LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

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July 27, 2020[1]

RE: Physician Compounding

During its most recent meeting, the Louisiana State Board of Medical Examiners considered your inquiry relative to physician compounding of sterile products. As we understand, you wish to know if "mixing antibiotics, Infusion Therapies, Chemotherapy,"[2] that is patient specific and compounded for immediate use under the oversight of a licensed physician, can be done in the absence of a pharmacist or pharmacy license.[3]

The Board asked that I acknowledge your inquiry and advise you that compounding is regulated by both federal state and law. Under federal regulation, the compounding of: sterile preparations must comply with Title 21 of the *Code of Federal Regulations* (CFR), section 503A of the U.S. Food, Drug and Cosmetic Act (FDCA), as amended, and the United States Pharmacopeiaary (USP) chapter 797; non-sterile preparations should comply with the provisions of section 503A of the FDCA and USP chapter 795; positron emission tomography (PET) drugs should comply with the provisions of section 212 of title 21 of the CFR; and compounding copies of commercially available products should comply with section 503A of the FDCA as amplified by recent federal guidance.

By virtue of an exception to the state's pharmacy law, Louisiana licensed physicians are permitted to compound and dispense medications to their patients provided they meet standards akin to those utilized by pharmacists.[4] The Louisiana State Board of Pharmacy (Pharmacy Board) regulations require a patient-specific prescription as a prerequisite to compounding medication by a pharmacist and compliance with the above cited federal regulations. Among other items, such rules provide that all compounding activities be

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[1] A prior version of this opinion was released on September 10, 2018.

[2] E-mail to LSBME.

[3] Please note: Section 503A, cited in your communication, has been amended by the Compounding Quality Act, as described in Section 106(a) of the Act.

[4] La. Rev. Stat. §37:1201.

accomplished utilizing accepted pharmacy techniques, practices, and equipment; compliance with the most recent amendments of federal law and regulations *e.g.,* Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, the current edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the 2014 edition of the United States Pharmacopeia-National Formulary (USP 37NF 32); and adherence to minimum current good compounding practices, as defined in the Pharmacy Board's General Standards for Compounding of Drugs.[5]

In addition to the above-note requirements, we should also note that the Board fully expects physicians will not provide medical care or services, including supervising these activities, that he or she is not fully qualified by education, training and experience to provide or perform. Further, in the event that dispensing[6] compounded medication is contemplated, the physician would be required to possess a dispensing registration from the Board and comply with the Board's dispensing rules.[7] Finally, the Board is currently developing a rule-making effort governing compounding that will likely require registration, inspections and rules similar to those of the Board of Pharmacy.

In sum, compounding[8] medications such as those described may be performed by a physician in this state provided he or she is fully trained in compounding, does so with the use of the appropriate techniques, practices and equipment and compliance with applicable federal and state law and regulations. Failure to so may provide the Board[9] (and other regulators) a basis for administrative action.

I trust our advice is responsive. If not, please let us know.

Very truly yours,

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

By: _____

Vincent A. Culotta, Jr., M.D.
Executive Director

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[5] The Louisiana State Board of Pharmacy rules governing compounding are set forth at LAC 46:LIII.2531-2535.

[6] Per the Board rules, the term *dispense* means 'to give, provide, or supply for later oral ingestion, insertion, application, injection, or other use. "LAC 46:XLV.6503A.

[7] LAC. 46:XLV.6501 *et seq.* The rules provide, among other items, that '. . .[N]o physician shall dispense any medication, other than a bona fide medication sample, unless he is currently registered with the board as a dispensing physician, in accordance with Subchapter C of this Chapter, and the physician's dispensation of medications is within the scope of such registration. LAC 46:XLV. 6505B.

[8] We note that the dilution of the concentration of a drug prior to injecting or the addition of sterile water to powder antibiotic or other solutions may be considered "preparation for administration." Although these activities meet the definition of *compounding*, we understand that the Board of Pharmacy has elected to use enforcement discretion and not assert its jurisdiction over such activities.

[9] La. Rev. Stat. §37:1285A provides that the Board may take action against the license of a physician for '(13) [U]nprofessional conduct, including . . . failing to practice within the scope of education, training, and experience;' and '(14) [C]ontinuing or recurring medical practice which fails to satisfy the prevailing and usually accepted standards of medical practice in this state.'