General Assembly

Raised Bill No. 1102

January Session, 2023

LCO No. **4736**

Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT CONCERNING PHARMACIES AND PHARMACISTS.

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

Section 1. Section 20-571 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

As used in this chapter and sections 2 and 3 of this act, unless the context otherwise requires:

(1) "Administer" or **[**"Administration"**]** "administration" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion or any other means;

(2) "Automated prescription dispensing machine" means a device and associated software operated by a pharmacy or a pharmacy that is registered as a nonresident pharmacy pursuant to section 20-627, in a nursing home or skilled nursing facility licensed pursuant to sections 19a-490 and 19a-491**,** that packages and labels patient-specific medication or multiple medications for the purposes of administration by a registered nurse or a licensed practical nurse based on a prescription that has completed final verification by a licensed

pharmacist;

(3) "Care-giving institution" means an institution that provides medical services and is licensed, operated, certified or approved by the Commissioner of Public Health, the Commissioner of Developmental Services or the Commissioner of Mental Health and Addiction Services;

(4) "Commission" means the Commission of Pharmacy appointed under the provisions of section 20-572;

(5) "Commissioner" means the Commissioner of Consumer Protection;

(6) "Compound" means to combine, mix or put together two or more ingredients pursuant to a prescription and includes the preparation of drugs or devices in anticipation of prescriptions based on routine, regularly-observed prescribing patterns;

(7) "Correctional or juvenile training institution" means a facility for the detention or incarceration of persons convicted or accused of crimes or offenses or for training of delinquent juveniles, including those state facilities under the jurisdiction of the Commissioner of Correction, training schools for delinquent juveniles and any other facilities operated by the state or municipalities for such detention, incarceration or training;

(8) "Device" means instruments, apparatuses and contrivances, including their components, parts and accessories, intended: (A) **[**for**]** For use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; **[**,**]** or (B) to affect the structure or any function of the body of humans or other animals, but does not mean contact lenses;

(9) "Department" means the Department of Consumer Protection;

(10) "Deprescribing" means the systematic process of identifying and discontinuing drugs in instances in which existing or potential harms outweigh existing or potential benefits within the context of an

individual patient's care goals, current level of functioning, life expectancy, values and preferences;

(11) "Dispense" means those acts of processing a drug or device for delivery or for administration for a patient pursuant to a prescription consisting of: (A) Comparing the directions on the label with the directions on the prescription to determine accuracy; (B) the selection of the drug or device from stock to fill the prescription; (C) the counting, measuring, compounding or preparation of the drug or device; (D) the placing of the drug or device in the proper container; (E) the affixing of the label to the container; and (F) the addition to a written prescription of any required notations. "Dispense" does not include the acts of delivering a drug or device to a patient or of administering the drug or device to the patient;

(12) "Dispensing outpatient facility" means a facility operated by a corporation or municipality which provides medical services to patients on an outpatient basis and which maintains stocks of drugs for dispensing of drugs on a regular basis to patients for use off the premises;

(13) "Drug" means: (A) **[**an**]** An article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; **[**,**]** (B) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; **[**,**]** (C) an article, other than food, intended to affect the structure or any function of the body of humans or any other animal; **[**,**]** and (D) an article intended for use as a component of any article specified in this subdivision, but does not include a device;

(14) "Health care institution" means institution, as defined in section 19a-490;

(15) "Health care institutional pharmacy" means an institutional pharmacy located within a health care institution;

[(14)**]** (16) "Institutional pharmacy" means that area within a care-giving institution or within a correctional or juvenile training institution, commonly known as the pharmacy, that is under the direct charge of a pharmacist and in which drugs are stored and dispensed;

[(15)**]** (17) "Legend device" means a device that is required by applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only or that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

[(16)**]** (18) "Legend drug" means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

[(17)**]** (19) "Medical device and oxygen provider" means a person who distributes devices or oxygen pursuant to a medical order or prescription, except if such person already maintains an active pharmacy license;

[(18)**]** (20) "Medication reconciliation" means a process of comparing the medications a patient is taking and should be taking with newly ordered medications: (A) **[**for**]** For the purpose of addressing duplications, omissions and interactions and the need to continue current medications; **[**,**]** and (B) by looking at information such as the medication name, dose, frequency, route of administration and purpose;

