Senate

General Assembly

File No. 361

January Session, 2021

Substitute Senate Bill No. 895

Senate, April 8, 2021

The Committee on General Law reported through SEN. MARONEY of the 14th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING CHANGES TO VARIOUS PHARMACY STATUTES.

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

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 Section 20-571 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

As used in **[**sections 20-570 to 20-630, inclusive**]** this chapter, unless the context otherwise requires:

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

(2) "Automated prescription dispensing machine" means a device and associated software operated by a pharmacy or a pharmacy that is registered as a nonresident pharmacy pursuant to section 20-627, in a nursing home or skilled nursing facility licensed pursuant to sections 19a-490 and 19a-491, that packages and labels patient-specific

medication or multiple medications for the purposes of administration by a registered nurse or a licensed practical nurse based on a prescription that has completed final verification by a licensed pharmacist;

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

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

[(4)**]** (5) "Commissioner" means the Commissioner of Consumer Protection;

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

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

[(7)**]** (8) "Device" means instruments, apparatuses 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, but does not mean contact lenses;

[(8)**]** (9) "Department" means the Department of Consumer Protection;

(10) "Deprescribing" means the systematic process of identifying and discontinuing drugs in instances in which existing or potential harms outweigh existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values and preferences;

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

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

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

[(12)**]** (14) "Institutional pharmacy" means that area within a care-giving institution or within a correctional or juvenile training institution, commonly known as the pharmacy, that is under the direct

charge of a pharmacist and in which drugs are stored and dispensed;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[(30)**]** (34) "Virtual wholesale distributor" means a person who facilitates or brokers the transfer of drugs, devices or cosmetics without taking physical possession of the drugs, devices or cosmetics.

Sec. 2. (NEW) (*Effective from passage*) (a) As used in this section, (1) "long-term care pharmacy" (A) means a pharmacy licensed under section 20-594 of the general statutes that stores and dispenses legend drugs and legend devices to patients or residents of licensed nursing homes, rest homes, residential care homes or other supervised residential facilities and from which related pharmaceutical care

services are provided, and (B) includes pharmacies located both inside and outside of such facilities but does not include those that are part of a licensed hospital, (2) "nursing home" has the same meaning as provided in section 19a-490 of the general statutes, and (3) "automated prescription dispensing machine" has the same meaning as provided in section 20-571 of the general statutes, as amended by this act. A long-term care pharmacy may operate an automated prescription dispensing machine in a nursing home in accordance with a protocol approved in writing by the Department of Consumer Protection, until such time as regulations are adopted pursuant to subsection (b) of this section. The annual fee to operate an automated prescription dispensing machine shall be one hundred dollars per machine.

(b) The Commissioner of Consumer Protection shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of subsection (a) of this section. After the adoption of such regulations, the operation of an automated prescription dispensing machine, as described in subsection (a) of this section, shall be in accordance with such regulations.

Sec. 3. Section 21a-65 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) A licensed manufacturer or licensed wholesaler may sell hypodermic needles and syringes only to the following: (1) To a licensed manufacturer, licensed wholesaler or licensed pharmacy; (2) to a physician, dentist, veterinarian, embalmer, podiatrist or scientific investigator licensed to practice in this state; (3) to a person in charge of a care-giving institution, as defined in subdivision **[**(2)**]** (3) of section 20-571, as amended by this act, incorporated college or scientific institution, but only for use by or in such care-giving institution, college or institution for medical or scientific purposes; (4) to a person in charge of a licensed or registered laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to a farmer but only for use on the farmer's own animals or poultry; (6) to a business authorized in accordance with the regulations adopted under section 21a-66 to

purchase hypodermic needles and syringes but only for legitimate industrial or medical use within that business; and (7) to a syringe services program established pursuant to section 19a-124.

