General Assembly **Substitute Bill No. 5225**

February Session, 2026

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AN ACT PROHIBITING CERTAIN LICENSEES AND REGISTRANTS FROM SELLING, DISPENSING, TRANSFERRING OR DELIVERING ANY DRUG OR DEVICE TO EXECUTE A COURT-IMPOSED SENTENCE OF DEATH.

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

Section 1. Section 21a-70 of the 2026 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(a) As used in this section: **[**(1) "Drugs", "devices" and "cosmetics" have the same meanings as defined in section 21a-92, "wholesaler" or "distributor" means a person, including, but not limited to, a medical device and oxygen provider, a third-party logistics provider, a virtual manufacturer or a virtual wholesale distributor, as such terms are defined in section 20-571, whether within or without the boundaries of the state of Connecticut, who supplies drugs, devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in section 20-571, pharmacies, federal, state or municipal agencies, clinics or any other person as permitted under subsection (h) of this section, except that: (A) A retail pharmacy or a pharmacy within a licensed hospital that supplies to another such pharmacy a quantity of a noncontrolled drug or a schedule II, III, IV or

V controlled substance normally stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, (B) a pharmacy within a licensed hospital that supplies drugs to another hospital or an authorized practitioner for research purposes, (C) a retail pharmacy that supplies a limited quantity of a noncontrolled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home, of a rest home with nursing supervision, of a hospice inpatient facility licensed pursuant to section 19a-491 or of a state correctional institution, and (D) a pharmacy within a licensed hospital that contains another hospital wholly within 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, 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 the commissioner's designee.**]**

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

(2) "Cosmetic" has the same meaning as provided in section 21a-92;

(3) "Device" has the same meaning as provided in section 21a-92;

(4) "Distributor" or "wholesaler" (A) means a person, including, but not limited to, a medical device and oxygen provider, a third-party logistics provider, a virtual manufacturer or a virtual wholesale distributor, as such terms are defined in section 20-571, whether within or without the boundaries of the state of Connecticut, who supplies drugs, devices or cosmetics prepared, produced or packaged by manufacturers to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in section 20-571, pharmacies, federal, state or municipal agencies, clinics or any other person as permitted under subsection (i) of this section, and (B) does not include (i) 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, (ii) a pharmacy within a licensed hospital that supplies drugs to another hospital or an authorized practitioner for research purposes, (iii) 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 (I) a chronic and convalescent nursing home, (II) a rest home with nursing supervision, (III) a hospice inpatient facility licensed pursuant to section 19a-491, or (IV) a correctional institution unless the correctional institution has actual knowledge that the noncontrolled drug or controlled substance will be used to execute a sentence of death imposed by a court, and (iv) a pharmacy within a licensed hospital that contains another hospital wholly within 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;

(5) "Drug" has the same meaning as provided in section 21a-92;

(6) "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; and

(7) "Person" means any individual, partnership, corporation, limited liability company, association or other legal entity.

(b) No **[**wholesaler or manufacturer**]** person shall operate as **[**such**]** a manufacturer or wholesaler until **[**he**]** such person has received a certificate of registration issued by the commissioner, which certificate shall be renewed annually, provided no such certificate shall be required of a manufacturer, except a sterile compounding pharmacy, as defined in subsection (a) of section 20-633b, whose principal place of business is located outside the state, who is registered with the federal Food and Drug Administration or any successor agency and who files a copy of such registration with the commissioner. A fee of one hundred ninety dollars shall be charged for each wholesaler's certificate and renewal thereof. A separate certificate and corresponding fee is required for each location existing in this state and for each location existing

outside of this state that distributes products into this state. The fee for a manufacturer's certificate and renewal thereof shall be two hundred eighty-five dollars for manufacturers employing not more than five licensed pharmacists or qualified chemists or both; three hundred seventy-five dollars for manufacturers employing not more than ten licensed pharmacists or qualified chemists or both; and nine hundred forty dollars for manufacturers employing more than ten licensed pharmacists or qualified chemists or both. No such certificate shall be issued to a manufacturer unless such drugs, devices or cosmetics are manufactured or compounded under the direct supervision of a licensed pharmacist or a qualified chemist. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant is equipped as to facilities and apparatus to properly carry on the business described in his application and that the applicant conforms to chapter 418 and regulations adopted thereunder.

