Senate

General Assembly **File No. 156**

February Session, 2018 Substitute Senate Bill No. 195

Senate, April 3, 2018

The Committee on General Law reported through SEN. LEONE of the 27th Dist. and SEN. WITKOS of the 8th Dist., Chairpersons of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING CHANGES TO PHARMACY AND DRUG CONTROL STATUTES.

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

Section 1. Subsection (a) of section 20-579 of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(a) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke, suspend or place conditions on a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a pharmacy intern or a pharmacy technician, and may assess a civil penalty of up to one thousand dollars <u>per violation of any provision of this chapter</u> or take other action permitted in subdivision (7) of section 21a-7 if the applicant or

holder of the license, temporary permit or registration: (1) Has violated a statute or regulation relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar to grounds on which Connecticut could refuse to issue or renew such a license or registration; (5) has illegally possessed, diverted, sold or dispensed drugs or devices; (6) abuses or excessively uses drugs, including alcohol; (7) has made false, misleading or deceptive representations to the public or the commission; (8) has maintained exclusive telephone lines to, has maintained exclusive electronic communication with, or has exclusive access to computers located in offices of prescribing practitioners, nursing homes, clinics, hospitals or other health care facilities; (9) has substituted drugs or devices except as permitted in section 20-619; (10) has accepted, for return to regular stock, any drug already dispensed in good faith or delivered from a pharmacy, and exposed to possible and uncontrolled contamination or substitution; (11) has split fees for professional services, including a discount or rebate, with a prescribing practitioner or an administrator or owner of

a nursing home, hospital or other health care facility; (12) has entered into an agreement with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility for the compounding or dispensing of secret formula or coded prescriptions; (13) has performed or been a party to a fraudulent or deceitful practice or transaction; (14) has presented to the commission a diploma, license or certificate illegally or fraudulently obtained, or obtained from a college or school of pharmacy not approved by the commission; (15) has performed incompetent or negligent work; (16) has falsified a continuing education document submitted to the commission or department or a certificate retained in accordance with the provisions of subsection (d) of section 20-600; (17) has permitted a person not licensed to practice pharmacy in this state to practice pharmacy in violation of section 20-605, to use a pharmacist license or pharmacy display document in violation of section 20-608, or to use words, displays or symbols in violation of section 20-609; (18) has failed to maintain the entire pharmacy premises, its components and contents in a clean, orderly and sanitary condition; (19) has failed to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding–Sterile Preparations, as amended from time to time; or (20) has failed to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding–Nonsterile Preparations, as amended from time to time.

Sec. 2. Section 20-601 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

The department shall collect the following nonrefundable fees:

(1) The fee for issuance of a pharmacist license is two hundred dollars, payable at the date of application for the license.

(2) The fee for renewal of a pharmacist license is the professional services fee for class A, as defined in section 33-182*l*. Before the commission grants a license to an applicant who has not held a license authorized by the commission within five years of the date of

application, the applicant shall pay the fee required in subdivision (1) of this section.

(3) The fee for issuance of a pharmacy license is seven hundred fifty dollars.

(4) The fee for renewal of a pharmacy license is one hundred ninety dollars.

(5) The late fee for an application for renewal of a license to practice pharmacy, a pharmacy license or a permit to sell nonlegend drugs is the amount set forth in section 21a-4.

(6) The fee for notice of a change in officers or directors of a corporation holding a pharmacy license is sixty dollars for each pharmacy license held. A late fee for failing to give such notice within ten days of the change is fifty dollars in addition to the fee for notice.

(7) The fee for filing notice of a change in name, ownership or management of a pharmacy is ninety dollars. A late fee for failing to give such notice within ten days of the change is fifty dollars in addition to the fee for notice.

(8) The fee for application for registration as a pharmacy intern is sixty dollars.

(9) The fee for application for a permit to sell nonlegend drugs is one hundred forty dollars.

(10) The fee for renewal of a permit to sell nonlegend drugs is one hundred dollars.

(11) The late fee for failing to notify the commission of a change of ownership, name or location of the premises of a permit to sell nonlegend drugs within five days of the change is twenty dollars.

(12) The fee for issuance of a nonresident pharmacy certificate of registration is seven hundred fifty dollars.

