Committee on Health Policy

CS/CS/HB 365 — Pharmacy

by Health and Human Services Committee; Health Quality Subcommittee; and Reps. Hudson, Jones, and others (CS/CS/SB 732 by Appropriations Committee; Health Policy Committee; and Senator Grimsley)

The bill authorizes a Class II institutional pharmacy (typically a hospital pharmacy) to add biological products, biosimilars, and biosimilar interchangeables to its institutional formulary system.

Under the bill, pharmacists may only dispense biosimilar products to patients in place of prescribed biological products if:

- The federal Food and Drug Administration (FDA) has determined that the substitute biological product is biosimilar to and interchangeable for the prescribed biological product;
- The prescriber does not express any preference against such a substitution;
- The person presenting the prescription is notified of the substitution in a manner consistent with s. 465.025(3), F.S., which includes advising the presenter that he or she may refuse the substitution and request the brand name biological product and that any savings in dispensing the biosimilar will be passed on to the presenter; and
- The pharmacist retains a record of the substitution for at least 2 years.

A pharmacist who practices in a Class II or modified Class II institutional pharmacy must comply with the reporting provisions by entering the substitution into the institution's medical record system. The bill also requires the Board of Pharmacy to maintain on its public website a list of biological products that the FDA has determined to be biosimilar and interchangeable.

If approved by the Governor, these provisions take effect July 1, 2013.
Vote: Senate 36-1; House 116-1