General Assembly

# *Raised Bill No. 6768*

*January Session, 2023*

LCO No. **4607**

Referred to Committee on GENERAL LAW

Introduced by:
(GL)

## *AN ACT CONCERNING THE DEPARTMENT OF CONSUMER PROTECTION'S RECOMMENDATIONS REGARDING PRESCRIPTION DRUG REGULATION.*

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

Section 1. (NEW) (*Effective January 1, 2024*) (a) For the purposes of this section:

(1) "Centralized dispensing practitioner" means a prescribing practitioner (A) who is employed by, or affiliated with, a dispensing group practice, and (B) whom the dispensing group practice designates as the prescribing practitioner who is authorized to dispense legend drugs and legend devices on behalf of other prescribing practitioners who are employed by, or affiliated with, such dispensing group practice;

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

(3) "Dispense" has the same meaning as provided in section 20-571 of the general statutes;

(4) "Dispensing assistant" means an individual who is (A) registered with the department under subdivision (1) of subsection (d) of this section, (B) employed by a dispensing group practice, and (C) supervised by (i) the centralized dispensing practitioner, or (ii) a pharmacist employed by the dispensing group practice;

(5) "Dispensing group practice" means a group practice that (A) centralizes the dispensing of legend drugs or legend devices prescribed by prescribing practitioners who are employed by, or affiliated with, the group practice through (i) a centralized dispensing practitioner, or (ii) a pharmacist employed by the dispensing group practice, and (B) is registered with the department pursuant to subsection (b) of this section;

(6) "Group practice" has the same meaning as provided in section 19a-486i of the general statutes;

(7) "Legend device" has the same meaning as provided in section 20-571 of the general statutes;

(8) "Legend drug" has the same meaning as provided in section 20-571 of the general statutes;

(9) "Pharmacist" has the same meaning as provided in section 20-571 of the general statutes;

(10) "Pharmacy technician" means an individual who is registered with the department and qualified in accordance with section 20-598a of the general statutes;

(11) "Prescribing practitioner" has the same meaning as provided in section 20-571 of the general statutes;

(12) "Prescription" has the same meaning as provided in section 20-635 of the general statutes;

(13) "Professional samples" has the same meaning as provided in section 20-14c of the general statutes; and

(14) "Seventy-two hour supply" means a quantity of a legend drug or legend device that does not exceed the dosage amount necessary for seventy-two hours according to the directions for use of the legend drug or legend device.

(b) (1) No group practice may dispense legend drugs or legend devices as a dispensing group practice unless such group practice submits an application to, and receives a registration from, the department under this subdivision. Each application submitted to the department under this subdivision shall be submitted on a form, and in a manner, prescribed by the department and designate a centralized dispensing practitioner or a pharmacist who is employed by the group practice and shall serve as the primary contact for the department, and shall be accompanied by a registration fee in the amount of two hundred dollars. Each registration issued pursuant to this subdivision shall be valid for a period of two years, and the department may renew such registration for additional two-year periods upon its receipt of a complete renewal application submitted on a form, and in a manner, prescribed by the department and a renewal fee of two hundred dollars.

(2) Except as provided in subdivision (3) of this subsection, each dispensing group practice that dispenses, or proposes to dispense, in this state more than a seventy-two hour supply of any legend drug or legend device shall (A) register for access to the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254 of the general statutes, and (B) comply with all reporting and usage requirements for the electronic prescription drug monitoring program as set forth in subsection (j) of section 21a-254 of the general statutes.

(3) No dispensing group practice that dispenses, or proposes to dispense, less than a seventy-two hour supply of legend drugs or legend devices shall be subject to the provisions of subdivision (2) of this subsection if such dispensing group practice exclusively dispenses such supply of legend drugs or legend devices as professional samples.

(c) A dispensing group practice that employs a pharmacist for the purpose of dispensing legend drugs or legend devices shall not be required to obtain a pharmacy license for the dispensing group practice's premises under section 20-594 of the general statutes. The pharmacist shall report directly to a prescribing practitioner who is employed by, or affiliated with, the dispensing group practice, and may supervise dispensing assistants employed by such dispensing group practice, perform in-process and final checks without obtaining any additional verification from the prescribing practitioner to whom such pharmacist reports and perform any component of the practice of pharmacy.