(13) The fee for renewal of a nonresident pharmacy certificate of registration is one hundred ninety dollars.

(14) The fee for notice of a change in officers or directors of a corporation holding a nonresident pharmacy certificate of registration is sixty dollars for each pharmacy license held. A late fee for failing to give such notice within ten days of the change is fifty dollars, in addition to the fee for notice.

(15) The fee for filing notice of a change in name, ownership or management of a nonresident pharmacy is ninety dollars. A late fee for failing to give such notice within ten days of the change is fifty dollars, in addition to the fee for notice.

[(14)**]** (16) The fee for application for registration as a pharmacy technician is one hundred dollars.

[(15)**]** (17) The fee for renewal of a registration as a pharmacy technician is fifty dollars.

[(16)**]** (18) The fee for issuance of a temporary permit to practice pharmacy is two hundred dollars.

Sec. 3. Section 21a-70 of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(a) As used in this section: (1) "Drugs", "devices" and "cosmetics" have the same meanings as defined in section 21a-92, "wholesaler" or "distributor" means a person, including, but not limited to, a medical device and oxygen provider, a third-party logistics provider, a virtual manufacturer or a virtual wholesale distributor, as such terms are defined in section 20-571, whether within or without the boundaries of the state of Connecticut, who supplies drugs, devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in subdivision (22) of section 20-571, pharmacies, federal, state or municipal agencies, clinics or any other

person as permitted under subsection (h) of this section, except that: (A) A retail pharmacy or a pharmacy within a licensed hospital that supplies to another such pharmacy a quantity of a noncontrolled drug or a schedule II, III, IV or V controlled substance normally stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, (B) a pharmacy within a licensed hospital that supplies drugs to another hospital or an authorized practitioner for research purposes, (C) a retail pharmacy that supplies a limited quantity of a noncontrolled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home, of a rest home with nursing supervision or of a state correctional institution, and (D) a pharmacy within a licensed hospital that contains another hospital wholly within its physical structure that supplies to such contained hospital a quantity of a noncontrolled drug or a schedule II, III, IV, or V controlled substance normally stocked by such hospitals to provide for the needs of a patient, pursuant to a prescription or medication order of an authorized practitioner, receiving inpatient care on a unit that is operated by the contained hospital shall not be deemed a wholesaler under this section; (2) "manufacturer" means (A) a person, whether within or without the boundaries of the state of Connecticut, who produces, prepares, cultivates, grows, propagates, compounds, converts or processes, directly or indirectly, by extraction from substances of natural origin or by means of chemical synthesis or by a combination of extraction and chemical synthesis, or who packages, repackages, labels or relabels a container under such manufacturer's own or any other trademark or label any drug, device or cosmetic for the purpose of selling such items, or (B) a sterile compounding pharmacy, as defined in section 20-633b, as amended by this act, that dispenses sterile pharmaceuticals without a prescription or a patient-specific medical order; (3) "drug", "device" and "cosmetic" have the same meanings as provided in section 21a-92; and (4) "commissioner" means the Commissioner of Consumer Protection or his or her designee.

(b) No wholesaler or manufacturer shall operate as such until he has received a certificate of registration issued by the commissioner, which certificate shall be renewed annually, provided no such certificate shall be required of a manufacturer, except a sterile compounding pharmacy, as defined in subsection (a) of section 20-633b, whose principal place of business is located outside the state, who is registered with the federal Food and Drug Administration or any successor agency and who files a copy of such registration with the commissioner. A fee of one hundred ninety dollars shall be charged for each wholesaler's certificate and renewal thereof. A separate certificate and corresponding fee is required for each location existing in this state and for each location existing outside of this state that distributes products into this state. The fee for a manufacturer's certificate and renewal thereof shall be two hundred eighty-five dollars for manufacturers employing not more than five licensed pharmacists or qualified chemists or both; three hundred seventy-five dollars for manufacturers employing not more than ten licensed pharmacists or qualified chemists or both; and nine hundred forty dollars for manufacturers employing more than ten licensed pharmacists or qualified chemists or both. No such certificate shall be issued to a manufacturer unless such drugs, devices or cosmetics are manufactured or compounded under the direct supervision of a licensed pharmacist or a qualified chemist. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant is equipped as to facilities and apparatus to properly carry on the business described in his application and that the applicant conforms to chapter 418 and regulations adopted thereunder.

