Senate

General Assembly **File No. 537**

January Session, 2019 Substitute Senate Bill No. 1006

Senate, April 8, 2019

The Committee on General Law reported through SEN. FONFARA of the 1st Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

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

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-633b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(a) As used in this section:

(1) "Medical order" means a written, oral or electronic order by a prescribing practitioner, as defined in section 20-14c, for a drug to be dispensed by a pharmacy for administration to a patient;

(2) "Sterile compounding pharmacy" means a pharmacy, as defined in section 20-571, a nonresident pharmacy registered pursuant to section 20-627, that dispenses or compounds sterile pharmaceuticals; **[**and**]**

(3) "Sterile pharmaceutical" means any dosage form of a drug, including, but not limited to, parenterals, injectables, surgical irrigants

and ophthalmics devoid of viable microorganisms; **[**.**]** and

(4) "USP chapters" means chapters 797, 800 and 825 of the United States Pharmacopia that pertain to compounding sterile pharmaceuticals and their referenced companion documents, as amended from time to time.

(b) (1) If an applicant for a new pharmacy license pursuant to section 20-594, as amended by this act, intends to compound sterile pharmaceuticals, the applicant shall file an addendum to its pharmacy license application to include sterile pharmaceutical compounding. The Department of Consumer Protection shall inspect the proposed pharmacy premises of the applicant and the applicant shall not compound sterile pharmaceuticals until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

(2) If an existing pharmacy licensed pursuant to section 20-594, as amended by this act, intends to compound sterile pharmaceuticals for the first time on or after July 1, 2014, such pharmacy shall file an addendum application to its application on file with the department to include sterile pharmaceutical compounding. The Department of Consumer Protection shall inspect the pharmacy premises and the pharmacy shall not compound sterile pharmaceuticals until it receives notice that such addendum application has been approved by the department and the Commission of Pharmacy.

(3) If an applicant for a nonresident pharmacy registration intends to compound sterile pharmaceuticals for sale or delivery in this state, the applicant shall file an addendum to its application to include sterile pharmaceutical compounding. The applicant shall provide the department with written proof it has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such pharmacy shall not compound sterile pharmaceuticals for sale or delivery in this state until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

(4) If a nonresident pharmacy registered pursuant to section 20-627 intends to compound sterile pharmaceuticals for sale or delivery in this state for the first time on or after July 1, 2014, the nonresident pharmacy shall file an addendum to its application to include sterile pharmaceutical compounding. The nonresident pharmacy shall provide the department with written proof it has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such pharmacy shall not compound sterile pharmaceuticals until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

(c) A sterile compounding pharmacy shall comply with the **[**most recent version of the United States Pharmacopeia, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time**]** USP chapters. A sterile compounding pharmacy shall also comply with all applicable federal and state statutes and regulations.

(d) An institutional pharmacy within a facility licensed pursuant to section 19a-490 that compounds sterile pharmaceuticals shall comply with the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time**]** USP chapters, and shall also comply with all applicable federal and state statutes and regulations. Such institutional pharmacy may request from the Commissioner of Consumer Protection an extension of time, not to exceed six months, to comply, for state enforcement purposes, with any amendments to USP Chapter 797, for good cause shown. The commissioner may grant an extension for a length of time not to exceed six months. Nothing herein shall prevent such institutional pharmacy from requesting a subsequent extension of time or shall prevent the commissioner from granting such extension.

(e) (1) A sterile compounding pharmacy may only provide patient-specific sterile pharmaceuticals to patients, practitioners of medicine, osteopathy, podiatry, dentistry or veterinary medicine, or to an acute care or long-term care hospital or health care facility licensed by the

Department of Public Health.

(2) If a sterile compounding pharmacy provides sterile pharmaceuticals without a patient-specific prescription or medical order, the sterile compounding pharmacy shall also obtain a certificate of registration from the Department of Consumer Protection pursuant to section 21a-70 and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site inventory of sterile pharmaceuticals no greater than a thirty-day supply, calculated from the completion of compounding, which thirty-day period shall include the period required for third-party analytical testing, to be performed in accordance with the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time**]** USP chapters.

(f) (1) If a sterile compounding pharmacy plans to remodel a pharmacy clean room within the sterile compounding facility, relocate a pharmacy clean room within the facility or upgrade or conduct a nonemergency repair to the heating, ventilation, air conditioning or primary engineering controls for a pharmacy clean room within the facility, the sterile compounding pharmacy shall notify the Department of Consumer Protection, in writing, not later than ten days prior to commencing such remodel, relocation, upgrade or repair. If a sterile compounding pharmacy makes an emergency repair, the sterile compounding pharmacy shall notify the department of such repair, in writing, as soon as possible after such repair is commenced.

(2) If the **[**United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time, requires**]** USP chapters require sterile recertification after such remodel, relocation, upgrade or repair, the sterile compounding pharmacy shall provide a copy of its sterile recertification to the Department of Consumer Protection not later than five days after the sterile recertification approval. The recertification shall only be performed by an independent licensed environmental monitoring entity.

(g) A sterile compounding pharmacy shall report, in writing, to the Department of Consumer Protection any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined in the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time**]** USP chapters, not later than the end of the next business day after discovering such violation or noncompliance.