(b) Except as provided in subsection (a) of this section, no licensed manufacturer, licensed wholesaler or licensed pharmacist shall sell and no person shall buy a hypodermic needle or syringe except upon a prescription of a prescribing practitioner, as defined in subdivision **[**(24)**]** (28) of section 20-571, as amended by this act, in a quantity greater than ten. Any such prescription shall be retained on file by the seller for a period of not less than three years and shall be accessible to any public officer engaged in the enforcement of this section. Such a prescription shall be valid for one year from the date thereof and purchases and sales may be made thereunder during such period, provided the seller shall confirm the continued need for such sales with such practitioner at least every six months if sales continue to be made thereunder. Hypodermic needles and syringes in a quantity of ten or less without a prescription may be provided or sold at retail only by the following: (1) By a pharmacy licensed in accordance with section 20-594 and in such pharmacy only by a licensed pharmacist or under **[**his**]** the pharmacist's direct supervision; (2) by a syringe **[**services**]** service program established pursuant to section 19a-124; and (3) by a health care facility or a licensed health care practitioner for use by their own patients.

(c) A registered syringe service program established pursuant to section 19a-124 may apply to the Department of Consumer Protection for approval to provide access to not more than ten hypodermic needles and syringes per transaction to program participants authorized by said department, through a secured machine with the use of a patient-specific access number, personalized magnetic strip card or any technology that identifies an individual for the purpose of providing access to hypodermic needles and syringes. The secured machine shall prevent unauthorized access and be immobile. Any products provided by the secured machine shall provide information on access to treatment services to assist individuals obtaining products from the secured machine. The machine shall only be placed in an area where contents

can be stored in accordance with the manufacturer's recommendation, unless the secured machine can provide adequate environmental controls independent of the external environment. A locked syringe disposal container to accept hypodermic needles and syringes that have already been used shall be available as part of the secured machine or in the area around the secured machine. Only authorized personnel of such program may collect the used syringes for proper disposal.

[(c) At**]** (d) Except as provided in subsection (c) of this section, at all locations where hypodermic needles and syringes are kept they shall be stored in a manner so as to be available only to authorized personnel and not be openly available to customers or patients. All used, disposable hypodermic needles and used, disposable syringes shall be destroyed. Destruction shall be conducted in a manner which renders such needles and syringes nonrecoverable. Used needles and syringes which have been discarded and are awaiting destruction shall be securely safeguarded or rendered nonreusable.

[(d)**]** (e) Any person who violates any provision of this section shall be fined not more than five hundred dollars or imprisoned not more than one year or both.

Sec. 4. Section 20-631 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) Except as provided in section 20-631b, one or more pharmacists licensed under this chapter who are determined competent in accordance with regulations adopted pursuant to subsection (d) of this section may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 or advanced practice registered nurses licensed under chapter 378 to manage the drug therapy of individual patients. In order to enter into a written protocol-based collaborative drug therapy management agreement, such physician or advanced practice registered nurse shall have established a provider-patient relationship with the patient who will receive collaborative drug therapy. Each patient's collaborative drug therapy management shall be governed by a written

protocol [specific to that patient] which may include guideline-directed management established by the treating physician or advanced practice registered nurse in consultation with the pharmacist. For purposes of this subsection, a "provider-patient relationship" is a relationship based on (1) the patient making a medical complaint, (2) the patient providing a medical history, (3) the patient receiving a physical examination, and (4) a logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient.

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify, [or] continue, discontinue or deprescribe a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. Such agreement may specifically address issues that may arise during a medication reconciliation and concerns related to polypharmacy that enable an authorized pharmacist to implement, modify, continue, discontinue or deprescribe drug therapy. In instances where drug therapy is discontinued or deprescribed, the pharmacist shall notify the treating physician or advanced practice registered nurse of such discontinuance or deprescribing no later than twenty-four hours from the time of such discontinuance or deprescribing. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified, [or] continued, discontinued or deprescribed, (3) the conditions and events upon which the pharmacist is required to notify the physician or advanced practice registered nurse, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report [at least every] any encounters within the scope of the collaborative drug therapy management agreement within thirty days to the physician or

advanced practice registered nurse regarding the patient's drug therapy management or document such information within a shared medical record. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) A pharmacist shall be responsible for demonstrating, in accordance with regulations adopted pursuant to subsection (d) of this section, the competence necessary for participation in each drug therapy management agreement into which such pharmacist enters.

(d) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, shall adopt regulations, in accordance with chapter 54, concerning competency requirements for participation in a written protocol-based collaborative drug therapy management agreement described in subsection (a) of this section, the minimum content of the collaborative drug therapy management agreement and the written protocol and such other matters said commissioners deem necessary to carry out the purpose of this section.