[(19)**]** (21) "Nonlegend device" means a device that is not a legend device;

[(20)**]** (22) "Nonlegend drug" means a drug that is not a legend drug;

(23) "Nonresident pharmacy" has the same meaning as provided in section 20-627;

[(21)**]** (24) "Person" means an individual, corporation, business trust, estate trust, partnership, association, joint venture or any other legal or commercial entity;

[(22)**]** (25) "Pharmacist" means an individual who is licensed to practice pharmacy under the provisions of section 20-590, 20-591, 20-592 or 20-593, and who is thereby recognized as a health care provider by the state of Connecticut;

[(23)**]** (26) "Pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license has been issued to an applicant under the provisions of section 20-594, as amended by this act;

[(24)**]** (27) "Pharmacy intern" means an individual registered under the provisions of section 20-598;

[(25)**]** (28) "Pharmacy technician" means an individual who is registered with the department and qualified in accordance with section 20-598a;

[(26)**]** (29) "Polypharmacy" means the use of multiple drugs by a patient, including any medication that is inappropriate or not medically necessary, such as those not indicated, not effective or constituting a therapeutic duplication;

[(27)**]** (30) "Practice of pharmacy" or "to practice pharmacy" means the sum total of knowledge, understanding, judgments, procedures, securities, controls and ethics used by a pharmacist to assure optimal safety and accuracy in the distributing, dispensing and use of drugs and

devices;

[(28)**]** (31) "Prescribing practitioner" means an individual licensed by the state of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States who is authorized to issue a prescription within the scope of the individual's practice;

[(29)**]** (32) "Prescription" means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug or device for a specific patient;

[(30)**]** (33) "Sale" includes barter, exchange or gift or offer and each such transaction made by a person whether as principal proprietor, agent, servant or employee;

[(31)**]** (34) "Substitute" means to dispense without the prescribing practitioner's express authorization a different drug product than the drug product prescribed;

[(32)**]** (35) "Third-party logistics provider" means a person who distributes drugs, devices or cosmetics while taking possession of the drugs, devices or cosmetics but who does not take title of the drugs, devices or cosmetics;

[(33)**]** (36) "Virtual manufacturer" means a person who engages in the manufacture of drugs, devices or cosmetics for which such person: (A) Owns the new drug application or abbreviated new drug application number, if a prescription drug; (B) owns the unique device identification number, as available, for a prescription device; (C) contracts with a contract manufacturing organization for the physical manufacture of the drugs, devices or cosmetics; (D) is not involved in the physical manufacture of the drugs, devices or cosmetics; and (E) at no time takes physical possession of or stores the drugs, devices or cosmetics; and

[(34)**]** (37) "Virtual wholesale distributor" means a person who

facilitates or brokers the transfer of drugs, devices or cosmetics without taking physical possession of the drugs, devices or cosmetics.

Sec. 2. (NEW) (*Effective July 1, 2023*) (a) For the purposes of this section:

(1) "COVID-19" means the respiratory disease designated by the World Health Organization on February 11, 2020, as coronavirus 2019, and any related mutation thereof recognized by said organization as a communicable respiratory disease;

(2) "COVID-19-related test" means any laboratory test, or series of laboratory tests, for any virus, antibody, antigen or etiologic agent thought to cause, or indicate the presence of, COVID-19;

(3) "HIV-related prophylaxis" means any drug approved by the federal Food and Drug Administration or any successor agency as a pre-exposure or post-exposure prophylaxis for the human immunodeficiency virus;

(4) "HIV-related test" has the same meaning as provided in section 19a-7o of the general statutes; and

(5) "Influenza-related test" means any laboratory test, or series of laboratory tests, for any virus, antibody, antigen or etiologic agent thought to cause, or indicate the presence of, influenza disease.

