January Session, 2021

Proposed Substitute Bill No. 694

LCO No. **4345**

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 Section 21a-319 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2021*):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 an epinephrine auto injector under the following conditions:

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

(2) The pharmacist identifies the patient's practitioner identified 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;

(4) The prescription issued by the pharmacist is for not more than two epinephrine auto injectors;

(5) 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)