House of Representatives

General Assembly

File No. 453

January Session, 2023

Substitute House Bill No. 6669

House of Representatives, April 5, 2023

The Committee on Public Health reported through REP. MCCARTHY VAHEY of the 133rd Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT PROTECTING PATIENTS AND PROHIBITING UNNECESSARY HEALTH CARE COSTS.

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

Section 1. (NEW) (*Effective October 1, 2023*) (a) The Comptroller shall establish the Drug Discount Card Program to be made available to all residents of this state. To further the purpose of such program, the Comptroller may cooperate with other states and territories of the United States, or regional consortia to pool prescription drug purchasing power to (1) lower prescription drug costs, (2) negotiate discounts with prescription drug manufacturers, (3) centralize the purchasing of prescription drugs, and (4) establish volume discount contracting. As used in this subsection, "volume discount contracting" means a negotiated purchase of a prescription drug in a large quantity for a decreased cost.

(b) The Comptroller shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section, including, but not limited to, establishing criteria and procedures for the Drug Discount Card Program.

Notwithstanding the requirements of sections 4-168 to 4-172, inclusive, of the general statutes, in order to effectuate this section, prior to adopting such regulations and not later than January 1, 2024, the Comptroller shall issue policies and procedures to implement the provisions of this section concerning the Drug Discount Card Program that shall have the force and effect of law. The Comptroller shall post all policies and procedures on the Comptroller's Internet web site and submit such policies and procedures to the Secretary of the State for posting on the eRegulations System, not less than fifteen days prior to the effective date of any policy or procedure. Any such policy or procedure shall no longer be effective upon the earlier of either the adoption of the policy or procedure as a final regulation under section 4-172 of the general statutes or forty-eight months from July 1, 2023, if such regulations have not been submitted to the standing legislative regulation review committee for consideration under section 4-170 of the general statutes.

Sec. 2. Section 21a-254 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(a) The Commissioner of Consumer Protection, after investigation and hearing, may by regulation designate certain substances as restricted drugs or substances by reason of their exceptional danger to health or exceptional potential for abuse so as to require written records of receipt, use and dispensation, and may, after investigation and hearing, remove the designation as restricted drugs or substances from any substance so previously designated.

(b) Each physician, dentist, veterinarian or other person who is authorized to administer or professionally use schedule I substances shall keep a record of such schedule I substances received by **[**him**]** <u>such person</u> and a record of all such schedule I substances administered, dispensed or professionally used by **[**him**]** <u>such person</u>. The record of schedule I substances received shall in each case show the date of receipt, the name and address of the person from whom received and the kind and quantity of schedule I substances received. The record of

all schedule I substances administered, dispensed or otherwise disposed of shall show the date of administering or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the substances were administered or dispensed and the kind and quantity of substances.

(c) Practitioners obtaining and dispensing controlled substances shall keep a record of all such controlled substances, received and dispensed by them in accordance with the provisions of subsections (f) and (h) of this section.

(d) Manufacturers and wholesalers shall keep records of all controlled substances, compounded, mixed, cultivated or grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section.

(e) Pharmacies, hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision, clinics, infirmaries, freestanding ambulatory surgical centers and laboratories shall keep records of all controlled substances, received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section, except that hospitals and chronic and convalescent nursing homes using a unit dose drug distribution system may instead keep such records in accordance with the provisions of subsections (g) and (h) of this section, and except that hospitals and freestanding ambulatory surgical centers shall not be required to maintain separate disposition records for schedule V controlled substances or records of administering of individual doses for ultra-short-acting depressants, including, but not limited to, Methohexital, Thiamylal and Thiopental.

(f) The form of record to be kept under subsection (c), (d) or (e) of this section shall in each case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of controlled substances received, or, when applicable, the kind and quantity of controlled substances produced or removed from process of manufacture and the date of such production or removal from process

of manufacture; and the record shall in each case show the proportion of controlled substances. The record of all controlled substances sold, administered, dispensed or otherwise disposed of shall show the date of selling, administering or dispensing, the name of the person to whom or for whose use, or the owner and species of animal for which, the substances were sold, administered or dispensed, the address of such person or owner in the instance of records of other than hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision and infirmaries, and the kind and quantity of substances. In addition, hospital and infirmary records shall show the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the substance. Each such record of controlled substances shall be separately maintained apart from other drug records and kept for a period of three years from the date of the transaction recorded.

(g) Hospitals using a unit dose drug distribution system shall maintain a record noting all dispositions of controlled substances from any area of the hospital to other hospital locations. Such record shall include, but need not be limited to, the name, form, strength and quantity of the drug dispensed, the date dispensed and the location within the hospital to which the drug was dispensed. Such dispensing record shall be separately maintained, apart from other drug or business records, for a period of three years. Such hospital shall, in addition, maintain for each patient a record which includes, but need not be limited to, the full name of the patient and a complete description of each dose of medication administered, including the name, form, strength and quantity of the drug administered, the date and time administered and identification of the nurse or practitioner administering each drug dose. Entries for controlled substances shall be specially marked in a manner which allows for ready identification. Such records shall be filed in chronological order and kept for a period of three years.

