

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

* * *

§2535. General Standards

- A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.
 1. ...
 2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, ~~as well as~~ and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, ~~most recently in November 2013,~~ the ~~2016~~ current edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the ~~2014~~ current edition of the United States Pharmacopeia-National Formulary (USP 37—NF 32).

A.2.a. – E.4. ...

- F. ~~Compounding Copies Variations of Commercial Drug Products not Available.~~ A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:
 - ~~1. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health System Pharmacists (ASHP).~~
 - ~~2. Products temporarily unavailable from manufacturers, as demonstrated by invoice or other communication from the distributor or manufacturer.~~
 1. Copies Variations of commercial drug products contain the same active pharmaceutical ingredient(s) and excipients in the same, similar, or easily substitutable dosage strength which can be used by the same route of administration. In the event a prescriber determines a change in the formulation of a commercial drug product is necessary to produce a significant clinical difference for the patient and documents that determination on the prescription, the pharmacy may prepare the copy variation of the commercial drug product, provided:
 - a. The prescriber’s determination shall identify both the relevant change requested and the clinically significant difference the change will produce for the patient;
 - b. Changes in strength of less than 10 percent from the commercial drug product shall not be considered significant enough to warrant the preparation of a copy variation of a commercial drug product; and
 - c. The pharmacy does not prepare copies variations of commercial drug products regularly or in inordinate amounts.
 2. A pharmacy may prepare a copy variation of a commercial drug product when that product has been discontinued and is no longer marketed, or the drug product appears on the drug shortage list maintained by the federal Food and Drug Administration (FDA).

G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR 42:891 (June 2016), amended by the Department of Health, Board of Pharmacy, LR

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51