Sec. 5. Subsection (j) of section 21a-254 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(j) (1) The commissioner shall, within available appropriations, establish an electronic prescription drug monitoring program to collect, by electronic means, prescription information for schedules II, III, IV and V controlled substances that are dispensed by pharmacies, nonresident pharmacies, as defined in section 20-627, outpatient pharmacies in hospitals or institutions or by any other dispenser, including, but not limited to, the federal Substance Abuse and Mental Health Services Administration certified substance use disorder clinics licensed under section 19a-495 in accordance with 42 CFR 2. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances and shall not infringe on the

legitimate prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.

(2) The commissioner may identify other products or substances to be included in the electronic prescription drug monitoring program established pursuant to subdivision (1) of this subsection.

(3) Prior to July 1, 2016, each pharmacy, nonresident pharmacy, as defined in section 20-627, outpatient pharmacy in a hospital or institution and dispenser shall report to the commissioner, at least weekly, by electronic means or, if a pharmacy or outpatient pharmacy does not maintain records electronically, in a format approved by the commissioner, the following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy: (A) Dispenser identification number; (B) the date the prescription for the controlled substance was filled; (C) the prescription number; (D) whether the prescription for the controlled substance is new or a refill; (E) the national drug code number for the drug dispensed; (F) the amount of the controlled substance dispensed and the number of days' supply of the controlled substance; (G) a patient identification number; (H) the patient's first name, last name and street address, including postal code; (I) the date of birth of the patient; (J) the date the prescription for the controlled substance was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement Agency's identification number; and (K) the type of payment.

(4) (A) Except as provided in this subdivision, on and after July 1, 2016, each pharmacy, nonresident pharmacy, as defined in section 20-627, outpatient pharmacy in a hospital or institution, and dispenser shall report to the commissioner by electronic means, in a format approved by the commissioner, the following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy immediately upon, but in no event later than the next business day after, dispensing such prescriptions: (i) Dispenser identification number; (ii) the date the prescription for the controlled

substance was filled; (iii) the prescription number; (iv) whether the prescription for the controlled substance is new or a refill; (v) the national drug code number for the drug dispensed; (vi) the amount of the controlled substance dispensed and the number of days' supply of the controlled substance; (vii) a patient identification number; (viii) the patient's first name, last name and street address, including postal code; (ix) the date of birth of the patient; (x) the date the prescription for the controlled substance was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement Agency's identification number; and (xi) the type of payment.

(B) If the electronic prescription drug monitoring program is not operational, such pharmacy or dispenser shall report the information described in this subdivision not later than the next business day after regaining access to such program. For purposes of this subdivision, "business day" means any day during which the pharmacy is open to the public.

(C) Each veterinarian, licensed pursuant to chapter 384, who dispenses a controlled substance prescription shall report to the commissioner the information described in subparagraph (A) of this subdivision, at least weekly, by electronic means or, if the veterinarian does not maintain records electronically, in a format approved by the commissioner.

(5) The commissioner may contract with a vendor for purposes of electronically collecting such controlled substance prescription information. The commissioner and any such vendor shall maintain the information in accordance with the provisions of chapter 400j.

(6) The commissioner and any such vendor shall not disclose controlled substance prescription information reported pursuant to subdivisions (3) and (4) of this subsection, except as authorized pursuant to the provisions of sections 21a-240 to 21a-283, inclusive. Any person who knowingly violates any provision of this subdivision or subdivision (5) of this subsection shall be guilty of a class D felony.

(7) The commissioner shall provide, upon request, controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to the following: (A) The prescribing practitioner or such practitioner's authorized agent, who is treating or has treated a specific patient, provided the information is obtained for purposes related to the treatment of the patient, including the monitoring of controlled substances obtained by the patient; (B) the prescribing practitioner with whom a patient has made contact for the purpose of seeking medical treatment or such practitioner's authorized agent, provided the request is accompanied by a written consent, signed by the prospective patient, for the release of controlled substance prescription information; or (C) the pharmacist who is dispensing controlled substances for a patient, or such pharmacist's authorized pharmacy technician, provided the information is obtained for purposes related to the scope of the pharmacist's practice and management of the patient's drug therapy, including the monitoring of controlled substances obtained by the patient. The prescribing practitioner, such practitioner's authorized agent, the pharmacist or such pharmacist's authorized pharmacy technician shall submit a written and signed request to the commissioner for controlled substance prescription information. Such prescribing practitioner, pharmacist or pharmacist's authorized pharmacy technician shall not disclose any such request except as authorized pursuant to sections 20-570 to 20-630, inclusive, or sections 21a-240 to 21a-283, inclusive.