(c) The commissioner shall have the right to deny a certificate of registration if **[**he**]** the commissioner determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider, at a minimum, the following factors:

(1) Any convictions or regulatory actions involving the applicant under any federal, state or local law relating to drug samples, wholesale or retail drug distribution, or distribution or possession of drugs including controlled substances;

(2) Any felony convictions of the applicant under federal, state or local laws;

(3) The applicant's past experience in the manufacture or distribution of drugs;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension, revocation or other sanction by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs;

(6) Compliance with licensing or registration requirements under previously granted licenses or registrations;

(7) Compliance with requirements to maintain or make available to the commissioner or to federal, state or local law enforcement officials those records required by any federal or state statute or regulation;

(8) Failure to provide adequate control against the diversion, theft and loss of drugs;

(9) Provision of required security for legend drugs and, in the case of controlled substances, compliance with security requirements for wholesalers set forth in regulations adopted under chapter 420b; **[**and**]**

(10) Manufacturing, selling or dispensing any drug or device with actual knowledge that the person purchasing or receiving such drug or device directly from the applicant intends to use such drug or device to execute a sentence of death imposed by a court; and

[(10)**]** (11) Compliance with all regulations adopted to enforce the provisions of this section.

(d) The commissioner may suspend, revoke or refuse to renew a registration, or may issue a letter of reprimand or place a registrant on probationary status, for sufficient cause. Any of the following shall be sufficient cause for such action:

(1) The furnishing of false or fraudulent information in any application or other document filed with the commissioner;

(2) Any criminal conviction of the registrant under any federal or state statute concerning drugs;

(3) The suspension, revocation or other restriction or penalty issued

against a license or registration related to drugs;

(4) Failure to provide adequate control against the diversion, theft and loss of drugs; **[**or**]**

(5) Manufacturing, selling or dispensing any drug or device with actual knowledge that the person purchasing or receiving such drug or device directly from the registrant intends to use such drug or device to execute a sentence of death imposed by a court; or

[(5)**]** (6) A violation of any provision of any federal or state statute or regulation concerning drugs.

(e) The commissioner shall not issue or renew a certificate of registration unless the applicant or registrant seeking such certificate or renewal submits to the commissioner, in a form and manner prescribed by the commissioner, a signed, written statement attesting that such applicant or registrant shall not manufacture, sell or dispense any drug or device with actual knowledge that the person purchasing or receiving such drug or device directly from such applicant or registrant intends to use such drug or device to execute a sentence of death imposed by a court.

[(e)**]** (f) **[**Wholesalers and manufacturers**]** Manufacturers and wholesalers shall operate in compliance with applicable federal, state and local statutes, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing.

[(f) Wholesalers and manufacturers**]** (g) Manufacturers and wholesalers shall permit the commissioner, or his authorized representatives, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner.

[(g)**]** (h) Before denying, suspending, revoking or refusing to renew a registration, or before issuing a letter of reprimand or placing a

registrant on probationary status, the commissioner shall afford the applicant or registrant an opportunity for a hearing in accordance with the provisions of chapter 54. Notice of such hearing may be given by certified mail. The commissioner may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing.