(h) A complete and accurate record of all stocks of controlled substances on hand shall, on and after July 1, 1981, be prepared annually

within four days of the first day of May of the calendar year, except that a registrant may change this date provided the general physical inventory date of such registrant is not more than six months from the annual inventory date, and kept on file for three years; and shall be made available to the commissioner or his authorized agents. All records required by this chapter shall be kept on the premises of the registrant and maintained current and separate from other business records in such form as to be readily available for inspection by the authorized agent at reasonable times. The use of a foreign language, codes or symbols to designate controlled substances or persons in the keeping of any required record is not deemed to be a compliance with this chapter.

(i) Whenever any record is removed by a person authorized to enforce the provisions of this chapter or the provisions of the state food, drug and cosmetic laws for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of three years.

(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 and legend drugs, legend devices, nonlegend drugs and nonlegend devices, as such terms are defined in section 20-571, 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, legend drugs, legend devices, nonlegend drugs and nonlegend devices in order to prevent the improper or illegal use of **[**the**]** controlled substances, **[**and**]** legend drugs, legend devices, nonlegend drugs and nonlegend devices and to improve the ability of prescribing practitioners to identify medications that should be

discontinued, deprescribed or modified in the best interest of the patient. The program shall not infringe on the legitimate prescribing of a controlled substance, legend drug, legend device, nonlegend drug or nonlegend device 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**]** 2024, 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**]** not less than 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device prescriptions dispensed by such pharmacy or outpatient pharmacy or prescribing practitioner: (A) Dispenser identification number; (B) the date the prescription for the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device was filled; (C) the prescription number; (D) whether the prescription for the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device is new or a refill; (E) the national drug code number for the drug or medical device dispensed; (F) the amount of the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device dispensed and the number of days' supply of the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device; (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, legend drug, legend medical device, nonlegend drug or nonlegend medical device was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement Agency's identification number; (K) the prescribing

practitioner's national provider identification number; (L) the date the prescription was delivered to the patient; and **[**(K)**]** (M) the type of payment.

(4) (A) Except as provided in this subdivision, on and after July 1, **[**2016**]** 2024, 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device was filled; (iii) the prescription number; (iv) whether the prescription for the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device is new or a refill; (v) the national drug code number for the drug or medical device dispensed; (vi) the amount of the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device dispensed and the number of days' supply of the controlled substance, legend drug, legend medical device, nonlegend drug or nonlegend medical device; (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, legend drug, legend medical device, nonlegend drug or nonlegend medical device was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement Agency's identification number; (xi) the prescribing practitioner's national provider identification number; (xii) the date the drug or medical device was delivered to the patient; and **[**(xi)**]** (xiii) 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device prescription shall report to the commissioner the information described in subparagraph (A) of this subdivision, [at least] not less than 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drugs, legend medical devices, nonlegend drugs or nonlegend medical devices 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device prescription information; or (C) the pharmacist who is dispensing controlled substances, legend drugs, legend medical devices, nonlegend drugs or nonlegend medical devices 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, legend drugs, legend medical devices, nonlegend drugs or nonlegend medical devices 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device 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, legend drug or medical device and nonlegend drug or medical device 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, legend drug, legend medical device, nonlegend drug or nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device prescription information.

(12) The provisions of this section shall not apply to (A) samples of

controlled substances, legend drugs, legend medical devices, nonlegend drugs or nonlegend medical devices dispensed by a physician to a patient, or (B) any controlled substances, legend drugs, legend medical devices, nonlegend drugs or nonlegend medical devices 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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**]** not less than 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, legend drug, legend medical device, nonlegend drug and nonlegend medical device 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.

(17) The electronic prescription drug monitoring program shall collect transaction information for controlled substances, legend drugs, legend medical devices, nonlegend drugs and nonlegend medical devices that have been electronically deprescribed and transmitted to licensed pharmacies and nonresident pharmacies. For purposes of this subdivision, "deprescribed" has the same meaning as provided in section 20-571, and "nonresident pharmacy" has the same meaning as provided in section 20-627.

Sec. 3. (*Effective from passage*) (a) For the purposes of this section, "academic detailing" means the process of identifying the best evidence-based practices for a particular medical condition and appropriate treatments for such medical condition, and providing such information to prescribing practitioners and qualified pharmacists participating in collaborative drug therapy management agreements to advance patient care.