(8) No person or employer shall prohibit, discourage or impede a prescribing practitioner, pharmacist or pharmacist's authorized pharmacy technician from requesting controlled substance prescription information pursuant to this subsection.

(9) Prior to prescribing greater than a seventy-two-hour supply of any controlled substance to any patient, the prescribing practitioner or such practitioner's authorized agent shall review the patient's records in the electronic prescription drug monitoring program established pursuant to this subsection. Whenever a prescribing practitioner prescribes a controlled substance, other than a schedule V nonnarcotic controlled

substance, for the continuous or prolonged treatment of any patient, such prescriber, or such prescriber's authorized agent, shall review, not less than once every ninety days, the patient's records in such prescription drug monitoring program. Whenever a prescribing practitioner prescribes a schedule V nonnarcotic controlled substance, for the continuous or prolonged treatment of any patient, such prescribing practitioner, or such prescribing practitioner's authorized agent, shall review, not less than annually, the patient's records in such prescription drug monitoring program. If such electronic prescription drug monitoring program is not operational, such prescribing practitioner may prescribe greater than a seventy-two-hour supply of a controlled substance to a patient during the time of such program's inoperability, provided such prescribing practitioner or such authorized agent reviews the records of such patient in such program not more than twenty-four hours after regaining access to such program.

(10) (A) A prescribing practitioner may designate an authorized agent to review the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the prescribing practitioner. The prescribing practitioner shall ensure that any authorized agent's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. The prescribing practitioner and any authorized agent shall be subject to the provisions of 45 CFR 164.308, as amended from time to time, concerning administrative safeguards for the protection of electronic protected health information. A prescribing practitioner may be subject to disciplinary action for acts of the authorized agent as provided in section 21a-322.

(B) Notwithstanding the provisions of subparagraph (A) of this subdivision, a prescribing practitioner who is employed by or provides professional services to a hospital shall, prior to designating an authorized agent to review the electronic prescription drug monitoring program and patient controlled substance prescription information on

behalf of the prescribing practitioner, (i) submit a request to designate one or more authorized agents for such purposes and a written protocol for oversight of the authorized agent or agents to the commissioner, in the form and manner prescribed by the commissioner, and (ii) receive the commissioner's approval to designate such authorized agent or agents and of such written protocol. Such written protocol shall designate either the hospital's medical director, a hospital department head, who is a prescribing practitioner, or another prescribing practitioner as the person responsible for ensuring that the authorized agent's or agents' access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. A hospital medical director, a hospital department head, who is a prescribing practitioner, or another prescribing practitioner designated as the person responsible for overseeing an authorized agent's or agents' access to such program and information in the written protocol approved by the commissioner may be subject to disciplinary action for acts of the authorized agent or agents as provided in section 21a-322. The commissioner may inspect hospital records to determine compliance with written protocols approved in accordance with this section.

(C) A pharmacist may designate a pharmacy technician to access the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the pharmacist only for the purposes of facilitating the pharmacist's review of such patient information. The pharmacist shall ensure that any such pharmacy technician's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. The pharmacist and any authorized pharmacy technician shall be subject to the provisions of 45 CFR 164.308, as amended from time to time, concerning administrative safeguards for the protection of electronic protected health information. A pharmacist may be subject to disciplinary action

for acts of the authorized pharmacy technician.

(D) Prior to designating a pharmacy technician to access the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the pharmacist, the supervising pharmacist shall provide training for the authorized pharmacy technicians. Such training shall designate a pharmacist as the person responsible for ensuring that the authorized pharmacy technician's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. A pharmacist designated as the person responsible for overseeing the pharmacy technician's access to such program may be subject to disciplinary action for acts of the authorized pharmacy technician. The commissioner may inspect records to document pharmacy technician training, that pharmacy technicians have access to the program and that patient controlled substance prescription information has been limited in accordance with the provisions of this section.

