential or confirmed harm to a patient, the pharmacist-**
22 **in-charge shall ensure that:**

23 **(A) each practitioner, facility, and/or pharmacy to which the preparation was**
24 **distributed is notified, in writing, of the recall;**

25 **(B) each patient to whom the preparation was dispensed is notified, in writing, of the**
26 **recall;**

27 **(C) the board is notified, in writing, of the recall;**

28 **(D) the Texas Department of State Health Services, Drugs and Medical Devices Group,**
29 **is notified of the recall, in writing, if the preparation is distributed for office use;**

30 **(E) the preparation is quarantined if there is potential for or confirmed harm to a**
31 **patient; and**

32 **(F) the pharmacy keeps a written record of the recall including all actions taken to**
33 **notify all parties and steps taken to ensure corrective measures.**

34
35 ~~[(1) The pharmacy shall have written procedure for the recall of any compounded non-sterile~~
36 ~~preparations provided to a patient, to a practitioner for office use, or to a pharmacy for~~
37 ~~administration. The recall procedures shall require:~~

38
39 ~~—(A) notification to each practitioner, facility, and/or pharmacy to which the preparation was~~
40 ~~distributed;~~

41
42 ~~—(B) notification to each patient to whom the preparation was dispensed;~~

43
44 ~~—(C) quarantine of the product if there is a suspicion of harm to a patient; and~~

45
46 ~~—(D) a recall if there is probable or confirmed harm to a patient.]~~

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48 ~~[(2)] If the pharmacy identifies a suspicion of, probable, or confirmed harm to a patient, the~~
49 ~~pharmacy shall immediately notify and provide information as required by the board to the~~
50 ~~following:~~

51
52 ~~—(A) the Texas Department of State Health Services, Drugs and Medical Devices Group, if the~~
53 ~~preparation is distributed for office use; and~~

55 —(B) the board.

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57 **(4)** [(3)] The board may require a pharmacy to **initiate** [institute] a recall if there is **potential for**
58 [probable] or confirmed harm to a patient.

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) – (f) (No change.)

9
10 (g) Recall Procedures.

11
12 **(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.**

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17 **(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.**

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21 **(3) If the pharmacy identifies a potential or confirmed harm to a patient, the pharmacist-in-charge shall ensure that:**

22 **(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;**

23 **(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;**

24 **(C) the board is notified, in writing, of the recall;**

25 **(D) the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing, if the preparation is distributed for office use;**

26 **(E) the preparation is quarantined if there is potential for or confirmed harm to a patient; and**

27 **(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.**

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35 ~~[(1) The pharmacy shall have written procedure for the recall of any compounded sterile preparations provided to a patient, to a practitioner for office use, or to a pharmacy for administration. The recall procedures shall require:~~

36 ~~—(A) notification to each practitioner, facility, and/or pharmacy to which the preparation was distributed;~~

37 ~~—(B) notification to each patient to whom the preparation was dispensed;~~

38 ~~—(C) quarantine of the product if there is a suspicion of harm to a patient; and~~

39 ~~—(D) a recall if there is probable or confirmed harm to a patient.]~~

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48 ~~[(2) If the pharmacy identifies a suspicion of, probable, or confirmed harm to a patient, the pharmacy shall immediately notify and provide information as required by the board to the following:~~

52 —(A) the Texas Department of State Health Services, Drugs and Medical Devices Group, if the
53 preparation is distributed for office use; and

54
55 —(B) the board.]

56
57 **(4)** ~~[(3)]~~ The board may require a pharmacy to **initiate** [institute] recall if there is **potential for**
58 ~~[probable]~~ or confirmed harm to a patient.