(d) (1) No individual may act as a dispensing assistant unless such individual submits an application to, and receives a registration from, the department under this subdivision. Each application submitted to the department under this subdivision shall be submitted on a form, and in a manner, prescribed by the department, and shall be accompanied by a registration fee in the amount of one hundred dollars. Each registration issued pursuant to this subdivision shall be valid for a period of two years, and the department may renew such registration for additional two-year periods upon its receipt of a complete renewal application submitted on a form, and in a manner, prescribed by the department and a renewal fee of one hundred dollars.

(2) A dispensing assistant who is registered with the department under subdivision (1) of this subsection may perform the duties of a pharmacy technician, provided the dispensing assistant performs such duties under the supervision of a prescribing practitioner who is employed by or affiliated with, or a pharmacist who is employed by, the dispensing group practice that employs such dispensing assistant. Each dispensing assistant shall be subject to the same responsibilities and liabilities set forth in chapter 400j of the general statutes, and any regulations adopted pursuant to chapter 400j of the general statutes, concerning pharmacy technicians.

(e) A prescribing practitioner who is employed by, or affiliated with,

a dispensing group practice may dispense legend drugs or legend devices to the prescribing practitioner's patients without engaging the services of the centralized dispensing practitioner or a pharmacist who is employed by the dispensing group practice.

(f) (1) No centralized dispensing practitioner or pharmacist employed by a dispensing group practice shall dispense a legend drug, legend device or controlled substance for, or order that a legend drug, legend device or controlled substance be dispensed to, any individual who is not being treated by a prescribing practitioner who is employed by, or affiliated with, the dispensing group practice.

(2) No dispensing group practice shall accept or dispense any prescription from a prescribing practitioner who is not employed by, or affiliated with, the dispensing group practice.

(3) No dispensing group practice shall exhibit within or upon the outside of the premises occupied by such dispensing group practice, or include in any advertisement for such dispensing group practice, (A) the words "drug store", "pharmacy", "apothecary" or "medicine shop" or any combination thereof, or (B) any other display, symbol or word indicating that such dispensing group practice or premises is a pharmacy.

(g) The department may refuse to issue or renew a dispensing group practice registration under subsection (b) of this section or dispensing assistant registration under subsection (d) of this section, revoke, suspend or place conditions on a dispensing group practice's registration issued under subsection (b) of this section or a dispensing assistant's registration under subsection (d) of this section, and assess a civil penalty not to exceed one thousand dollars per violation if the dispensing group practice or a centralized dispensing practitioner, dispensing assistant or pharmacist employed by, or acting as an agent on behalf of, such dispensing group practice violates any provision of (1) subsections (a) to (f), inclusive, of this section, or (2) chapter 400j of the general statutes, or any regulations adopted pursuant to chapter 400j

of the general statutes, concerning dispensing legend drugs or legend devices.

Sec. 2. (NEW) (*Effective from passage*) (a) For the purposes of this section, "drug", "legend device", "pharmacist" and "prescribing practitioner" have the same meanings as provided in section 20-571 of the general statutes.

(b) A pharmacist may authorize or refill a prescription for a legend device if such legend device is approved by the federal Food and Drug Administration for use in combination with a drug prescribed by a prescribing practitioner.

(c) A pharmacist who dispenses a legend device as described in subsection (b) of this section shall identify the prescribing practitioner who prescribed the drug that is associated with such legend device, and shall send written notice to such prescribing practitioner, not later than seventy-two hours after the pharmacist dispenses such legend device to the patient, disclosing that such pharmacist dispensed such legend device to such patient.

