FLORIDA BOARD OF PHARMACY
REGULATION OF OUTSOURCING FACILITIES

FOOD AND DRUG ADMINISTRATION
INTERGOVERNMENTAL MEETING
NOVEMBER 16-17, 2015

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Board of Pharmacy Response to New England Compounding Center

- Created Special Sterile Compounding Permit (September 2013)
- Amended Board's definition of compounding

  Made clear that any pharmacy engaging in office use compounding of sterile products must comply with 21 U.S.C. § 353b and be registered as an outsourcing facility.

Legislative Response
CS/HB 7077

- Effective October 1, 2014
- Established nonresident sterile compounding permit
- Authorizes inspection and discipline of non-resident pharmacies
- Created first definition in Florida Statutes for “outsourcing facility” within the Pharmacy Practice Act

Legislative Response
CS/HB 7077

Requires outsourcing facilities to obtain Nonresident Sterile Compounding Permit with the following requirements:

- Proof of registration as outsourcing facility with HHS;
- Current inspection showing compliance with Current Good Manufacturing Practices (CGMP);
- Submission of policies and procedures that show compliance with CGMP.

Inspection Entities for Non-Resident Outsourcing Facilities

- Food and Drug Administration
- Regulatory agency where outsourcing facility is registered
- Department of Health Inspectors
- Others entities approved by Board

In-State Outsourcing Facilities

- All registered with the Board and inspected by the Department
- Must comply with CGMP pursuant to 21 U.S.C. § 353b

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