(b) (1) Any person who is licensed as a pharmacist under part II of chapter 400j of the general statutes and employed by a pharmacy that has submitted to the Department of Public Health a complete clinical laboratory improvement amendment application for certification for a COVID-19-related test, HIV-related test or Influenza-related test may order and administer the COVID-19-related test, HIV-related test or Influenza-related test to any patient who is: (A) Eighteen years of age or older; or (B) at least twelve years of age but younger than eighteen years of age with (i) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (ii) proof that such

patient is an emancipated minor.

(2) If a pharmacist orders and administers a COVID-19-related test, HIV-related test or Influenza-related test to a patient under subdivision (1) of this subsection, the pharmacist shall: (A) Provide to the patient, in writing, the results of such test; (B) maintain a record of the results of such test for a period of three years; and (C) provide to the Commissioner of Consumer Protection or the commissioner's designee, upon a request made by the commissioner or the commissioner's designee, a copy of the results of such test.

(c) (1) If a pharmacist orders and administers any HIV-related test to a patient under subdivision (1) of subsection (b) of this section and the result of such test is negative, the pharmacist may prescribe and dispense to the patient any HIV-related prophylaxis according to the manufacturer's package insert, provided: (A) Such patient's circumstances satisfy the criteria established in such package insert; and (B) prescribing and dispensing such HIV-related prophylaxis satisfies all applicable requirements established in chapter 400j of the general statutes.

(2) If a pharmacist prescribes any HIV-related prophylaxis under subdivision (1) of this subsection, the pharmacist shall provide to the Commissioner of Consumer Protection or the commissioner's designee, upon a request made by the commissioner or the commissioner's designee: (A) A copy of the results of the HIV-related test; (B) prescription information maintained pursuant to chapter 400j of the general statutes; and (C) any other documentation the commissioner requires in regulations adopted pursuant to subsection (d) of this section.

(d) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health and the Commission of Pharmacy, shall adopt regulations, in accordance with chapter 54 of the general statutes, to implement the provisions of this section. Such regulations shall, at a minimum: (1) Identify qualifying training programs, which

are accredited by the National Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education or another appropriate national accrediting body; and (2) establish a system of control and reporting.

Sec. 3. (NEW) (*Effective July 1, 2023*) (a) (1) A pharmacy may apply to the department, in a form and manner prescribed by the commissioner, to operate a mobile pharmacy in a temporary location for the purpose of: (A) Conducting (i) a temporary clinic, (ii) a vaccination event, or (iii) an opioid antagonist training and prescribing event; or (B) serving a community that may not have adequate access to such pharmacy's services.

(2) No pharmacy may operate a mobile pharmacy without prior approval from the department. Each mobile pharmacy shall be supervised by a pharmacist. The department may inspect a mobile pharmacy before pharmacy services are provided in the mobile pharmacy, and at any time during usual business hours. The department may issue an order closing a mobile pharmacy if the department determines that: (A) The mobile pharmacy has failed to comply with the provisions of this section; (B) conditions are unsafe to store and dispense drugs; or (C) there is insufficient security at such mobile pharmacy.

(b) A pharmacy that operates a mobile pharmacy under this section shall: (1) Maintain a record of all drugs that are removed from the pharmacy premises for the purpose of operating such mobile pharmacy; (2) maintain a record of each drug that is dispensed at such mobile pharmacy and include such record in such pharmacy's records not later than twenty-four hours after such drug is dispensed; (3) except as provided in subsection (c) of this section, inventory and return all unused drugs to the pharmacy premises by the close of business each day; (4) while operating such mobile pharmacy, store all drugs in such mobile pharmacy in a manner that (A) prevents any drug diversion, and (B) is consistent with the storage conditions specified by the manufacturers of such drugs; (5) establish and maintain a plan to ensure

that patients receive necessary treatments if such mobile pharmacy is unavailable; and (6) if permitted by the federal Drug Enforcement Administration or a successor agency, store controlled substances in the mobile pharmacy in accordance with regulations adopted by the commissioner pursuant to section 21a-262 of the general statutes.

(c) No pharmacy shall, without prior approval from the department: (1) Operate a mobile pharmacy for more than (A) seven consecutive days in a single location, or (B) fourteen days in any geographic area; or (2) store drugs overnight in a mobile pharmacy or outside of the pharmacy premises.