(c) The commissioner shall have the right to deny a certificate of registration if he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider, at a minimum, the following factors:

(1) Any convictions or regulatory actions involving the applicant under any federal, state or local law relating to drug samples,

wholesale or retail drug distribution, or distribution or possession of drugs including controlled substances;

(2) Any felony convictions of the applicant under federal, state or local laws;

(3) The applicant's past experience in the manufacture or distribution of drugs;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension, revocation or other sanction by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs;

(6) Compliance with licensing or registration requirements under previously granted licenses or registrations;

(7) Compliance with requirements to maintain or make available to the commissioner or to federal, state or local law enforcement officials those records required by any federal or state statute or regulation;

(8) Failure to provide adequate control against the diversion, theft and loss of drugs;

(9) Provision of required security for legend drugs and, in the case of controlled substances, compliance with security requirements for wholesalers set forth in regulations adopted under chapter 420b; and

(10) Compliance with all regulations adopted to enforce the provisions of this section.

(d) The commissioner may suspend, revoke or refuse to renew a registration, or may issue a letter of reprimand or place a registrant on probationary status, for sufficient cause. Any of the following shall be sufficient cause for such action:

(1) The furnishing of false or fraudulent information in any application or other document filed with the commissioner;

(2) Any criminal conviction of the registrant under any federal or state statute concerning drugs;

(3) The suspension, revocation or other restriction or penalty issued against a license or registration related to drugs;

(4) Failure to provide adequate control against the diversion, theft and loss of drugs; or

(5) A violation of any provision of any federal or state statute or regulation concerning drugs.

(e) Wholesalers and manufacturers shall operate in compliance with applicable federal, state and local statutes, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing.

(f) Wholesalers and manufacturers shall permit the commissioner, or his authorized representatives, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner.

(g) Before denying, suspending, revoking or refusing to renew a registration, or before issuing a letter of reprimand or placing a registrant on probationary status, the commissioner shall afford the applicant or registrant an opportunity for a hearing in accordance with the provisions of chapter 54. Notice of such hearing may be given by certified mail. The commissioner may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing.

(h) No wholesaler or manufacturer shall sell any drugs except to the state or any political subdivision thereof, to another manufacturer or wholesaler, to any hospital recognized by the state as a general or specialty hospital, to any institution having a full-time pharmacist who

is actively engaged in the practice of pharmacy in such institution not less than thirty-five hours a week, to a chronic and convalescent nursing home having a pharmacist actively engaged in the practice of pharmacy based upon the ratio of one-tenth of one hour per patient per week but not less than twelve hours per week, to a practicing physician, podiatrist, dentist, optometrist or veterinarian or to a licensed pharmacy or a store to which a permit to sell nonlegend drugs has been issued as provided in section 20-624. The commissioner may adopt such regulations as are necessary to administer and enforce the provisions of this section.

(i) Each registered manufacturer or wholesaler of drugs shall operate a system to identify suspicious orders of controlled substances and shall immediately inform the Director of the Drug Control Division of suspicious orders. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. Each registered manufacturer or wholesaler of drugs shall also send the Drug Control Division a copy of any suspicious activity reporting submitted to the federal Drug Enforcement Administration pursuant to 21CFR 1301.74.

[(i)**]** (j) Any person who violates any provision of this section shall be fined not more than five hundred dollars or imprisoned not more than six months, or both.

Sec. 4. Subsection (h) of section 21a-254 of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(h) A complete and accurate record of all stocks of controlled substances on hand shall, on and after July 1, 1981, be prepared **[**biennially**]** annually within four days of the first day of May of the calendar year, except that a registrant may change this date provided the general physical inventory date of such registrant is not more than six months from the **[**biennial**]** annual inventory date, and kept on file for three years; and shall be made available to the commissioner or his authorized agents. **[**The keeping of a record required by or under the

federal Controlled Substances Act, or federal food and drug laws, containing substantially the same information as is specified above, shall constitute compliance with this section, provided each record shall in addition contain a detailed list of any controlled substances lost, destroyed or stolen, the kind and quantity of such substances and the date of the discovery of such loss, destruction or theft and provided such record shall be made available to the commissioner or his authorized agents.**]** All records required by this chapter shall be kept on the premises of the registrant and maintained current and separate from other business records in such form as to be readily available for inspection by the authorized agent at reasonable times. The use of a foreign language, codes or symbols to designate controlled substances or persons in the keeping of any required record is not deemed to be a compliance with this chapter.