Sec. 3. (NEW) (*Effective from passage*) (a) For the purposes of this section:

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

(2) "Emergency contraceptive" means a drug, or a combination of drugs, approved by the federal Food and Drug Administration to prevent pregnancy as soon as possible following (A) unprotected sexual intercourse, or (B) a known or suspected contraceptive failure;

(3) "Hormonal contraceptive" means a drug, including, but not limited to, a hormonal contraceptive patch, an intravaginal hormonal contraceptive or an oral hormonal contraceptive, composed of a hormone, or a combination of hormones, approved by the federal Food and Drug Administration to prevent pregnancy;

(4) "Legend drug" has the same meaning as provided in section 20-

571 of the general statutes;

(5) "Pharmacist" has the same meaning as provided in section 20-571 of the general statutes;

(6) "Pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

(7) "Pharmacy technician" has the same meaning as provided in section 20-571 of the general statutes; and

(8) "Prescribe" means to order, or designate a remedy or any preparation of, a legend drug for a specific patient.

(b) A pharmacist certified in accordance with the provisions of this section may prescribe, in good faith, an emergency contraceptive or hormonal contraceptive to a patient subject to the following conditions:

(1) The pharmacist has completed an educational training program that (A) concerns prescribing emergency contraceptives and hormonal contraceptives by a pharmacist, (B) addresses appropriate medical screening of patients, contraindications, drug interactions, treatment strategies and modifications and when to refer patients to medical providers, and (C) is accredited by the Accreditation Council for Pharmacy Education;

(2) The pharmacist has reviewed the most current version of the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention, or any successor document thereto, prior to prescribing any emergency contraceptive or hormonal contraceptive and, if the pharmacist deviates from the guidance provided in such document, documents the pharmacist's rationale in deviating from such guidance in writing;

(3) Prior to dispensing an emergency contraceptive or hormonal contraceptive and at least once per calendar year thereafter for any returning patient, the pharmacist completes a screening document, which the department shall make available on the department's Internet

web site, and the pharmacist, or the pharmacy that employs such pharmacist, retains such document for at least three years, except nothing in this subdivision shall be construed to prevent a pharmacist, in the pharmacist's professional discretion, from issuing a prescription for a hormonal contraceptive for a period not to exceed twelve months or from requiring more frequent screenings;

(4) If the pharmacist determines that prescribing an emergency contraceptive or hormonal contraceptive to a patient is clinically appropriate, the pharmacist shall (A) counsel the patient about what the patient should monitor and when the patient should seek additional medical attention, and (B) send notice to any health care provider that the patient identifies as the patient's primary care provider or, if the patient does not disclose the identity of the patient's primary care provider, provide to the patient any relevant documentation; and

(5) The pharmacist provides to the patient a document outlining age-appropriate health screenings that are consistent with recommendations made by the Centers for Disease Control and Prevention.

(c) A pharmacy technician may, at a pharmacist's request, assist the pharmacist in prescribing an emergency contraceptive or hormonal contraceptive to a patient by providing screening documentation to the patient, taking and recording the patient's blood pressure and documenting the patient's medical history, provided the pharmacy technician has completed an educational training program that satisfies the requirements established in subdivision (1) of subsection (b) of this section.

(d) If a pharmacist is morally or ethically opposed to issuing a prescription for an emergency contraceptive or a hormonal contraceptive, the pharmacist shall provide to any patient who requests such a prescription a list of the nearest pharmacies that may provide such a prescription to the patient.

(e) Each pharmacy shall maintain copies of all documents concerning any screening performed under this section for at least three years, and

each pharmacy shall, upon request by the department, make such screening documents available to the department for inspection.

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

Sec. 4. (NEW) (*Effective from passage*) (a) For the purposes of this section, "drug", "pharmacist" and "pharmacy" have the same meanings as provided in section 20-571 of the general statutes.

(b) A pharmacist who is employed by a pharmacy that has been approved to dispense drugs for the termination of a pregnancy shall provide to any patient who is seeking any such drug a list of the pharmacies nearest to such patient that dispense such drug if (1) the pharmacy does not have a supply of such drug, or (2) the pharmacist is morally or ethically opposed to dispensing such drug to such patient.

(c) A pharmacist who is, or has been, licensed in another state or jurisdiction shall not be subject to automatic reciprocal discipline in this state for any disciplinary action taken in such other state or jurisdiction, provided such disciplinary action was based solely on the termination of a pregnancy under conditions which would not violate the laws of this state.