(d) The commissioner may, with the advice and consent of the commission, adopt regulations in accordance with chapter 54 of the general statutes to implement the provisions of this section.

Sec. 4. Section 20-633 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(a) (1) Any person licensed as a pharmacist under part II of this chapter may **[**(1)**]** administer: **[**, to an adult, any**]**

(A) Any vaccine, approved or authorized by the United States Food and Drug Administration that is listed on the National Centers for Disease Control and Prevention's Adult Immunization Schedule, **[**and (2) on and after July 1, 2022, administer to any person between the ages of twelve and seventeen, with the consent of such person's parent or guardian, the influenza vaccine approved by the United States Food and Drug Administration, provided the administration of any vaccine under this subsection is conducted pursuant to the order of a licensed health care provider and in accordance with the regulations established pursuant to subsection (b) of this section.**]** to any patient who is: (i) Eighteen years of age or older; or (ii) at least twelve years of age but younger than eighteen years of age with (I) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (II) proof that such patient is an emancipated minor.

(B) Any vaccine not included on the National Centers for Disease Control and Prevention's Adult Immunization Schedule, provided the vaccine administration instructions for such vaccine are available on the National Centers for Disease Control and Prevention's Internet web site; and

(C) Any vaccine pursuant to a verbal or written prescription of a prescribing practitioner for a specific patient.

(2) A pharmacist shall make a reasonable effort to review a patient's vaccination history to prevent any inappropriate use of a requested vaccine.

(3) All vaccines administered pursuant to this section shall be administered in accordance with the: (A) Vaccine manufacturer's package insert or upon the orders of a prescribing practitioner based on the age of the patient being vaccinated; and (B) regulations adopted pursuant to subsection (c) of this section.

(b) A pharmacist who has completed the training required in regulations adopted pursuant to subsection (c) of this section may administer an epinephrine cartridge injector, as defined in section 19a-909, to a patient whom the pharmacist reasonably believes, based on such pharmacist's knowledge and training, is experiencing anaphylaxis, regardless of whether such patient has a prescription for an epinephrine cartridge injector. Such pharmacist, or such pharmacist's designee, shall call the 9-1-1 emergency telephone number either before or immediately after such pharmacist administers the epinephrine cartridge injector to such patient. Such pharmacist shall document the date, time and circumstances in which such pharmacist administered such epinephrine cartridge injector, and maintain such documentation for at least three years.

[(b)**]** (c) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health and the Commission of Pharmacy, shall adopt regulations, in accordance with the provisions of chapter 54, to implement the provisions of this section. Such regulations

shall: (1) **[**require**]** Require any pharmacist who administers a vaccine pursuant to this section to successfully complete an immunization training program for pharmacists; (2) define the basic requirements of such training program, which shall include training and instruction in pre-administration education and screening, vaccine storage and handling, subcutaneous and intramuscular injections, recordkeeping, vaccine safety, cardiopulmonary resuscitation, basic cardiac life support and adverse event reporting; (3) identify qualifying training programs, which are accredited by the National Centers for Disease Control Prevention, the Accreditation Council for Pharmacy Education or **[**other**]** another appropriate national accrediting body; and (4) establish a system of control and reporting.

[(c) For purposes of this section, "adult" means a person who has attained the age of eighteen years.**]**

Sec. 5. Subsection (a) of section 20-576 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(a) The commissioner may, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, to govern the performance of the commission's duties, the practice of pharmacy and the business of retailing drugs and devices. Such regulations may include, but are not limited to, provisions (1) concerning the licensing of any pharmacist or pharmacy, disciplinary action that may be taken against a licensee, the conduct of a pharmacist and the operation of a pharmacy, (2) specifying various classes of pharmacy licenses issued under section 20-594, as amended by this act, including, but not limited to, licenses for infusion therapy pharmacies, **[**and**]** nuclear pharmacies and health care institutional pharmacies, and specifying requirements for operation of pharmacies under the classes of pharmacy licenses permitted under the regulations, (3) concerning creation and maintenance of prescription records, and (4) concerning registration and activities of pharmacy interns, registered pharmacy technicians and certified pharmacy technicians.

