
OLR Bill Analysis

sSB 1006

AN ACT CONCERNING REVISIONS TO THE PHARMACY AND DRUG CONTROL STATUTES.

SUMMARY

This bill makes various changes to the laws that govern pharmacies that dispense or compound sterile pharmaceuticals. The bill (1) generally requires compounding pharmacies to additionally comply with United States Pharmacopeia (USP) chapters 800 and 825, rather than only USP chapter 797, and (2) requires state-licensed and institutional compounding pharmacies to designate a pharmacist responsible for overseeing compounding activities (§ 1).

It also:

1. requires state-licensed pharmacies to report to the Department of Consumer Protection (DCP) any administrative or legal action commenced against them by a state or federal regulatory agency or accreditation entity (§ 2);
2. terminates the temporary designation of controlled substances by virtue of federal action and instead makes such classifications permanent, unless DCP opts to change them (§ 3);
3. reclassifies on the state's controlled substances schedule federally approved medical marijuana products (§ 4); and
4. makes technical and conforming changes.

EFFECTIVE DATE: Upon passage, except the provisions on compounding pharmacies (§ 1) are effective January 1, 2020.

§ 1 — COMPOUNDING PHARMACIES

Compliance with Additional USP Chapters

Currently, throughout the law regulating nonresident, state-licensed, and institutional compounding pharmacies, such pharmacies are required to comply with the most recent version of USP chapter 797 (“pharmaceutical compounding - sterile preparations”). The bill additionally requires covered pharmacies to comply with the most recent version of USP chapters 800 (“hazardous drugs - handling in healthcare settings”) and 825 (“radiopharmaceuticals - preparation, compounding, dispensing, and repackaging”).

Under the bill, compounding pharmacies must also comply with any companion documents referenced in USP chapters 797, 800, and 825.

Clean Room Remodels, Relocations, Upgrades, and Repairs

Under current law, if a compounding pharmacy plans to remodel or relocate a pharmacy clean room, or conduct nonemergency repair work to such room, notice of such plans must be provided to DCP. The bill specifies that this notice must be in writing.

Designated Pharmacist

The bill requires state-licensed and institutional pharmacies that provide sterile pharmaceuticals to designate a pharmacist responsible for overseeing sterile pharmaceutical compounding and the application of USP chapters as they relate to sterile compounding (i.e., chapters 797, 800, and 825). Designated pharmacists must provide DCP proof that they have completed a DCP-approved program that demonstrates the competence necessary for the compounding of sterile pharmaceuticals in compliance with all applicable federal and state laws.

Each pharmacy must notify DCP of its designated pharmacist; if such pharmacist loses the designation, he or she must notify DCP immediately. The bill specifies that designated pharmacists are allowed to serve as pharmacy managers.

§ 2 — GIVING DCP NOTICE OF CERTAIN ACTIONS

The bill requires state-licensed pharmacies to report to DCP any

administrative or legal action commenced against them by a state or federal regulatory agency or accreditation entity within 10 business days after receiving notice of the action.

Existing law, unchanged by the bill, requires (1) state-licensed compounding pharmacies to report such information to DCP within 5 business days and (2) nonresident pharmacies to report similar information within 10 business days (CGS §§ 20-627(b)(8) & 20-653b(j)).

§ 3 — CLASSIFICATION OF CONTROLLED SUBSTANCES

Under current law, if a drug that is not classified in Connecticut's controlled substances schedule is classified under the federal Controlled Substances Act, the federal classification automatically applies in Connecticut for 240 days. The bill eliminates the temporary nature of such classifications, making them permanent. But the bill specifies that the DCP commissioner, through regulations, may opt to change the classification of any controlled substance that is automatically classified under the bill's provisions.

§ 4 — CLASSIFICATION OF MEDICINAL MARIJUANA PRODUCTS

Under current state law, DCP's regulations must classify marijuana and marijuana products as schedule II controlled substances. The bill creates an exception from this requirement for marijuana products that are approved by the federal Food and Drug Administration (FDA) or a successor agency as having a medical use. The bill requires the commissioner to adopt the schedule designated by the FDA. Meaning, such products must be classified in Connecticut the same as they are under federal law (and if unclassified at the federal level, they must also be unclassified in Connecticut).

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute

Yea 16 Nay 0 (03/21/2019)