Proposed Substitute Bill No. 135

LCO No. **2889**

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 Section 21a-319 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2020*):

(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;

(2) The pharmacist identifies the patient's current medical provider;

(3) The pharmacist informs the patient's current medical 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; and

(5) The prescription issued by the pharmacist does not have any refills.

(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 2020 supplement to 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,**]** <u>any area utilized for the compounding of sterile pharmaceuticals or adjacent space,</u> relocate **[**a pharmacy clean room within the facility**]** <u>any space</u>

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 2020 supplement to 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 chapter 400j, 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. Section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) All prescriptions for controlled drugs shall include (1) the name and address of the patient, or the name and address of the owner of an animal and the species of the animal, (2) whether the patient is an adult or a child, or his specific age, (3) the compound or preparation prescribed and the amount thereof, (4) directions for use of the medication, (5) the name and address of the prescribing practitioner, (6) the date of issuance, and (7) the Federal Registry number of the practitioner. No prescription blank containing a prescription for a schedule II substance shall contain more than one prescription. No prescription or order for a controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription within the meaning of this chapter.

(b) Each prescribing practitioner, as defined in section 20-14c, who the Department of Consumer Protection authorizes to prescribe controlled substances, within the scope of practice of his or her license, shall electronically transmit the controlled substance prescription to a pharmacy. Electronically transmitted prescriptions shall be promptly printed out in hardcopy or created as an electronic record and filed by the prescriber. Electronically transmitted prescriptions shall be consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time. All records shall be kept on file for three years at the premises of the licensed practitioner and maintained in such form as to be readily available for inspection by the commissioner, his or her authorized agent or other persons, as authorized in section 21a-265, at reasonable times. For purposes of this subsection and subsections (c), (d) and (e) of this section, the term "electronically transmit" means to transmit by computer modem or other similar electronic device.

(c) A licensed practitioner shall not be required to electronically transmit a prescription when:

(1) Electronic transmission is not available due to a temporary technological or electrical failure. In the event of a temporary technological or electrical failure, the practitioner shall, without undue delay, reasonably attempt to correct any cause for the failure that is within his or her control. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record as soon as practicable, but in no instance more than seventy-two hours following the end of the temporary technological or electrical failure that prevented the electronic transmittal of the prescription. For purposes of this subdivision, "temporary technological or electrical failure" means failure of a computer system, application or device or the loss of electrical power to such system, application or device, or any other service interruption to such system, application or device that reasonably prevents the practitioner from utilizing his or her certified application to electronically transmit the prescription in accordance with subsection (b) of this section;

(2) The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronically transmitted prescription in a timely manner and that such delay would adversely impact the patient's medical condition, provided if such prescription is for a controlled substance, the quantity of such controlled substance does not exceed a five-day supply for the patient, if the controlled substance was used in accordance with the directions for use. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;

(3) The prescription is to be dispensed by a pharmacy located outside this state. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;

(4) Use of an electronically transmitted prescription may negatively impact patient care, such as a prescription containing two or more products to be compounded by a pharmacist, a prescription for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, a prescription that contains long or complicated directions, a prescription that requires certain elements to be included by the federal Food and Drug and Administration, or an oral prescription communicated to a pharmacist by a health care practitioner for a patient in a chronic and convalescent nursing home, licensed pursuant to chapter 368v; or

(5) The practitioner demonstrates, in a form and manner prescribed by the commissioner, that such practitioner does not have the technological capacity to issue electronically transmitted prescriptions. For the purposes of this subsection, "technological capacity" means possession of a computer system, hardware or device that can be used to electronically transmit controlled substance prescriptions consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time. The provisions of this subdivision shall not apply to a practitioner when such practitioner is prescribing as a telehealth provider, as defined in section 19a-906, pursuant to subdivision (2) of subsection (c) of said section.

(d) Any prescription issued in a form other than an electronically transmitted prescription pursuant to subsection (c) of this section may be issued as a written order or, to the extent permitted by the federal Controlled Substance Act, 21 USC 801, as from time to time amended, as an oral order or transmitted by facsimile machine. Such oral order or order transmitted by facsimile machine shall be promptly reduced to writing on a prescription blank or a hardcopy printout or created as an electronic record and filed by the pharmacist filling it. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter.