(11) The commissioner shall adopt regulations, in accordance with chapter 54, concerning the reporting, evaluation, management and storage of electronic controlled substance prescription information.

(12) The provisions of this section shall not apply to (A) samples of controlled substances dispensed by a physician to a patient, or (B) any controlled substances dispensed to hospital inpatients.

(13) The provisions of this section shall not apply to any institutional pharmacy or pharmacist's drug room operated by a facility, licensed under section 19a-495 and regulations adopted pursuant to said section 19a-495, that dispenses or administers directly to a patient an opioid agonist for treatment of a substance use disorder, unless the patient has signed a consent to disclose the patient's records to a prescription drug monitoring program that is compliant with 42 CFR 2 Subpart B. Each signed consent form shall be made available for review by the commissioner upon request. If consent is withdrawn by the patient, the

institutional pharmacy or pharmacist's drug room operated by a facility shall immediately discontinue disclosing information about the specific patient who withdrew consent.

(14) The commissioner may provide controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to other state agencies, pursuant to an agreement between the commissioner and the head of such agency, provided the information is obtained for a study of disease prevention and control related to opioid abuse or the study of morbidity and mortality caused by overdoses of controlled substances. The provision of such information shall be in accordance with all applicable state and federal confidentiality requirements.

(15) Nothing in this section shall prohibit a prescribing practitioner or such prescribing practitioner's authorized agent from disclosing controlled substance prescription information submitted pursuant to subdivisions (3) and (4) of this subsection to the Department of Social Services for the purposes of administering any of said department's medical assistance programs.

(16) Each pharmacy, nonresident pharmacy, as defined in section 20-627, outpatient pharmacy in a hospital or institution, and dispenser shall report to the commissioner, at least daily, by electronic means or, if a pharmacy or outpatient pharmacy does not maintain records electronically, in a format approved by the commissioner information for all insulin drugs, glucagon drugs, diabetes devices and diabetic ketoacidosis devices prescribed and dispensed by such pharmacy or outpatient pharmacy, except such reporting requirement shall not apply to any veterinarian, licensed under chapter 384, who dispenses insulin drugs, glucagon drugs, diabetes devices and diabetic ketoacidosis devices for animal patients. Such pharmacy or outpatient pharmacy shall report such information to the commissioner in a manner that is consistent with the manner in which such pharmacy or outpatient pharmacy reports information for controlled substance prescriptions pursuant to subdivision (4) of this subsection. For the purposes of this

subdivision, "insulin drug", "glucagon drug", "diabetes devices" and "diabetic ketoacidosis device" have the same meanings as provided in section 20-616.

Sec. 6. Subsection (a) of section 21a-70 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) As used in this section: (1) "Drugs", "devices" and "cosmetics" have the same meanings as defined in section 21a-92, "wholesaler" or "distributor" means a person, including, but not limited to, a medical device and oxygen provider, a third-party logistics provider, a virtual manufacturer or a virtual wholesale distributor, as such terms are defined in section 20-571, as amended by this act, whether within or without the boundaries of the state of Connecticut, who supplies drugs, devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in subdivision **[**(24)**]** (28) of section 20-571, as amended by this act, pharmacies, federal, state or municipal agencies, clinics or any other person as permitted under subsection (h) of this section, except that: (A) A retail pharmacy or a pharmacy within a licensed hospital that supplies to another such pharmacy a quantity of a noncontrolled drug or a schedule II, III, IV or V controlled substance normally stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, (B) a pharmacy within a licensed hospital that supplies drugs to another hospital or an authorized practitioner for research purposes, (C) a retail pharmacy that supplies a limited quantity of a noncontrolled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home, of a rest home with nursing supervision or of a state correctional institution, and (D) a pharmacy within a licensed hospital that contains another hospital wholly within its physical structure that supplies to such contained hospital a quantity of a noncontrolled drug or a schedule II, III, IV, or V controlled substance normally stocked by such hospitals

to provide for the needs of a patient, pursuant to a prescription or medication order of an authorized practitioner, receiving inpatient care on a unit that is operated by the contained hospital 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 his or her designee.