Sec. 6. Section 20-594 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(a) Except as limited by section 20-596, a pharmacist, health care institution or any other person may apply to the commission for a pharmacy license or for renewal of a pharmacy license.

(b) The applicant shall disclose on the application the name and address of the applicant and the owner of the pharmacy, the name and street and mailing address of the pharmacy and the name, address and license number of the pharmacist who manages the pharmacy. The commissioner may, by regulation adopted with the advice and assistance of the commission, in accordance with chapter 54, require such other information on the application as is necessary for the department to carry out **[**its**]** the department's duties under sections 20-570 to 20-630, inclusive.

(c) The department shall, after receipt of an application under this section, (1) issue, on authorization of the commission, a pharmacy license to an applicant for a new pharmacy on payment of the fee required in section 20-601 and on satisfactory evidence to the commission that the pharmacy will be managed by a pharmacist and will be operated in accordance with the general statutes and the regulations adopted by the commissioner in accordance with chapter 54, and (2) issue a renewal of a pharmacy license to an applicant on payment of the fee required in section 20-601.

(d) Pharmacy licenses shall expire annually. Pharmacy licenses may be renewed on application and payment of the fee required in section 20-601 for a period not to exceed one year.

(e) When a pharmacy is transferred to a new location the pharmacy license for such pharmacy shall terminate. A pharmacy license that has been terminated under this subsection may be renewed under the provisions of subsection (d) of this section and on satisfactory evidence to the commission that the pharmacy will be managed by a pharmacist and will be operated in accordance with the general statutes and the

regulations adopted by the commissioner in accordance with chapter 54.

(f) Each pharmacy licensed pursuant to this section shall report to the department any administrative or legal action commenced against **[**it**]** such pharmacy 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. 7. Section 20-633b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(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) "Prescribing practitioner" has the same meaning as provided in section 20-14c;

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

[(3)**]** (4) "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)**]** (5) "USP chapters" means chapters 797, 800 and 825 of the United States Pharmacopeia that pertain to compounding sterile pharmaceuticals and their referenced companion documents, as amended from time to time.

(b) (1) (A) 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**]** the pharmacy license application such applicant files pursuant to section 20-

594, as amended by this act, to include sterile pharmaceutical compounding. The **[**Department of Consumer Protection**]** department shall inspect the proposed pharmacy premises of **[**the**]** such applicant and **[**the**]** such applicant shall not compound sterile pharmaceuticals until **[**it**]** such applicant receives notice that the addendum to such applicant's application has been approved by the department and the **[**Commission of Pharmacy**]** commission.

[(2)**]** (B) 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**]** apply for an addendum **[**application to its**]** to such pharmacy's application on file with the department to include sterile pharmaceutical compounding. The **[**Department of Consumer Protection**]** department shall inspect the pharmacy premises of such pharmacy and **[**the**]** such pharmacy shall not compound sterile pharmaceuticals until **[**it**]** such pharmacy receives notice that such addendum application has been approved by the department and the **[**Commission of Pharmacy**]** commission.

(C) If an existing health care institutional 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, 2023, such health care institutional pharmacy shall apply for an addendum to such health care institutional pharmacy's application on file with the department to include sterile pharmaceutical compounding. The department shall inspect the pharmacy premises of such health care institutional pharmacy and such health care institutional pharmacy shall not compound sterile pharmaceuticals until such health care institutional pharmacy receives notice that such health care institutional pharmacy's application has been approved by the department and the commission.

[(3)**]** (2) (A) If an applicant for a new nonresident pharmacy registration intends to compound sterile pharmaceuticals for sale or delivery in this state, the applicant shall file an addendum to **[**its**]** the

registration application such applicant files pursuant to section 20-627 to include sterile pharmaceutical compounding. **[**The**]** Such applicant shall provide to the department **[**with**]** written proof **[**it**]** that such applicant has passed inspection by the appropriate state agency in the state where such **[**nonresident pharmacy**]** applicant is located. Such **[**pharmacy**]** applicant shall not compound sterile pharmaceuticals for sale or delivery in this state until **[**it**]** such applicant receives notice that **[**the**]** such addendum **[**application**]** has been approved by the department and the **[**Commission of Pharmacy**]** commission.