(e) Prescriptions for schedule II substances shall be electronically

transmitted by the prescribing practitioner at the time of issuance and previously signed orders for such schedule II substances shall not be considered valid prescriptions within the meaning of this chapter. No practitioner shall prescribe, dispense or administer schedule II sympathomimetic amines as anorectics, except as may be authorized by regulations adopted by the Departments of Public Health and Consumer Protection acting jointly. To the extent permitted by the federal Controlled Substances Act, 21 USC 801, as from time to time amended, in an emergency, the dispensing of schedule II substances may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist. The filling pharmacist shall promptly reduce such oral order to writing on a prescription blank, provided such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter. The Department of Public Health and the Department of Consumer Protection, acting jointly, may adopt regulations, in accordance with chapter 54, allowing practitioners to prescribe, dispense or administer schedule II sympathomimetic amines as anorectics under certain specific circumstances. Nothing in this subsection shall be construed to require a licensed pharmacist to determine the diagnosis of a patient prior to dispensing a prescription for such substances to a patient.

(f) All prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, the federal Controlled Substances Act, and state laws and regulations adopted under this chapter.

(g) Repealed by P.A. 82-419, S. 46, 47.

(h) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in

schedule III or IV, which is a prescription drug as determined under federal food and drug laws, shall not be dispensed without a written, electronically transmitted or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

(i) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.

(j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571.

(k) Pharmacies shall file filled prescriptions for controlled substances separately from other prescriptions. All schedule II prescriptions shall be filed in a separate file or in an electronic file. All schedule III, IV and V prescriptions shall be filed in another separate file or in an electronic file, except as otherwise provided for in regulations adopted pursuant to section 21a-243, 21a-244 or 21a-244a. All written controlled substance prescriptions shall, immediately upon filling, be filed chronologically and consecutively.

(l) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in the federal Controlled Substances Act 21 USC 801 et seq.**,** **[**and the regulations promulgated thereunder,**]** as from time to time amended.

(m) A practitioner authorized to prescribe controlled substances shall not prescribe anabolic steroids for the sole purpose of enhancing a patient's athletic ability or performance.

(n) Each pharmacy, as defined in section 20-571, shall accept an electronically transmitted prescription for a controlled substance from a practitioner, as defined in section 21a-316. All records shall be kept on file for three years at the premises of the pharmacy and maintained

current and separate from other business records in such form as to be readily available at the pharmacy for inspection by the Commissioner of Consumer Protection, his or her authorized agent or other persons, as authorized in section 21a-265, at reasonable times. Prescription records received from the practitioner electronically may be stored electronically, provided the files are maintained in the pharmacy computer system for not less than three years. If the electronically transmitted prescription is printed, it shall be filed as required in subsection (k) of this section.

(o) Any pharmacy may transfer an unfilled prescription for a schedule II, III, IV, or V controlled substance that was electronically transmitted consistent with the federal Controlled Substances Act, 21 USC 801 et seq., as amended from time to time. The transfer of the unfilled electronic prescription may be performed by telephone or electronic transmission that is consistent with any current Drug Enforcement Administration Policy or said federal Controlled Substances Act and shall comply with the following:

(1) The pharmacy that received the original electronically transmitted prescription shall take measures to prevent the prescription from being filled at any pharmacy other than the pharmacy to which the prescription is being transferred. The pharmacy that received the original electronic prescription shall record the name, phone number, and address of the pharmacy receiving the transferred prescription and the name and license number of the pharmacist who received the prescription.

(2) The pharmacy receiving the transferred prescription shall record: (A) All information required on a prescription pursuant to this section, (B) the fact that the prescription has been transferred, (C) the name of the original pharmacy receiving the electronic prescription, (D) the date of issuance of the prescription, (E) the date of the transfer, and (F) any refills issued for prescriptions in schedule III, IV or V. A facsimile may be sent from the original receiving pharmacy with the prescription information for prescriptions that are being transferred via telephone.

Sec. 6. Subsection (a) of section 21a-70 of the 2020 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2020*):

(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, 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, 2020*	21a-319
Sec. 2	*from passage*	New section
Sec. 3	*from passage*	20-633b(f)
Sec. 4	*from passage*	20-614(d)
Sec. 5	*from passage*	21a-249
Sec. 6	*July 1, 2020*	21a-70(a)