Sec. 5. (NEW) (*Effective January 1, 2019*) (a) As used in this section, "pharmacy" and "institutional pharmacy" have the same meanings as provided in section 20-571 of the general statutes.

(b) Each pharmacy and institutional pharmacy shall maintain a perpetual inventory of each Schedule II controlled substance, designated as such in regulations adopted pursuant to section 21a-243 of the general statutes.

(c) The perpetual inventory required pursuant to subsection (b) of this section shall be reconciled on a monthly basis. Any loss, theft or unauthorized destruction of a controlled substance discovered during the reconciliation shall be reported by a pharmacy or institutional pharmacy not later than seventy-two hours after discovery of any such occurrence to the Commissioner of Consumer Protection pursuant to section 21a-262 of the general statutes and section 21a-262-3 of the regulations of Connecticut State Agencies.

(d) Schedule II controlled substance perpetual inventory records shall be (1) kept on the premises of the pharmacy or institutional pharmacy, (2) maintained in an orderly manner separate from all other records, (3) filed by date, and (4) retained for a period of not less than

three years. Such records shall be made immediately available for inspection and copying by the Commissioner of Consumer Protection, the commissioner's authorized representative or other persons authorized to review such records pursuant to section 21a-265 of the general statutes.

(e) The Commissioner of Consumer Protection may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 6. Subsection (c) of section 20-633b of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(c) A sterile compounding pharmacy shall comply with the most recent version of the United States Pharmacopeia, **[**Chapter 797,**]** Pharmaceutical Compounding - Sterile Preparations, as amended from time to time. A sterile compounding pharmacy shall also comply with all applicable federal and state statutes and regulations.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2019*	20-579(a)
Sec. 2	*January 1, 2019*	20-601
Sec. 3	*January 1, 2019*	21a-70
Sec. 4	*January 1, 2019*	21a-254(h)
Sec. 5	*January 1, 2019*	New section
Sec. 6	*January 1, 2019*	20-633b(c)

Statement of Legislative Commissioners:
In Section 3, the bolded language was deleted, for uniformity.

GL *Joint Favorable Subst. -LCO*

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:

Agency Affected	Fund-Effect	FY 19 $	FY 20 $
Consumer Protection, Dept.	GF - Revenue Gain	20,000	20,000

Note: GF=General Fund

Municipal Impact: None

Explanation

This bill makes various changes to the pharmacy and drug control statutes and results in a revenue gain to the state.

Section 1 clarifies that a civil penalty of up to $1,000 may be assessed per violation of any provision of this chapter and results in no fiscal impact to the state. This is a conforming change to the current practice of the Department of Consumer Protection (DCP).

Section 2 results in additional fees for nonresident pharmacies. There are approximately 1,050 nonresident pharmacies in the state and it is estimated that these new fees will generate approximately $20,000 per year. Below are the new fees for nonresident pharmacies:

- A fee for notice of a change in officers or directors of a corporation is $60 for each pharmacy license held;
- A late fee for failing to provide notice of a change in officers or directors of a corporation is $50;
- A fee for filing a notice of a change in name, ownership, or

management is $90;

- A late fee for failing to give notice of a change in name, ownership, or management is $50.

Sections 4 and 5, which tighten pharmacy inventory requirements, result in no fiscal impact to the University of Connecticut Health Center as its pharmacy's practices exceed the bill's requirements.

Section 5 also allows the DCP Commissioner to adopt regulations and results in no fiscal impact to the state because this can be accomplished through existing staff and expertise of the department.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

OLR Bill Analysis

SB 195

AN ACT CONCERNING CHANGES TO PHARMACY AND DRUG CONTROL STATUTES.