[(4)**]** (B) If **[**a**]** an existing 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**]** such nonresident pharmacy shall **[**file**]** apply for an addendum to **[**its**]** such nonresident pharmacy's application on file with the department to include sterile pharmaceutical compounding. **[**The**]** Such nonresident pharmacy shall provide to the department **[**with**]** written proof **[**it**]** that such nonresident pharmacy has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such nonresident pharmacy shall not compound sterile pharmaceuticals until **[**it**]** such nonresident pharmacy receives notice that **[**the**]** such addendum application has been approved by the department and the **[**Commission of Pharmacy**]** commission.

(c) A sterile compounding pharmacy shall comply with the 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 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 chapters, for good cause shown. The commissioner may grant an extension for a length of time

not to exceed six months. Nothing in this section shall prevent such institutional pharmacy from requesting a subsequent extension of time or shall prevent the commissioner from granting such extension.**]**

[(e)**]** (d) (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, as amended by this act, 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 USP chapters.

[(f)**]** (e) (1) If a sterile compounding pharmacy plans to remodel any area utilized for the compounding of sterile pharmaceuticals or adjacent space, relocate 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 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 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, 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**]** such sterile compounding pharmacy's 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)**]** (f) 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 USP chapters, not later than the end of the next business day after discovering such violation or noncompliance.

[(h)**]** (g) (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)**]** (h) 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 USP chapters.

[(j)**]** (i) Each sterile compounding pharmacy shall report to the Department of Consumer Protection any administrative or legal action commenced against **[**it**]** such sterile compounding pharmacy 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)**]** (j) Notwithstanding the provisions of **[**subdivisions (3) and (4)**]** subdivision (2) 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**]** such nonresident pharmacy has passed an inspection in such nonresident pharmacy's home state, based on the USP chapters. Such nonresident pharmacy shall submit to the Department of Consumer Protection a copy of the most recent inspection report with **[**its**]** such nonresident pharmacy's initial nonresident pharmacy application and shall submit to the department a copy of **[**its**]** such nonresident pharmacy's most recent inspection report every two years thereafter. If the state in which **[**the**]** such nonresident pharmacy is located does not conduct inspections based on standards required in the USP chapters, such nonresident pharmacy shall provide satisfactory proof to the department that **[**it**]** such nonresident pharmacy is in compliance with the standards required in the USP chapters.

[(l)**]** (k) A practitioner, as specified in subdivision (1) of subsection **[**(e)**]** (d) 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)**]** (l) (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 said chapters pertain 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**]** such pharmacy's designated pharmacist.

(3) The designated pharmacist shall be responsible for providing proof **[**he or she**]** such designated pharmacist 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**]** such designated pharmacist ceases such designation.

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

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

Sec. 8. Subsections (a) and (b) of section 21a-65 of the general statutes are repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(a) A licensed manufacturer or licensed wholesaler may sell hypodermic needles and syringes only to the following: (1) To a licensed manufacturer, licensed wholesaler or licensed pharmacy; (2) to a physician, dentist, veterinarian, embalmer, podiatrist or scientific investigator licensed to practice in this state; (3) to a person in charge of a care-giving institution, as defined in **[**subdivision (3) of**]** section 20-571, as amended by this act, incorporated college or scientific institution, but only for use by or in such care-giving institution, college or institution for medical or scientific purposes; (4) to a person in charge of a licensed or registered laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to a farmer but only for use on the farmer's

own animals or poultry; (6) to a business authorized in accordance with the regulations adopted under section 21a-66 to purchase hypodermic needles and syringes but only for legitimate industrial or medical use within that business; and (7) to a syringe services program established pursuant to section 19a-124.

