

THE FLORIDA SENATE
2014 SUMMARY OF LEGISLATION PASSED
Committee on Health Policy

CS/HB 7077 — Nonresident Sterile Compounding Permits

by Health and Human Services Committee; Health Quality Subcommittee; and Rep. Patronis and others (CS/CS/SB 662 by Appropriations Committee; Regulated Industries Committee; and Health Policy Committee)

The bill requires a nonresident pharmacy or an outsourcing facility that is not located in this state to obtain a nonresident sterile compounding permit prior to sending a compounded sterile product into this state. Currently-registered nonresident pharmacies must be permitted by February 28, 2015. However, any compounded sterile product shipped, mailed, delivered, or dispensed into this state must meet or exceed this state's standards for sterile compounding.

An outsourcing facility is defined in the bill as a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a drug or product is conducted.

The bill establishes application and inspection requirements for the nonresident sterile compounding permit as well as responsibilities for the Department of Health (department) and the Board of Pharmacy (board) to develop application forms, fees, and additional procedures to administer the permit.

The department and board are provided with enhanced oversight responsibility for these entities including authority to inspect a nonresident pharmacy or a nonresident sterile compounding permittee; the cost of which is to be borne by the pharmacy or permittee. The board is authorized to discipline a nonresident pharmacy for conduct which causes or could cause serious bodily or psychological injury to a human or serious bodily injury to an animal immediately, without waiting 180 days for the resident state to act. The board is also authorized to discipline nonresident pharmacies and nonresident sterile compounding permittees for specified acts of noncompliance.

If approved by the Governor, these provisions take effect October 1, 2014.

Vote: Senate 39-0; House 117-0