Sec. 7. Subsection (k) of section 21a-106 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(k) If it is a legend drug, as defined in subdivision **[**(14)**]** (16) of section 20-571, as amended by this act, that is not administered, dispensed, prescribed or otherwise possessed or distributed in accordance with federal and state laws and regulations;

Sec. 8. Subsection (e) of section 21a-115 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(e) In the promulgation of regulations under the provisions of this section applicable to prescribing practitioners, care-giving institutions, and correctional and juvenile training institutions, as defined in subdivision **[**(6)**]** (7) of section 20-571, as amended by this act, the Commissioner of Consumer Protection shall act in place of the director. Existing regulations shall continue in effect unless superseded by action

of said commissioner pursuant to this subsection.

Sec. 9. Subsection (j) of section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in subdivision **[**(24)**]** (28) of section 20-571, as amended by this act.

Sec. 10. Section 38a-492a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (6), (10), (11) and (12) of section 38a-469, delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for hypodermic needles or syringes prescribed by a prescribing practitioner, as defined in subdivision **[**(24)**]** (28) of section 20-571, as amended by this act, for the purpose of administering medications for medical conditions, provided such medications are covered under the policy. Such benefits shall be subject to any policy provisions that apply to other services covered by such policy.

Sec. 11. Section 38a-518a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (6), (10), (11) and (12) of section 38a-469, delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for hypodermic needles or syringes prescribed by a prescribing practitioner, as defined in subdivision **[**(24)**]** (28) of section 20-571, as amended by this act, for the purpose of administering medications for medical conditions, provided such medications are covered under the policy. Such benefits shall be subject to any policy provisions that apply to other services covered by such policy.

Sec. 12. Subdivision (1) of subsection (b) of section 53a-13 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(b) (1) It shall not be a defense under this section if such mental disease or defect was proximately caused by the voluntary ingestion, inhalation or injection of intoxicating liquor or any drug or substance, or any combination thereof, unless such drug was prescribed for the defendant by a prescribing practitioner, as defined in subdivision **[**(24)**]** (28) of section 20-571, as amended by this act, and was used in accordance with the directions of such prescription.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	20-571
Sec. 2	*from passage*	New section
Sec. 3	*from passage*	21a-65
Sec. 4	*from passage*	20-631
Sec. 5	*from passage*	21a-254(j)
Sec. 6	*from passage*	21a-70(a)
Sec. 7	*from passage*	21a-106(k)
Sec. 8	*from passage*	21a-115(e)
Sec. 9	*from passage*	21a-249(j)
Sec. 10	*from passage*	38a-492a
Sec. 11	*from passage*	38a-518a
Sec. 12	*from passage*	53a-13(b)(1)

GL *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 22 $	FY 23 $
Consumer Protection, Dept.	GF - Cost	Up to 200,000	None

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill requires opioid agonists for the treatment of a substance use disorder to be uploaded to the Prescription Drug Monitoring Program (PDMP) resulting in a cost of up to $200,000 in FY 22. The cost is for the vendor to make programmatic changes to the PDMP so the database can collect the data required by the bill.

The Out Years

None.

OLR Bill Analysis

sSB 895

AN ACT CONCERNING CHANGES TO VARIOUS PHARMACY STATUTES.

SUMMARY

This bill makes several unrelated changes concerning pharmacy practice, including:

1. allowing long-term care pharmacies to use automated prescription dispensing machines in nursing homes (§§ 1 & 2);

2. making minor changes to the law on collaborative drug therapy agreements between pharmacists and practitioners (§§ 1 & 4);

3. authorizing registered syringe service programs, with Department of Consumer Protection (DCP) approval, to use secure machines to provide patients with clean needles and syringes (§ 3);

4. requiring dispensed opioid agonists for treatment of a substance use disorder to be uploaded into the electronic Prescription Drug Monitoring Program's (PMP) database (§ 5); and

5. exempting veterinarians from reporting to the PMP database dispensed diabetes drugs and devices (§ 5).

The bill also makes minor, technical, and conforming changes.