[(h)**]** (i) No **[**wholesaler or**]** manufacturer or wholesaler shall sell any drugs except to the state or any political subdivision thereof, to another manufacturer or wholesaler, to any hospital recognized by the state as a general or specialty hospital, to any institution having a full-time pharmacist who is actively engaged in the practice of pharmacy in such institution not less than thirty-five hours a week, to a chronic and convalescent nursing home having a pharmacist actively engaged in the practice of pharmacy based upon the ratio of one-tenth of one hour per patient per week but not less than twelve hours per week, to a practicing physician, podiatrist, dentist, optometrist or veterinarian, to a licensed pharmacy or a store to which a permit to sell nonlegend drugs has been issued as provided in section 20-624 or to an authorized entity, as defined in section 19a-909, as amended by this act, that has established a medical protocol with a prescribing practitioner pursuant to section 19a-909, as amended by this act, provided drugs sold to an authorized entity shall be limited to epinephrine, as defined in section 19a-909, as amended by this act. **[**The commissioner may adopt such regulations as are necessary to administer and enforce the provisions of this section.**]**

[(i)**]** (j) (1) Each registered manufacturer or wholesaler of drugs shall operate a system to identify suspicious orders of controlled substances and shall immediately inform the Director of the Drug Control Division of suspicious orders. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. Each registered manufacturer or wholesaler of drugs shall also send the Drug Control Division a copy of any suspicious orders submitted to the federal Drug Enforcement Administration pursuant to 21 CFR 1301.74.

(2) Each registered manufacturer or wholesaler of drugs that, based on concerns of potential diversion, ceases or declines distribution of any schedule II, III, IV or V controlled substance to a pharmacy, as defined in section 20-594, or to a practitioner, as defined in section 21a-316, in the state of Connecticut shall report the name of the pharmacy or practitioner, location of the pharmacy or practitioner and the reasons for ceasing or declining distribution of such controlled substance in writing to the Director of the Drug Control Division, or to an electronic system designated by the Drug Control Division, not later than five business days after ceasing or declining distribution of such controlled substance.

(k) The commissioner may adopt regulations, in accordance with the provisions of chapter 54, to administer and enforce the provisions of this section.

[(j)**]** (l) Any person who violates any provision of this section shall be fined not more than five hundred dollars or imprisoned not more than six months, or both.

Sec. 2. Subdivision (4) of subsection (a) of section 19a-909 of the 2026 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(4) "Authorized entity" means any for-profit or nonprofit entity or organization that employs at least one person with training. "Authorized entity" does not include the state or any political subdivision thereof authorized to purchase epinephrine pursuant to subsection **[**(h)**]** (i) of section 21a-70, as amended by this act, a local or regional board of education required to maintain epinephrine pursuant to subdivision (2) of subsection (d) of section 10-212a or a licensed or a certified ambulance service required to be equipped with epinephrine cartridge injectors pursuant to subsection (b) of section 19a-197a.

Sec. 3. Section 21a-248 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective June 15, 2026*):

(a) (1) A licensed manufacturer or wholesaler may sell and dispense

controlled drugs to any of the following-named persons, but in the case of schedule II drugs only on an official written order or electronically through the Drug Enforcement Agency's Controlled Substance Ordering System: **[**(1)**]** (A) To a manufacturer, wholesaler or pharmacist; **[**(2)**]** (B) to a physician, dentist or veterinarian; **[**(3)**]** (C) to a person in charge of a hospital, incorporated college or scientific institution, but only for use by or in that hospital, incorporated college or scientific institution for medical or scientific purposes; **[**(4)**]** (D) to a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes; and **[**(5)**]** (E) to any registrant as defined in section 21a-240.

[(b)**]** (2) A licensed manufacturer or wholesaler may sell controlled drugs only to registrants when permitted under federal and state laws and regulations.

(3) Notwithstanding the provisions of subdivisions (1) and (2) of this subsection, no licensed manufacturer or wholesaler shall sell or dispense a controlled drug directly to another person with actual knowledge that such other person intends to use the controlled drug to execute a sentence of death imposed by a court.

[(c)**]** (b) An official order for any schedule I or II drug shall be signed by the person giving such order or by such person's authorized agent and such order shall be presented to the person who sells or dispenses the drug or drugs named therein as provided by federal law. If such order is accepted by such person, each party to the transaction shall preserve such party's copy of such order for a period of three years in such a way so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter.

