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From: Terrence "Joe" Donahue, Jr.
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Occupational Licensing Review Program

Date: November 3, 2022

Subject: OLRP File No. 22-09-OR-0009
Proposed LAC 46:LIII.2535 – General Standards (Compounding)

I. Summary

The Louisiana Board of Pharmacy (the "Board") proposes amending LAC 46:LIII.2535 to eliminate the reference to the "2014 edition" of the United States Pharmacopeia – National Formulary ("USP-NF"), thereby making the most current edition of the publication applicable to the compounding of drugs and devices by the Board's licensees. The Board published a Notice of Intent to promulgate the proposed regulation on July 20, 2022 and conducted a public hearing on August 26, 2022 during which no comments or testimony were offered.

The U.S. Supreme Court has noted that private standard setting organizations "can be rife with opportunities for anticompetitive activity," therefore proposed § 2535 has the potential to create reasonably foreseeable anti-competitive effects meriting review by the Louisiana Attorney General.[1] The Board submitted the proposed amendment to the Attorney General on September 25, 2022 and supplemented the submission on October 6, 2022. The OLRP invited public comments on the proposed amendment to § 2535 for a 30-day period ending on October 29, 2022, but received no comments. The Attorney General has determined the proposed amendment adheres to clearly articulated state policy and therefore approves its adoption as drafted by the Board.

II. Analysis

The Louisiana Pharmacy Practice Act, La. R.S. 37:1161 *et seq.*, subjects the practice of pharmacy in the state of Louisiana to regulation by the Board for the purpose of

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[1] *Am. Soc. of Mech. Engineers, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 571 (1982).

promoting, preserving, and protecting the public health, safety and welfare.[2] The practice of pharmacy encompasses the compounding of drugs and medical devices, and the Board is authorized to establish minimum specifications for compounding procedures and to designate an official compendium of substances recognized for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.[3]

Pharmacopeias or formularies, collectively known as drug compendia, are reference books whose purpose is to assure drug product standardization by providing specification limits for identity, quality, purity, and potency of drugs and dosages.[4] The USP-NF is a compendium created by a private non-profit entity that has been designated an "official compendium" for purposes of federal law since the passage of the Pure Food and Drug Act of 1906.[5] The USP-NF currently retains this designation in the federal Food, Drug and Cosmetic Act ("FDCA").[6] Louisiana first adopted the USP-NF as an official compendium in 1882, having declared it unlawful to sell a drug recognized in the United States Pharmacopeia if "its strength or purity fall below the professed standard..."[7] The USP-NF, and "any supplement" thereto, currently remain designated as an official compendium for purposes of Louisiana law.[8] Under these circumstances, the amended regulation proposed by the Board does not involve the exercise of any discretion, but rather implements requirements that are mandated by state and federal law.

III. Determination

As the Attorney General has determined the amendment to LAC 46:LIII.2535 proposed by the Board adheres to clearly articulated state policy, the regulation is approved as drafted and may be finally adopted.

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[2] La. R.S. 37:1163 and La. R.S. 37:1171.
[3] La. R.S. 37:1164(7), (14), and (44); La. R.S. 37:1182(A)(13).
[4] Martin Blake, *The Role of the Compendia in Establishing Drug Standards*, 31 Food Drug Cosm. L.J. 276 (1976).
[5] *Id.* at 277-278.
[6] 21 U.S.C. § 321(g)(1)(A) and 21 U.S.C. § 351(j).
[7] Act No. 82 of the 1882 Louisiana Legislative Regular Session at § 2.
[8] La. R.S. 40:602(11) and La. R.S. 40:618.