(b) Except as provided in subsection (a) of this section, no licensed manufacturer, licensed wholesaler or licensed pharmacist shall sell and no person shall buy a hypodermic needle or syringe except upon a prescription of a prescribing practitioner, as defined in **[**subdivision (28) of**]** section 20-571, as amended by this act, in a quantity greater than ten. Any such prescription shall be retained on file by the seller for a period of not less than three years and shall be accessible to any public officer engaged in the enforcement of this section. Such a prescription shall be valid for one year from the date thereof and purchases and sales may be made thereunder during such period, provided the seller shall confirm the continued need for such sales with such practitioner at least every six months if sales continue to be made thereunder. Hypodermic needles and syringes in a quantity of ten or less without a prescription may be provided or sold at retail only by the following: (1) By a pharmacy licensed in accordance with section 20-594, as amended by this act, and in such pharmacy only by a licensed pharmacist or under the pharmacist's direct supervision; (2) by a syringe service program established pursuant to section 19a-124; and (3) by a health care facility or a licensed health care practitioner for use by their own patients.

Sec. 9. Subsection (a) of section 21a-70 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(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, as amended by this act, 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 (28) of**]** section 20-571, as amended by this act, 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**]** such licensed hospital's 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**]** the commissioner's designee.

Sec. 10. Subsection (k) of section 21a-106 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(k) If it is a legend drug, as defined in **[**subdivision (16) of**]** section 20-571, as amended by this act, that is not administered, dispensed, prescribed or otherwise possessed or distributed in accordance with federal and state laws and regulations;

Sec. 11. Subsection (e) of section 21a-115 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(e) In the promulgation of regulations under the provisions of this section applicable to prescribing practitioners, care-giving institutions, and correctional and juvenile training institutions, as defined in **[**subdivision (7) of**]** section 20-571, as amended by this act, the Commissioner of Consumer Protection shall act in place of the director. Existing regulations shall continue in effect unless superseded by action of said commissioner pursuant to this subsection.

Sec. 12. Subsection (j) of section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in **[**subdivision (28) of**]** section 20-571, as amended by this act.

Sec. 13. Section 38a-492a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (6), (10), (11) and (12) of section 38a-469, delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for hypodermic needles or syringes prescribed by a prescribing practitioner, as defined in **[**subdivision (28) of**]** section 20-571, as amended by this act, for the purpose of administering medications for medical conditions, provided such medications are covered under the policy. Such benefits shall be subject to any policy provisions that apply to other services covered by such policy.

Sec. 14. Section 38a-518a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (6), (10), (11) and (12) of section 38a-469, delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for hypodermic needles or syringes prescribed by a prescribing practitioner, as defined in **[**subdivision (28) of**]** section 20-571, as amended by this act, for the purpose of administering medications for medical conditions, provided such medications are covered under the policy. Such benefits shall be subject to any policy provisions that apply to other services covered by such policy.

Sec. 15. Subdivision (1) of subsection (b) of section 53a-13 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(b) (1) It shall not be a defense under this section if such mental disease or defect was proximately caused by the voluntary ingestion, inhalation or injection of intoxicating liquor or any drug or substance, or any combination thereof, unless such drug was prescribed for the defendant by a prescribing practitioner, as defined in **[**subdivision (28)

of**]** section 20-571, as amended by this act, and was used in accordance with the directions of such prescription.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2023*	20-571
Sec. 2	*July 1, 2023*	New section
Sec. 3	*July 1, 2023*	New section
Sec. 4	*July 1, 2023*	20-633
Sec. 5	*July 1, 2023*	20-576(a)
Sec. 6	*July 1, 2023*	20-594
Sec. 7	*July 1, 2023*	20-633b
Sec. 8	*July 1, 2023*	21a-65(a) and (b)
Sec. 9	*July 1, 2023*	21a-70(a)
Sec. 10	*July 1, 2023*	21a-106(k)
Sec. 11	*July 1, 2023*	21a-115(e)
Sec. 12	*July 1, 2023*	21a-249(j)
Sec. 13	*July 1, 2023*	38a-492a
Sec. 14	*July 1, 2023*	38a-518a
Sec. 15	*July 1, 2023*	53a-13(b)(1)

Statement of Purpose:

To: (1) Authorize (A) pharmacists to administer additional vaccines, tests and drugs, and (B) pharmacies to operate mobile pharmacies; and (2) provide that an institutional pharmacy located in a licensed health care facility may compound sterile pharmaceuticals.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]