EFFECTIVE DATE: Upon passage

§§ 1 & 2 — PRESCRIPTION DISPENSING MACHINES

This bill allows licensed long-term care pharmacies to use "automated prescription dispensing machines" in nursing homes.

These are machines and associated software operated by a licensed state pharmacy or registered nonresident pharmacy through which the operators, based on a verified prescription, package and label patient-specific medications that are dispensed by the machine. A registered nurse or a licensed practical nurse must administer the dispensed medication packets.

The bill requires the DCP commissioner to adopt regulations concerning these machines but specifies that they may be operated before then if DCP approves the operational protocol in writing. Machines must be operated in compliance with the regulations, once they are adopted. The fee to operate a machine is $100 per machine per year.

§§ 1 & 4 — COLLABORATIVE DRUG THERAPY MANAGEMENT AGREEMENTS

By law, certain pharmacists may enter into written protocol-based collaborative drug therapy agreements with physicians or advanced practice registered nurses (providers) to manage a patient's drug therapy. These agreements can authorize a pharmacist to implement, modify, or discontinue a drug therapy the provider prescribes; order associated lab tests; and administer drugs. Each agreement must contain detailed direction concerning the pharmacist's permitted actions.

The bill specifies that (1) a pharmacist is also authorized to continue or deprescribe a drug therapy and (2) agreements may include guideline-directed management, rather than be patient-specific. The bill also allows an agreement to specifically address issues that may arise during medication reconciliation and concerns related to polypharmacy.

The bill replaces current law's requirement that a pharmacist update the patient's provider at least every 30 days with a requirement that they report any encounters within the agreement's scope within 30 days, or document it in a shared medical record.

Definitions

The bill defines "deprescribing" as the systematic process of identifying and discontinuing drugs when existing or potential harms outweigh existing or potential benefits in the context of an individual patient's care goals, current functioning level, life expectancy, values, and preferences.

"Medication reconciliation" is the process of comparing a patient's prescribed medications with newly ordered medications, to address duplication, omissions, and interactions.

"Polypharmacy" is a patient's use of multiple drugs, including medication that is inappropriate or not medically necessary, such as medications that are ineffective, duplicative, or not indicated.

§ 3 — SECURE SYRINGE DISPENSING MACHINES

The bill authorizes registered syringe service programs, after receiving DCP approval, to use secure, immobile machines to provide patients with up to 10 hypodermic needles and syringes ("needles") at a time. (Syringe service programs, overseen by the Department of Public Health, provide needle and syringe exchange services to intravenous drug users in communities impacted by HIV or hepatitis C.)

The machines must prevent unauthorized access and dispense only to patients using a patient-specific access number, personalized magnetic strip card, or another technology that identifies individual patients. Machines must store needles as recommended by the manufacturer, unless the machines can provide adequate environmental controls.

Machines must be equipped with a locked used needle disposal container, or one must be available near the machine. Only authorized program staff may collect and dispose of used needles. When dispensing needles, the machine must also give information on accessing treatment services.

§ 5 — PMP DATABASE

Opioid Agonists

Under certain conditions, the bill requires opioid agonists for treatment of a substance use disorder (e.g., methadone) to be uploaded into the PMP database (see BACKGROUND). The requirement applies to the currently exempt substance abuse treatment-related opioid agonist dispensers and administrators (including federal Substance Abuse and Mental Health Services Administration-certified substance use disorder clinics) when the patient has consented to disclosure and it complies with federal substance abuse confidentiality regulations.

Under the bill, signed consent forms must be available, upon request, to DCP for review. If a patient withdraws consent, opioid agonist information related to that patient must no longer be uploaded to the PMP.

Veterinary Diabetes Drugs and Devices

The bill eliminates a requirement that veterinarians upload to the PMP database or report to DCP information on dispensed animal patient (1) insulin and glucagon drugs and (2) diabetes and diabetic ketoacidosis devices.

BACKGROUND

PMP

The PMP collects prescription data on most controlled substances (i.e., Schedule II-V) into a centralized online database to prevent improper or illegal drug use or improper prescribing. As prescribing practitioners, veterinarians who dispense controlled substance prescriptions must submit information on the dispensed substance to the PMP.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 18 Nay 0 (03/23/2021)