SUMMARY

This bill makes the following changes in laws concerning pharmacies, pharmacists, and controlled substances:

1. specifies that the Commission of Pharmacy may assess, per violation, civil penalties of up to $1,000 for violations of pharmacy practice laws (§ 1);

2. extends to nonresident pharmacies the same fees and deadlines that apply to resident pharmacies when they notify the Department of Consumer Protection (DCP) of a change in officers, directors, name, ownership, or management (§ 2);

3. requires DCP-registered drug manufacturers and wholesalers to identify and report suspicious controlled substance orders to the department's Drug Control Division (§ 3);

4. requires specified individuals and entities manufacturing, distributing, administering, dispensing, or having custody of controlled substances to conduct a controlled substances inventory annually, rather than biennially (§4);

5. requires retail and institutional pharmacies to maintain a perpetual inventory of schedule II controlled substances (e.g., methadone, morphine, and oxycodone) and authorizes DCP to adopt regulations to implement the requirement (§ 5); and

6. makes a technical change updating a statutory reference to the United States Pharmacopeia's provisions on preparing

compounded sterile drugs (§ 6).

EFFECTIVE DATE: January 1, 2019

§ 2 — FEES FOR NONRESIDENT PHARMACIES

By law, when a resident pharmacy experiences a change in its officers, directors, name, ownership, or management, it must notify DCP within 10 days (CGS §§ 20-595 and 20-597). The fee for notice of a change to officers or directors is $60 and the fee for notice of a change in name, ownership, or management is $90. Pharmacies that do not submit this information within 10 days of the change must pay an additional $50 late fee.

The bill extends the same fees to nonresident pharmacies when they submit notice of these changes. However, neither existing law nor the bill requires nonresident pharmacies to file notice of these changes, except in the case of a change in officers. In this case, existing law requires nonresident pharmacies to notify DCP within 30 days of the change (CGS § 20-267), but the bill subjects such a filing to a late fee if it is made more than 10 days after the change.

By law, nonresident pharmacies are pharmacies that are not located in Connecticut but ship, mail, or deliver prescription drugs or devices to Connecticut residents (CGS § 20-627).

§ 3 — REPORTING SUSPICIOUS ORDERS

The bill requires DCP-registered drug manufacturers and wholesalers to operate a system to identify suspicious controlled substance orders. When they identify such orders, the manufacturers and wholesalers must immediately inform the director of DCP's Drug Control Division.

The bill also requires these manufacturers and wholesalers to send the Drug Control Division a copy of any suspicious order report that they submit to the federal Drug Enforcement Administration. Federal law requires such reporting by people that manufacture, distribute, dispense, import, or export controlled substances, or seek to do so.

Under the bill and federal law, "suspicious orders" include orders that are of an unusual size or frequency or deviate substantially from a normal pattern.

§ 4 — CONTROLLED SUBSTANCES RECORDKEEPING

The bill requires annual, rather than biennial, controlled substance inventories by (1) practitioners, (e.g., physicians, physician assistants, advanced practice registered nurses, dentists, veterinarians, and certain scientific investigators); (2) drug manufacturers and wholesalers; and (3) institutions, including pharmacies, hospitals, nursing homes, clinics, infirmaries, freestanding ambulatory surgical centers, and laboratories.

The bill also eliminates a provision that allows such individuals and entities to be deemed compliant with state controlled substances recordkeeping requirements if they comply with substantially similar federal requirements.

§ 5 — PERPETUAL INVENTORY OF SCHEDULE II DRUGS

The bill requires retail and institutional pharmacies to maintain a perpetual inventory of schedule II controlled substances. The inventory records must be:

1. kept on the pharmacy's premises and maintained in an orderly manner separate from other records,

2. filed by date,

3. retained for at least three years, and

4. made immediately available for inspection and copying upon the request of the DCP commissioner or her representative or other authorized inspectors.

Perpetual inventories must be reconciled on a monthly basis. Any discovered loss, theft, or unauthorized destruction must be reported to the DCP commissioner within 72 hours.

The DCP commissioner may adopt regulations to implement the perpetual inventory requirements.

COMMITTEE ACTION

General Law Committee

Joint Favorable
Yea 17 Nay 0 (03/15/2018)