[(d)**]** (c) The manufacturer or wholesaler shall keep records of all sales and dispensing of controlled drugs and shall comply fully with applicable provisions of the federal controlled drug laws and the federal food and drug laws, and the state food, drug and cosmetic laws in such sale or dispensing of controlled drugs.

[(e)**]** (d) Possession or control of controlled drugs obtained as authorized by this section shall be lawful only if obtained in the regular course of the business, occupation, profession, employment or duty of the possessor.

[(f)**]** (e) (1) A person in charge of a hospital, incorporated college or scientific institution, or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled drugs under the provisions of this section or otherwise, shall not administer, or dispense, or otherwise use such drugs within this state, except within the scope of such person's, master's or officer's employment or official duty, and then only for scientific or medicinal purposes or for the purposes of research or analysis and subject to the provisions of this chapter.

(2) The provisions of subdivision (1) of this subsection shall not be construed to authorize any person to obtain, administer, dispense or otherwise use a controlled drug to execute a sentence of death imposed by a court.

Sec. 4. Subsection (a) of section 20-579 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(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 one thousand dollars per violation of any provision of this chapter or take other action permitted in subdivision (7) 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 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 accepted, for return to general inventory or regular stock, any drug sold or delivered to a patient, unless accepting such drug for return to general inventory or regular stock is otherwise permitted or required by law; (12) has split

fees for professional services, including a discount or rebate, with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility; (13) 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; (14) has performed or been a party to a fraudulent or deceitful practice or transaction; (15) 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; (16) has performed incompetent or negligent work; (17) while holding such license, temporary permit or registration, has dispensed or distributed a drug or device directly to another person with actual knowledge that such other person intended to use such drug or device to execute a sentence of death imposed by a court; (18) 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; **[**(18)**]** (19) 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; **[**(19)**]** (20) has failed to maintain the entire pharmacy premises, its components and contents in a clean, orderly and sanitary condition; **[**(20)**]** (21) 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 **[**(21)**]** (22) has failed to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations, as amended from time to time.

Sec. 5. Subsection (c) of section 20-593 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(c) The commission shall not grant a renewal license to an applicant

who (1) has not held a license authorized by the commission within five years of the date of application unless the applicant has passed an examination satisfactory to the commission and has paid the fee required in section 20-601, or (2) within the calendar year preceding the date of application, dispensed or distributed a drug or device directly to another person with actual knowledge that such other person intended to use the drug or device to execute a sentence of death imposed by a court.

Sec. 6. Subsection (d) of section 20-613 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(d) Nothing in sections 20-570 to 20-630, inclusive, shall be construed to (1) 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, or (2) authorize a person to dispense or transfer a drug or device directly to another person with actual knowledge that such other person intends to use the drug or device to execute a sentence of death imposed by a court.

Sec. 7. Section 20-613a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(a) For the purposes of this section, "electronic questionnaire" means any form in an electronic format that may require personal, financial or medical information from a consumer or patient.

(b) In the absence of a documented patient evaluation that includes a physical examination, any request for a controlled substance issued solely on the results of answers to an electronic questionnaire shall be considered to be issued outside the context of a valid practitioner-patient relationship and not be a valid prescription.

(c) Any request for a controlled substance to execute a sentence of

death imposed by a court shall be considered to be issued outside the context of a valid practitioner-patient relationship and not be a valid prescription.

(d) The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, concerning **[**such**]** requests for controlled substances. **[**For the purposes of this section, "electronic questionnaire" means any form in an electronic format that may require personal, financial or medical information from a consumer or patient.**]**

Sec. 8. Subsection (a) of section 20-629 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2026*):

(a) The commission may deny, revoke or suspend any certificate of registration as a nonresident pharmacy for:

(1) Failure to comply with any requirement of this chapter or chapter 420b;

(2) Failure to comply with any federal or state statute or regulation concerning drugs or the practice of pharmacy;

(3) Delivering in any manner into this state legend drugs or legend devices that are adulterated or misbranded in violation of chapter 418; **[**or**]**

(4) Delivering a legend drug or legend device directly to another person with actual knowledge that such other person intends to use the legend drug or legend device to execute a sentence of death imposed by a court; or

[(4)**]** (5) Any disciplinary action taken against the nonresident pharmacy by any state or federal agency.