Sec. 5. Section 20-579 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, **[**may**]** refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, **[**and may**]** revoke, suspend or place conditions on a license or temporary permit to practice pharmacy, a license to operate a pharmacy **[**,**]** or a registration of a pharmacy intern or a pharmacy technician **[**,**]** and **[**may**]** assess a civil penalty **[**of up to**]** <u>not to exceed</u> one thousand dollars per violation of any provision of this chapter<u>,</u> or

take other action permitted in subdivision (7) of subsection (a) of section 21a-7, if the applicant or holder of the license, temporary permit or registration: (1) Has violated a statute or regulation relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar to grounds on which Connecticut could refuse to issue or renew such a license or registration; (5) has illegally possessed, diverted, sold or dispensed drugs or devices; (6) abuses or excessively uses drugs, including, but not limited to, alcohol; (7) has made false, misleading or deceptive representations to the public or the commission; (8) has maintained exclusive telephone lines to, has maintained exclusive electronic communication with, or has exclusive access to computers located in offices of prescribing practitioners, nursing homes, clinics, hospitals or other health care facilities; (9) has substituted drugs or devices except as permitted in section 20-619; (10) has accepted, for return to regular stock, any drug already dispensed in good faith or delivered from a pharmacy, and exposed to possible and uncontrolled contamination or substitution; (11) has split fees for professional services, including, but

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

(b) The commission may refuse to authorize the issuance or renewal of a license to operate a pharmacy, revoke, suspend or place conditions on a license to operate a pharmacy and assess a civil penalty not to exceed one thousand dollars per violation for any violation of this chapter, or take other action permitted in subdivision (7) of subsection (a) of section 21a-7, if the applicant or holder of the license: (1) Implements policies, procedures, systems or processes that result in any deviation from the safe practice of pharmacy; (2) prevents or delays patient access to prescribed drugs or other pharmacy services

unreasonably or without providing adequate notice and an opportunity to transfer such services to avoid such delay; (3) allows pharmacy conditions that inhibit the safe and competent practice of pharmacy by pharmacists or other pharmacy staff, or creates an unreasonable risk to patient care; or (4) fails to provide adequate resources, including, but not limited to, staffing, to pharmacists in such a manner as to inhibit a pharmacist's ability to perform all duties required under state and federal law.

**[**(b)**]** (c) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, **[**may**]** refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician **[**,**]** and **[**may**]** revoke, suspend or place conditions on a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a pharmacy intern or a pharmacy technician, or take other action permitted in subdivision (7) of subsection (a) of section 21a-7, if the commission determines that the applicant or holder of the license, temporary permit or registration has a condition, including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of pharmacy, operation of a pharmacy or activities as a pharmacy intern or pharmacy technician, provided the commission may not, in taking action against a license, temporary permit or registration holder on the basis of such a condition, violate the provisions of section 46a-73 or 42 USC Section 12132 of the federal Americans with Disabilities Act.

Sec. 6. Subsection (d) of section 20-613 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(d) Nothing in sections 20-570 to 20-630, inclusive, shall prevent a prescribing practitioner from dispensing the prescribing practitioner's own prescriptions to the prescribing practitioner's own patients when

authorized within the scope of the prescribing practitioner's own practice, **[**and**]** when done in compliance with sections 20-14c to 20-14g, inclusive, and, if the prescribing practitioner is compounding, performing compounding in adherence to all applicable provisions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, or Chapter 795, Pharmaceutical Compounding - Nonsterile Preparations, as both may be amended from time to time.

Sec. 7. Section 20-617a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) For purposes of this section, "flavoring agent" means an additive used in food or drugs when such additive **[**:**]** (1) **[**Is**]** is used in accordance with good manufacturing practice principles and in the minimum quantity required to produce its intended effect, (2) consists of one or more ingredients generally recognized as safe in food and drugs, has been previously sanctioned for use in food and drugs by the state or the federal government, meets United States Pharmacopeia standards or is an additive permitted for direct addition to food for human consumption pursuant to 21 CFR 172, (3) is inert and produces no effect other than the instillation or modification of flavor, and (4) is not greater than five per cent of the total weight of the product.