(h) (1) If a sterile compounding pharmacy initiates a recall of sterile pharmaceuticals that were dispensed pursuant to a patient-specific prescription or medical order, the sterile compounding pharmacy shall notify each patient or patient care giver, the prescribing practitioner and the Department of Consumer Protection of such recall not later than twenty-four hours after such recall was initiated.

(2) If a sterile compounding pharmacy initiates a recall of sterile pharmaceuticals that were not dispensed pursuant to a patient-specific prescription or a medical order, the sterile compounding pharmacy shall notify: (A) Each purchaser of such sterile pharmaceuticals, to the extent such sterile compounding pharmacy possesses contact information for each such purchaser, (B) the Department of Consumer Protection, and (C) the federal Food and Drug Administration of such recall not later than the end of the next business day after such recall was initiated.

(i) Each sterile compounding pharmacy and each institutional pharmacy within a facility licensed pursuant to section 19a-490 shall prepare and maintain a policy and procedure manual. The policy and procedure manual shall comply with the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time**]** USP chapters.

(j) Each sterile compounding pharmacy shall report to the Department of Consumer Protection any administrative or legal action commenced against it by any state or federal regulatory agency or accreditation entity not later than five business days after receiving notice of the commencement of such action.

(k) Notwithstanding the provisions of subdivisions (3) and (4) of subsection (b) of this section, a sterile compounding pharmacy that is a nonresident pharmacy shall provide the Department of Consumer Protection proof that it has passed an inspection in such nonresident pharmacy's home state, based on the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations compliance standards, as amended from time to time**]** USP chapters. Such nonresident pharmacy shall submit to the Department of Consumer Protection a copy of the most recent inspection report with its initial nonresident pharmacy application and shall submit to the department a copy of its most recent inspection report every two years thereafter. If the state in which the nonresident pharmacy is located does not conduct inspections based on standards required in the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding, as amended from time to time**]** USP chapters, such nonresident pharmacy shall provide satisfactory proof to the department that it is in compliance with the standards required in the **[**most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding as amended from time to time**]** USP chapters.

(l) A practitioner, as specified in subdivision (1) of subsection (e) of this section, a hospital or a health care facility that receives sterile pharmaceuticals shall report any errors related to such dispensing or any suspected adulterated sterile pharmaceuticals to the Department of Consumer Protection.

(m) (1) For purposes of this subsection, a "designated pharmacist" means a pharmacist responsible for overseeing the compounding of sterile pharmaceuticals and the application of the USP chapters, as it pertains to sterile compounding.

(2) Any pharmacy licensed pursuant to section 20-594, as amended by this act, or institutional pharmacy licensed pursuant to section 19a-490, that provides sterile pharmaceuticals shall notify the department of its designated pharmacist.

(3) The designated pharmacist shall be responsible for providing proof he or she has completed a program approved by the commissioner, that demonstrates the competence necessary for the compounding of sterile pharmaceuticals, in compliance with all applicable federal and state statutes and regulations.

(4) The designated pharmacist shall immediately notify the department whenever he or she ceases such designation.

(5) Nothing in this section shall prevent a designated pharmacist from being the pharmacy manager.

[(m)**]** (n) The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, to implement the provisions of this section.

Sec. 2. Section 20-594 of the general statutes is amended by adding subsection (f) as follows (*Effective from passage*):

(NEW) (f) Each pharmacy licensed pursuant to this section shall report to the department any administrative or legal action commenced against it by any state or federal regulatory agency or accreditation entity not later than ten business days after receiving notice of the commencement of such action.

Sec. 3. Subsection (h) of section 21a-243 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(h) When a drug that is not a controlled substance in schedule I, II, III, IV or V, as designated in the Connecticut controlled substance scheduling regulations, is designated to be a controlled substance under the federal Controlled Substances Act, such drug shall be considered to be controlled at the state level in the same numerical schedule **[**for a period of two hundred forty days**]** from the effective date of the federal classification. Nothing in this section shall prevent the Commissioner of Consumer Protection from designating a controlled substance differently in the Connecticut controlled

substance scheduling regulations than such controlled substance is designated in the federal Controlled Substances Act, as amended from time to time.

Sec. 4. Subsection (e) of section 21a-243 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(e) Notwithstanding the provisions of subsections (a) to (d), inclusive, of this section, not later than January 1, 2013, the Commissioner of Consumer Protection shall submit amendments to sections 21a-243-7 and 21a-243-8 of the regulations of Connecticut state agencies to the standing legislative regulation review committee to reclassify marijuana as a controlled substance in schedule II under the Connecticut controlled substance scheduling regulations, except that for any marijuana product that has been approved by the federal Food and Drug Administration or successor agency to have a medical use and that is reclassified in any schedule of controlled substances or unscheduled by the federal Drug Enforcement Administration or successor agency the commissioner shall adopt the schedule designated by the Drug Enforcement Administration or successor agency.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2020*	20-633b
Sec. 2	*from passage*	20-594
Sec. 3	*from passage*	21a-243(h)
Sec. 4	*from passage*	21a-243(e)

GL *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

The bill makes various revisions to the pharmacy and drug control statutes and results in no fiscal impact to the state.

The Out Years

State Impact: None

Municipal Impact: None

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)