Senate

General Assembly

File No. 108

January Session, 2021

Substitute Senate Bill No. 694

Senate, March 23, 2021

The Committee on General Law reported through SEN. MARONEY of the 14th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING REVISIONS TO PHARMACY AND DRUG CONTROL STATUTES.

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

Section 1. Section 21a-319 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2021*):

(a) No certificate of registration shall be issued, maintained or renewed under this chapter unless or until the applicant has furnished proof satisfactory to the Commissioner of Consumer Protection that he or she is licensed or duly authorized to practice his or her profession by the appropriate state licensing board, commission or registration agency; or, in the case of a hospital or other institution, by the appropriate state agency having jurisdiction over the licensure, registration or approval of such establishment.

(b) The Commissioner of Consumer Protection may change the status of a controlled substance registration to inactive for any practitioner who fails to maintain a license, registration or approval of a license to

practice his or her medical profession for a period longer than ninety days. Such change in license status shall not be considered disciplinary and the registration shall be reinstated without additional fee, if the practitioner restores his or her license, registration or approval to practice his or her profession with the Department of Public Health or associated board or commission, and the reinstatement occurs prior to the expiration of the controlled substance registration.

Sec. 2. (NEW) (*Effective from passage*) (a) For purposes of this section, "epinephrine auto injector" means a prefilled auto injector or similar automatic injectable equipment used to deliver epinephrine in a standard dose for emergency first aid response to allergic reactions.

(b) A pharmacist, in his or her professional discretion, may issue a prescription for not more than two epinephrine auto injectors under the following conditions:

(1) The pharmacist identifies that the patient requesting such prescription has received an epinephrine auto injector by prescription from another pharmacy within the previous two years;

(2) The pharmacist identifies the patient's practitioner specified by the patient as his or her primary care provider at the time the request is made;

(3) The pharmacist informs the patient's primary care provider of the issuance of the prescription not later than seventy-two hours after such issuance, by either phone, facsimile or electronic transmission; and

(4) The prescription issued by the pharmacist does not have any refills and is not filled more than once per year.

(c) Nothing in this section shall prevent a pharmacist from verifying a previous prescription at any pharmacy in any part of the United States, including any state, district, commonwealth, territory or insular possession thereof, or any area subject to the legal authority of the United States of America.

Sec. 3. Subsection (f) of section 20-633b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(f) (1) If a sterile compounding pharmacy plans to remodel **[**a pharmacy clean room within the sterile compounding facility**]** any area utilized for the compounding of sterile pharmaceuticals or adjacent space, relocate **[**a pharmacy clean room within the facility**]** any space utilized for the compounding of sterile pharmaceuticals or upgrade or conduct a nonemergency repair to the heating, ventilation, air conditioning or primary or secondary engineering controls for **[**a pharmacy clean room within the facility**]** any space utilized for the compounding of sterile pharmaceuticals, the sterile compounding pharmacy shall notify the Department of Consumer Protection, in writing, not later than **[**ten**]** forty-five days prior to commencing such remodel, relocation, upgrade or repair. Such written notification shall include a plan for such remodel, relocation, upgrade or repair and such plan shall be subject to department review and approval. If a sterile compounding pharmacy makes an emergency repair, the sterile compounding pharmacy shall notify the department of such emergency repair, in writing, **[**as soon as possible**]** not later than twenty-four hours after such repair is commenced.

(2) If the 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.

Sec. 4. Subsection (d) of section 20-614 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(d) Prior to or simultaneous with the dispensing of a drug, **[**pursuant to subsection (b) of this section**]** from a pharmacy licensed pursuant to

this chapter, a pharmacist or other employee of the pharmacy shall, whenever practicable, offer for the pharmacist to discuss the drug to be dispensed and to counsel the patient on the usage of the drug, except when the person obtaining the prescription is other than the person named on the prescription form or electronic record or the pharmacist determines it is appropriate to make such offer in writing. Any such written offer shall include an offer to communicate with the patient either in person at the pharmacy or by telephone.

Sec. 5. Subsection (a) of section 21a-70 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2021*):

(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 (24) 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, of a hospice inpatient facility licensed pursuant to section 19a-491 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, or receiving outpatient care in a setting operated by the contained hospital and such drug or substance is administered on-site 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.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2021*	21a-319
Sec. 2	*from passage*	New section
Sec. 3	*from passage*	20-633b(f)
Sec. 4	*from passage*	20-614(d)
Sec. 5	*July 1, 2021*	21a-70(a)

Statement of Legislative Commissioners:
Section 2(b) was reorganized for clarity.

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 changes to pharmacies and drug control statutes resulting in no fiscal impact to the state.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis

sSB 694

AN ACT CONCERNING REVISIONS TO PHARMACY AND DRUG CONTROL STATUTES.

