

Blog Post

Class III Hospital Permits – Efficient Drug Management May Become a Reality

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At the close of the 2018 session, the Florida Legislature passed Senate Bill (SB) 675, which if allowed to become law by the Governor, will help hospitals and their facilities that are under common control manage their patients' drugs much more efficiently. Under prior law, the hospitals had to obtain a restricted drug distributor-health care entity permit to allow the hospitals to distribute manufactured drugs throughout the facility. SB 675 shifts the regulation of internal hospital drug distribution from the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics ("DDC") to the Board of Pharmacy and eliminates the requirement for at least one permit in the process. It also allows the hospitals to deal with only one agency's requirements, fees and inspectors.

SB 675 creates a new "Class III Institutional Pharmacy" license, which allows the holder to compound, dispense, and fill prescriptions, prepackage and distribute drugs among the hospital facilities (including their facilities holding health care clinic establishment permits) without the need for a restricted drug distributor permit. This provides the hospitals with needed flexibility to quickly supply medicines when and where they are needed. Besides the obvious benefit to the hospitals for their drug distribution activities, this will also allow hospital-owned physician practices to obtain

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drugs directly from the hospital, though non-profit hospitals should still be cognizant of “own-use” requirements.

Another benefit of the permit is for hospitals that handle 340B drugs. DDC had interpreted prior law to require 340B covered entities that arranged to have their prescription drug wholesale distributors distribute 340B drugs directly to contract pharmacies for dispensing, to obtain a restricted drug distributor permit- health care entity from DDC. SB 675 includes an exemption for 340B entities from the definition of “wholesale distribution” to clarify that this permit is no longer required.

The Board of Pharmacy will likely promptly start on the rule-making process for the Class III Pharmacy permit applications once the Governor makes it official. Stay tuned.

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