Sec. 9. Subsections (d) to (n), inclusive, of section 20-633b of the 2026 supplement to the general statutes are repealed and the following is substituted in lieu thereof (*Effective June 15, 2026*):

(d) (1) A sterile compounding pharmacy may only provide patient-specific sterile pharmaceuticals to patients, to 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.

(3) Nothing in subdivision (1) or (2) of this subsection shall be construed to authorize a sterile compounding pharmacy to provide a sterile pharmaceutical directly to another person with actual knowledge that such other person intends to use the sterile pharmaceutical to execute a sentence of death imposed by a court.

(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 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.

(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.

(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.

(h) Each sterile compounding pharmacy shall prepare and maintain a policy and procedure manual. The policy and procedure manual shall

comply with the USP chapters.

(i) Each sterile compounding pharmacy shall report to the Department of Consumer Protection any administrative or legal action commenced against 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.

(j) Notwithstanding the provisions of subdivision (2) of subsection (b) of this section, a sterile compounding pharmacy that is a nonresident pharmacy shall submit to the Department of Consumer Protection an inspection report from a government agency with regulatory oversight over such nonresident pharmacy or from a third-party entity with expertise in sterile compounding. Such report shall demonstrate that such nonresident pharmacy is in compliance with the standards required in the most recent United States Pharmacopeia, Chapter 797, as amended from time to time. Such nonresident pharmacy shall submit to the department a copy of the most recent inspection report with such nonresident pharmacy's initial nonresident pharmacy application, which inspection report shall be dated by the inspector and evidence that the inspection was performed during the six-month period immediately preceding the submission date of such initial application. Not later than June thirtieth of each even-numbered calendar year following such initial application, such nonresident pharmacy shall submit to the department a new inspection report demonstrating that such nonresident pharmacy remains in compliance with the standards required in the most recent United States Pharmacopeia, Chapter 797, as amended from time to time, which inspection report shall be dated by the inspector and indicate that the inspection was performed not earlier than January first of such even-numbered calendar year. Notwithstanding the provisions of this subsection, a sterile compounding pharmacy that is a nonresident pharmacy shall not be required to submit more than one inspection report during the calendar year after the nonresident pharmacy is issued an initial registration.

(k) A practitioner, as specified in subdivision (1) of subsection (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.

(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 that provides sterile pharmaceuticals shall notify the department of such pharmacy's designated pharmacist.

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

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

(m) Notwithstanding the provisions of this section, (1) the addition of a flavoring agent in accordance with subsections (a) and (b) of section 20-617a 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, and (2) no sterile compounding pharmacy shall sell or transfer a sterile pharmaceutical directly to another person with actual knowledge that such other person intends to use the sterile pharmaceutical to execute a sentence of death imposed by

a court.

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

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2026*	21a-70
Sec. 2	*October 1, 2026*	19a-909(a)(4)
Sec. 3	*June 15, 2026*	21a-248
Sec. 4	*October 1, 2026*	20-579(a)
Sec. 5	*October 1, 2026*	20-593(c)
Sec. 6	*October 1, 2026*	20-613(d)
Sec. 7	*October 1, 2026*	20-613a
Sec. 8	*October 1, 2026*	20-629(a)
Sec. 9	*June 15, 2026*	20-633b(d) to (n)

Statement of Legislative Commissioners:
In Section 1(f) and (g), "Wholesalers and manufacturers" was changed to "**[**Wholesalers and manufacturers**]** Manufacturers and wholesalers" for consistency; and in Section 6(d), "be construed to" was added for consistency with standard drafting conventions.

GL *Joint Favorable Subst.*