TO: Board of Pharmacy

FROM: Louise St Laurent, General Counsel

Re: Memorandum of Understanding (MOU) Between the Florida Department of Health and the U.S. Food and Drug Administration Regarding Distribution of Compounded Drug Products

Date: September 6, 2019

You have inquired whether or not the Department of Health (Department) can enter into a memorandum of understanding (MOU) as provided for in section 503A(b)(3)(i) of the Federal Food, Drug, and Cosmetic Act (the FD & C Act) (21 U.S.C. 353a), with the U.S. Food and Drug Administration (FDA). An MOU which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for investigation by a state agency of complaints relating to compounded drug products distributed outside the state is necessary if certain exemptions from specific sections of the FD& C Act relating to good manufacturing practice, labeling and FDA approval prior to marketing may be claimed. The FDA is required by section 503A(b)(d) of the FD&C to develop a standard form for the MOU. The standard form is attached as Exhibit A. It is my opinion that Florida law renders the Department unable to comply with the conditions set forth in the standardized MOU.

Section III a.5. of the MOU requires the Department to notify the FDA by email no later than three business days after receiving a complaint related to a compounded drug product. Section 456.073, Florida Statutes, sets forth the process for disciplinary proceedings against Department licensees and permittees. This process requires complaints filed with the Department to be investigated and for the findings and recommendation of the department concerning the existence of probable cause to be submitted to the appropriate probable cause panel for consideration. The complaint and all information obtained pursuant to the investigation by the Department are confidential and exempt from section 119.07(1), Florida Statutes, until 10 days after probable cause has been found to exist by the probable cause panel or the Department or until the regulated professional or subject of the investigation waives his or her privilege of confidentiality, whichever occurs first. Cases dismissed prior to a finding of probable cause and those where probable cause is not found are confidential and exempt from s. 119.071(1), Florida Statutes. The restrictions on the release of a complaint and information related to that complaint prior to a finding of probable cause prevent the Department from providing a complaint regarding compounded drug products to the FDA within three business days of receipt as set forth in the standardized MOU.

Further, the standardized MOU form does not contain other provisions required in Department contracts and agreements. Specifically, the MOU does not refer to the FDA's duty to cooperate with the Inspector General in any investigation audit, inspection, review or hearing as required by section 20.055(5), Florida Statutes; does not allow the for termination upon 30 days written notice, without cause; does not provide for modification; does not address the FDA's obligation to allow public access to all documents, papers, letters or other materials, unless exempt, pursuant to Chapter 119, Florida Statutes; does not preserve the right to assert sovereign immunity; does not reference either party's obligations regarding costs; does not provide a dispute mechanism; does not address venue; does not assert that the parties to the MOU are independent contractors; does not contain a provision for attorney's fees; does not provide for waiver of rights, powers or privileges; makes no provision for compliance with applicable laws, and; contains no assertion that the MOU embodies the entire agreement and understanding between the parties.

This opinion is directed to legal and contractual issues regarding the standardized MOU and does not address issues that may exist with regard to pharmacy or physician compounding, recordkeeping, record maintenance, surveys, review of records during inspections, product distribution, numbers of prescription orders, or other pharmacy or compounding requirements contained in the standardized MOU.