(b) A flavoring agent may be added to a prescription product by **[**:**]** (1) **[**A**]** a pharmacist upon the request of the prescribing practitioner, patient for whom the prescription is ordered or such patient's agent, or (2) a pharmacist acting on behalf of a hospital, as defined in section 19a-490.

(c) The addition of a flavoring agent in accordance with subsections (a) and (b) of this section shall be exempt from the requirements established in subsections (a) to (m), inclusive, of section 20-633b, as amended by this act, any regulations adopted pursuant to subsection (o) of section 20-633b, as amended by this act, and United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding –

Nonsterile Preparations, and Chapter 800, Hazardous Drugs, as both may be amended from time to time.

Sec. 8. Section 20-623 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) No nonlegend drug may be sold at retail except at a pharmacy, **[**or**]** at a store or in a vending machine that has obtained from the commission or the department a permit to sell nonlegend drugs**[**.**]** pursuant to section 20-624. Nonlegend drugs may be sold in a vending machine, which vending machine shall be owned and operated by a business that has obtained from the department a permit for each vending machine in which such business offers nonlegend drugs for sale. If an applicant seeks to locate two or more vending machines selling nonlegend drugs at a single premises, only one permit to sell nonlegend drugs shall be required. Any person who is not licensed as a pharmacy and wishes to sell nonlegend drugs in a vending machine shall apply to the department, in a form and manner prescribed by the commissioner, in order to obtain a permit to sell nonlegend drugs. Nonlegend drugs shall be labeled and packaged in accordance with state and federal law.

(b) (1) A vending machine offering nonlegend drugs may also offer nonlegend devices. Each vending machine offering nonlegend drugs or nonlegend devices shall be individually registered with the department, and each application to register a vending machine offering nonlegend drugs or nonlegend devices shall designate an individual who shall be responsible for properly maintaining such vending machine.

(2) Each person who registers a vending machine pursuant to subdivision (1) of this subsection, and the individual designated as the individual responsible for properly maintaining the registered vending machine, shall ensure that such vending machine (A) maintains the proper temperature and humidity for each nonlegend drug offered in such vending machine as required by the original manufacturer of such nonlegend drug, (B) only contains nonlegend drugs and nonlegend

devices that remain in the original containers provided by the manufacturers of such nonlegend drugs or nonlegend devices, (C) only offers nonlegend drugs and nonlegend devices that are unexpired and unadulterated, (D) only offers nonlegend drugs and nonlegend devices that are not subject to a recall and, if a nonlegend drug or nonlegend device is the subject of a recall, the nonlegend drug or nonlegend device is promptly removed from such vending machine, (E) only contains nonlegend drugs and nonlegend devices, sundries and other nonperishable items, (F) has a clear and conspicuous written statement attached to such vending machine disclosing the name, address and toll-free telephone number of the owner and operator of such vending machine, (G) has a clear and conspicuous written statement attached to such vending machine advising a consumer to check the expiration date of a nonlegend drug or nonlegend device contained in such vending machine before the consumer uses such nonlegend drug or nonlegend device, (H) has attached to such vending machine, in a size and prominent location visible to consumers, a written notice stating "Drug tampering or expired product? Notify the Department of Consumer Protection, Drug Control Division, by calling (telephone number of the toll-free telephone line established by the department pursuant to section 21a-2)", (I) does not offer any nonlegend drug or nonlegend device that requires age verification, is subject to any quantity limit or is subject to any sales restriction under state or federal law, and (J) does not contain any package of a nonlegend drug that contains more than a five-day supply of the nonlegend drug as determined according to the usage directions provided by the manufacturer of such nonlegend drug.

**[**(b)**]** (c) Any person who violates any provision of this section shall be fined not **[**less**]** more than **[**one hundred dollars**]** one thousand dollars **[**nor more than five hundred dollars**]** per violation.