SUMMARY

This bill makes various unrelated changes to the laws concerning pharmacies and drugs, including:

1. allowing the Department of Consumer Protection (DCP) to immediately inactivate a practitioner's controlled substance registration if his or her license, registration, or approval of a license to practice is inactive for more than 90 days (§ 1);

2. allowing pharmacists to prescribe an epinephrine auto injector (e.g., EpiPen) to someone who previously had a prescription for one, under certain circumstances (§ 2);

3. increasing from 10 to 45 days, the advance notice a compounding facility must give DCP when it plans to remodel or repair its sterile compounding facilities, and requiring emergency repairs to be reported within 24 hours (§ 3); and

4. expanding the requirement that pharmacists offer to consult with patients when dispensing medications to include controlled substances, in addition to other drug types, and applying the requirement to all pharmacies (§ 4).

The bill also exempts from registering with DCP as a "drug wholesaler" (1) retail pharmacies that provide a limited quantity of drugs for emergency stock to a hospice inpatient facility's medical director and (2) pharmacies within a hospital that contains another hospital wholly within its physical structure, if providing prescribed medications to be administered onsite to the contained hospital's

outpatients (§ 5). Existing law provides similar exemptions for pharmacies (1) that provide emergency stock to nursing homes or (2) within a hospital that contains another hospital, when the drug will be used in the contained hospital's inpatient unit.

Lastly, the bill makes minor and technical changes.

EFFECTIVE DATE: Upon passage, except the controlled substance registration provision is effective October 1, 2021 (§ 1) and the drug wholesaler definition provision is effective July 1, 2021 (§ 5).

§ 1 — CONTROLLED SUBSTANCE REGISTRATIONS

The bill allows DCP to immediately inactivate a practitioner's controlled substance registration if his or her license to practice, or related registration or approval, is inactive for more than 90 days. Current law requires DCP to notify the practitioner and hold an administrative hearing prior to taking such action.

The bill specifies that an inactivation is not a disciplinary action and that the controlled substance registration must be reinstated without charge if the practitioner restores his or her license, registration, or approval to practice with the Department of Public Health or the associated board or commission before the registration was set to expire.

By law, a practitioner who prescribes, distributes, administers, or dispenses a controlled substance must obtain a registration from DCP. Practitioners eligible for the registration include physicians, dentists, veterinarians, advanced practice registered nurses, and scientific investigators, among others.

§ 2 — EPINEPHRINE AUTO INJECTOR PRESCRIPTIONS

The bill permits a pharmacist, in his or her professional discretion, to issue a prescription for up to two epinephrine auto injectors if the pharmacist:

1. confirms another pharmacy has dispensed the medication to the patient under a prescription within the past two years;

2. identifies the patient's primary care provider, based on information the patient provides when requesting the prescription;

3. informs the patient's primary care provider within seventy-two hours after issuing the prescription (by phone, fax, or electronic transmission); and

4. does not prescribe refills or fill the prescription more than once per year.

The bill defines "epinephrine auto injector" as a prefilled auto injector or similar automatic injectable equipment used to deliver epinephrine in a standard dose for emergency first aid response to allergic reactions.

The bill specifies that it does not prevent a pharmacist from verifying a previous prescription at any other U.S. pharmacy, including pharmacies in any area under U.S. jurisdiction (e.g., a territory).

§ 3 — STERILE COMPOUNDING FACILITY CHANGES

The bill increases, from 10 to 45 days, the advance notice a compounding facility must give DCP before it begins to remodel, relocate, upgrade, or repair sterile compounding areas or adjacent spaces, including:

1. remodeling an area used for compounding sterile pharmaceuticals or an adjacent space;

2. relocating the sterile compounding area; or

3. in a sterile compounding area, upgrading or conducting a nonemergency repair to the heating, ventilation, air conditioning, or primary or secondary engineering controls.

The bill also requires emergency repairs made in these pharmacies to be reported within 24 hours after they started, instead of as soon as possible as under current law.

Additionally, the bill makes related minor changes, including requiring notice when secondary engineering controls are upgraded or repaired.

§ 4 — PHARMACIST CONSULTATIONS

The bill requires pharmacists or pharmacy employees, before or while dispensing a controlled substance, to offer for the pharmacist to counsel a patient on the drug and its use. Current law already requires pharmacists and employees to do this for other dispensed drug types.

As under current law, the requirement does not apply if the (1) person picking up the prescription is not the patient or (2) pharmacist determines it is appropriate to make the offer in writing. A written offer must give the patient the option to communicate in person at the pharmacy or by telephone.

The bill specifies that the consultation requirement applies to all pharmacies instead of only (1) hospital pharmacies, when dispensing a drug for outpatient use or use by an employee or the employee's spouse or children, and (2) state-licensed pharmacies. As under current law, pharmacists are not required to provide counseling if a patient refuses it.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 19 Nay 0 (03/09/2021)