Sec. 9. Section 20-633b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

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

(3) "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) "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) If an applicant for a new pharmacy license pursuant to section 20-594 intends to compound sterile pharmaceuticals, the applicant shall file an addendum to its pharmacy license application to include sterile pharmaceutical compounding. The Department of Consumer Protection shall inspect the proposed pharmacy premises of the applicant and the applicant shall not compound sterile pharmaceuticals until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

(2) If an existing pharmacy licensed pursuant to section 20-594 intends to compound sterile pharmaceuticals for the first time on or after July 1, 2014, such pharmacy shall file an addendum application to its application on file with the department to include sterile pharmaceutical compounding. The Department of Consumer Protection shall inspect the pharmacy premises and the pharmacy shall not compound sterile pharmaceuticals until it receives notice that such addendum application has been approved by the department and the Commission of Pharmacy.

(3) If an applicant for a nonresident pharmacy registration intends to

compound sterile pharmaceuticals for sale or delivery in this state, the applicant shall file an addendum to its application to include sterile pharmaceutical compounding. The applicant shall provide the department with written proof it has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such pharmacy shall not compound sterile pharmaceuticals for sale or delivery in this state until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

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

(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) (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 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) (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 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) 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) (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**]** 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) 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) Each sterile compounding pharmacy shall report to the Department of Consumer Protection any administrative or legal action commenced against it 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) Notwithstanding the provisions of subdivisions (3) and (4) 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 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 initial nonresident pharmacy application and shall submit to the department a copy of its most recent inspection report every two years thereafter. If the state in which the 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 is in compliance with the standards required in the USP chapters.

(l) A practitioner, as specified in subdivision (1) of subsection (e) 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) (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 or institutional pharmacy licensed pursuant to section 19a-490 that provides sterile pharmaceuticals shall notify the department of its designated pharmacist.

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

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

(n) Notwithstanding the provisions of this section, the addition of a flavoring agent in accordance with subsections (a) and (b) of section 20-617a, as amended by this act, shall be exempt from the requirements of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations, and Chapter 800, Hazardous Drugs, as both may be amended from time to time.

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

Sec. 10. Subdivision (6) of section 21a-92 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(6) "Device", except when used in subdivision (15) of this section and in **[**subsection (i)**]** subdivision (9) of section 21a-93, as amended by this act, subdivision (6) of subsection (a) of section 21a-102, subsection (c) of section 21a-106 and subsection (c) of section 21a-112, means instruments, apparatus and contrivances, including their components, parts and accessories, intended (A) 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;

Sec. 11. Section 21a-93 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

The following acts and the causing thereof shall be prohibited: **[**(a)**]** (1) The sale in intrastate commerce of any food, drug, device or cosmetic

that is adulterated or misbranded; **[**(b)**]** (2) the adulteration or misbranding of any food, drug, device or cosmetic in intrastate commerce; **[**(c)**]** (3) the receipt in intrastate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise; **[**(d)**]** (4) the introduction or delivery for introduction into intrastate commerce of **[**(1)**]** (A) any food in violation of section 21a-103 or **[**(2)**]** (B) any new drug in violation of section 21a-110; **[**(e)**]** (5) the dissemination within this state, in any manner or by any means or through any medium, of any false advertisement; **[**(f)**]** (6) the refusal to permit **[**(1)**]** (A) entry and the taking of a sample or specimen or the making of an investigation as authorized by section 21a-116, or **[**(2)**]** (B) access to or copying of any record as authorized by section 21a-117; **[**(g)**]** (7) the refusal to permit entry or inspection as authorized by section 21a-118; **[**(h)**]** (8) the giving of a guaranty or undertaking in intrastate commerce, referred to in subsection (c) of section 21a-95, as amended by this act, that is false; **[**(i)**]** (9) the forging, counterfeiting, simulating or falsely representing, or, without proper authority, using, any mark, stamp, tag, label or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act; **[**(j)**]** (10) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a food, drug, device or cosmetic, or the doing of any other act with respect to a food, drug, device or cosmetic, or the labeling or advertisement thereof, which results in a violation of this chapter; **[**(k)**]** (11) the using in interstate commerce, in the labeling or advertisement of any drug, of any representation or suggestion that an application with respect to such drug is effective under Section 355 of the federal act or under section 21a-110, or that such drug complies with the provisions of either such section; **[**(l)**]** (12) the violation of any provision of section 21a-108; **[**(m)**]** (13) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable state law to administer such drug who makes written request for information as to such drug, true and correct copies of all

printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the commissioner or under the federal act. Nothing in this **[**subsection**]** subdivision shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter unless specifically exempted under the federal act, as effective on April 26, 1974; **[**(n)**]** (14) the using by any person to his own advantage, or revealing, other than to the commissioner or his duly authorized agents or to the courts when relevant in any judicial proceeding under this chapter, of any information acquired under authority of this chapter concerning any method, process, substance or any other subject which as a trade secret is entitled to protection; **[**(o) (1)**]** (15) (A) placing or causing to be placed upon any drug or device or upon the container of any drug or device, with intent to defraud, the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof; or **[**(2)**]** (B) selling, dispensing, disposing of or causing to be sold, dispensed or disposed of or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof transported, received or held for transportation in commerce, with knowledge that the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof has been placed thereon in a manner prohibited by **[**subdivision (1) hereof**]** subparagraph (A) of this subdivision; or **[**(3)**]** (C) making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof upon any drug, device or container thereof; (16) failing to adhere to applicable provisions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time, concerning compounding or preparation of sterile drugs; or (17) failing to adhere to applicable provisions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations, as amended from time to time, concerning

compounding or preparation of nonsterile drugs.

Sec. 12. Subsection (c) of section 21a-95 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(c) No person shall be subject to the penalties of subsection (a) of this section for having violated **[**subsection (a)**]** subdivision (1) or **[**(c)**]** (3) of section 21a-93, as amended by this act, if he establishes a guaranty or undertaking signed by and containing the name and address of the person residing in this state from whom he received the article in good faith, to the effect that such article is not adulterated or misbranded within the meaning of this chapter. In such guaranty this chapter shall be designated by title.

Sec. 13. Subsection (b) of section 21a-97 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(b) Before any violation of this chapter, except for any violation of subdivision **[**(l)**]** (12) of section 21a-93, as amended by this act, is reported by the commissioner to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views to the commissioner, either orally or in writing, with regard to such contemplated proceeding.

Sec. 14. Section 21a-286 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) For the purposes of this section:

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

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

(3) "Host agency" means a community health organization,

emergency medical service provider, government agency, law enforcement agency or local or regional board of education;

**[**(1)**]** (4) "Opioid antagonist" **[**shall have**]** has the same meaning set forth in section 17a-714a**¿ [.]**

**[**(2)**]** (5) "Prescribing practitioner" **[**shall have**]** has the same meaning set forth in section 20-14c**¿ [.]**

**[**(3)**]** (6) "Pharmacist" **[**shall have**]** has the same meaning set forth in section 20-609a**¿ [.]**

(7) "Secure box" means a container that (A) is securely affixed in a public location, (B) can be accessed by individuals for public use, (C) is temperature controlled or stored in an environment with temperature controls, (D) is tamper-resistant, (E) is equipped with an alarm capable of detecting and transmitting a signal when accessed by individuals, and (F) is equipped with an alarm capable of alerting first responders when accessed by individuals, unless equipping the container with such an alarm is commercially impracticable;

(8) "Secured machine" means a device that (A) restricts access to individuals participating in a syringe services program by utilizing a designated access number, personalized magnetic strip card or any other technology to identify such individuals for the purpose of providing access, and (B) is registered with the department in a form and manner prescribed by the commissioner; and

(9) "Syringe services program" means a program that is (A) established or authorized pursuant to section 19a-124, and (B) approved by the department under section 21a-65.

(b) A prescribing practitioner**¿** or a pharmacist who is certified to prescribe **[**naloxone**]** an opioid antagonist pursuant to section 20-633c**¿** may enter into an agreement with a **[**law enforcement agency, emergency medical service provider, government agency, community health organization or local or regional board of education**]** host agency

related to the distribution and administration of an opioid antagonist for the reversal of an opioid overdose. The prescribing practitioner or pharmacist shall provide training to persons who will distribute or administer the opioid antagonist pursuant to the terms of the agreement. Persons other than the prescribing practitioner or pharmacist shall receive training in the distribution or administration of opioid antagonists prior to distributing or administering an opioid antagonist. The agreement shall address the storage, handling, labeling, recalls and recordkeeping of opioid antagonists by the **[**law enforcement agency, emergency medical service provider, government agency, community health organization or local or regional board of education which**]** host agency that is party to the agreement.

(c) (1) A prescribing practitioner, or a pharmacist who is certified to prescribe an opioid antagonist pursuant to section 20-633c, may enter into an agreement with a host agency to provide an intranasally or orally administered opioid antagonist, or permit a host agency to install on the host agency's premises a secure box containing an intranasally or orally administered opioid antagonist. The agreement shall address the environmental controls necessary to store such opioid antagonist, establish procedures for replenishment of such opioid antagonist, establish a process for monitoring the expiration dates of such opioid antagonist and disposing of any expired opioid antagonist, and require that signs be posted disclosing the presence of such opioid antagonist, and usage directions for such opioid antagonist, in the language or languages spoken in the community in which the secure box is installed. The secure box shall not contain an amount of the opioid antagonist that is greater than the amount necessary to serve the community in which such secure box is installed. If the host agency is unable to maintain the secure box, or the supplies necessary to maintain the secure box are unavailable, such host agency shall remove such secure box, and all signs required under this subdivision concerning such secure box, as soon as practicable but in no event later than five days after such host agency discovers that such host agency is unable to maintain such secure box or the supplies necessary to maintain such secure box.

(2) Nothing in subdivision (1) of this subsection shall be construed to prohibit placement of an opioid antagonist in a container that also includes an automated external defibrillator or any other product used to treat a medical emergency.

(d) A prescribing practitioner, or a pharmacist who is certified to prescribe an opioid antagonist pursuant to section 20-633c, may enter into an agreement with a syringe services program to permit the syringe services program to include an opioid antagonist in such syringe services program's secured machine. The agreement shall address the environmental controls necessary to store such opioid antagonist, establish procedures for replenishment of such opioid antagonist, establish a process for monitoring the expiration dates of such opioid antagonist and disposing of any expired opioid antagonist, and require that signs be posted disclosing the presence of such opioid antagonist, and usage directions for such opioid antagonist, in the language or languages spoken in the community in which such secured machine is installed.

**[**(c)**]** (e) A prescribing practitioner or pharmacist who enters into an agreement pursuant to subsection (b), (c) or (d) of this section shall not be liable for damages in a civil action or subject to administrative or criminal prosecution for the administration or dispensing of an opioid antagonist by **[**such law enforcement agency, emergency medical service provider, government agency, community health organization or local or regional board of education**]** the host agency who is a party to such agreement.

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

| This act shall take effect as follows and shall amend the following sections: | | |
|---|---|---|
| Section 1 | *January 1, 2024* | New section |
| Sec. 2 | *from passage* | New section |

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|---|---|---|
| Sec. 3 | *from passage* | New section |
| Sec. 4 | *from passage* | New section |
| Sec. 5 | *from passage* | 20-579 |
| Sec. 6 | *from passage* | 20-613(d) |
| Sec. 7 | *from passage* | 20-617a |
| Sec. 8 | *from passage* | 20-623 |
| Sec. 9 | *from passage* | 20-633b |
| Sec. 10 | *from passage* | 21a-92(6) |
| Sec. 11 | *from passage* | 21a-93 |
| Sec. 12 | *from passage* | 21a-95(c) |
| Sec. 13 | *from passage* | 21a-97(b) |
| Sec. 14 | *from passage* | 21a-286 |

***Statement of Purpose:***

To implement the Department of Consumer Protection's recommendations concerning prescription drug regulation.

***[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.]***