(b) Not later than January 1, 2025, the Commissioner of Consumer Protection, in consultation with The University of Connecticut School of Pharmacy, shall submit a report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health. Such report may include, but need not be limited to, a framework for establishing an academic detailing program for physicians licensed pursuant to chapter 370 of the general statutes, advanced practice registered nurses licensed pursuant to chapter 378 of the general statutes and pharmacists licensed pursuant to chapter 400j of the general statutes, who participate in collaborative drug therapy management agreements, as defined in section 20-631 of the general statutes. Such report shall provide recommendations for ensuring that such physicians, advanced practice registered nurses and pharmacists participating in collaborative drug therapy management agreements are aware of cost-effective treatments for patients that are based on current practice and may include suggestions for cost-effective implementation and evaluation of an academic detailing program.

Sec. 4. (NEW) (*Effective October 1, 2023*) For the purposes of this section and sections 5 to 8, inclusive, of this act:

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

(2) "Contact" means any communication transmitted in person or by telephone, electronic mail, text message or other electronic means between a pharmaceutical representative and a prescribing practitioner, to promote or provide information relating to a legend drug;

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

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

(5) "Pharmaceutical manufacturer" means any person, including, but not limited to, a virtual manufacturer, as defined in section 20-571 of the

general statutes, who produces, prepares, cultivates, grows, propagates, compounds, converts or processes a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or packages or repackages a controlled substance container under such person's own name or a trademark or label for the purpose of selling such controlled substance;

(6) "Pharmaceutical representative" means any person, including, but not limited to, a sales representative or medical science liaison, who markets, promotes or provides legend drug information to a prescribing practitioner and is employed or compensated by a pharmaceutical manufacturer;

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

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

Sec. 5. (NEW) (*Effective October 1, 2023*) (a) No person shall engage in business as a pharmaceutical representative in this state unless such person has first obtained a license issued by the Commissioner of Consumer Protection.

(b) Any person seeking a license as a pharmaceutical representative shall (1) submit to the commissioner an application for such license in a form and manner prescribed by the commissioner, (2) pay a nonrefundable application fee of five hundred fifty dollars, and (3) submit evidence that such applicant has completed the continuing professional education requirements set forth in subsection (f) of this section.

(c) The commissioner shall issue to each applicant who meets the requirements for licensure, as set forth in subsection (b) of this section, a pharmaceutical representative license.

(d) Each licensee holding a license as a pharmaceutical representative

shall, annually, not later than June thirtieth, (1) renew such license with the commissioner, (2) submit a nonrefundable payment of five hundred fifty dollars, and (3) certify that such licensee has completed the continuing professional education requirements set forth in subsection (f) of this section.

(e) A licensee shall file a report with the commissioner not later than five business days after any change of name, address or other contact information for such licensee.

(f) Prior to submitting an application for (1) a license under subsection (b) of this section, or (2) a renewal of a license under subsection (d) of this section, such applicant or licensee shall furnish evidence satisfactory to the commissioner that such applicant or licensee has completed not less than five hours of continuing professional education. Continuing professional education shall include training in ethical standards, health equity, whistleblower protections, laws and regulations applicable to pharmaceutical marketing and any other training approved by the commissioner and published on the Department of Consumer Protection's Internet web site pursuant to subsection (g) of this section. Each applicant or licensee shall maintain continuing education certificate of completion records for not less than three years following the completion date for each continuing professional education training and, upon request by the commissioner, such applicant or licensee shall produce such records to the commissioner.

(g) The commissioner shall review submissions for continuing professional education programs and shall, upon approval by the commissioner, publish a list of approved continuing professional education programs on the department's Internet web site.

(h) Continuing professional education training programs shall (1) be approved by the commissioner, and (2) adhere to the following:

(A) An employer of a licensed pharmaceutical representative or an applicant for such license in this state shall not be a provider of

continuing professional education;

(B) A provider of continuing professional education shall disclose any conflicts of interests, including, but not limited to, any personal conflict of interest that would interfere or prevent such provider from conducting continuing professional education training honestly, objectively and effectively; and

(C) Funding for continuing professional education shall not be provided by an entity in the pharmaceutical industry or by a third-party entity that is compensated by an entity in the pharmaceutical industry.

(i) Upon renewal of a license under subsection (d) of this section, or not later than July thirty-first if such license is not renewed, such licensee shall provide the commissioner with the following information for the previous calendar year in a form and manner prescribed by the commissioner:

(1) The aggregate number of contacts such licensee had with prescribing practitioners;

(2) The names and specialties of the prescribing practitioners such licensee contacted;

(3) The location and length of each contact;

(4) The name and a description of each legend drug marketed to each contact;

(5) A description of each gift, voucher, coupon or other compensation of any value that was provided to a prescribing practitioner or staff in a prescribing practitioner's office; and

(6) Any other information requested by the commissioner.

(j) The license of a pharmaceutical representative in this state may be revoked, suspended or annulled, after notice and hearing if the commissioner determines that (1) such licensee obtained the license by means of fraud or misrepresentation, or (2) such licensee violated any

provisions of this section, or regulations adopted by the commissioner in accordance with the provisions of chapter 54 of the general statutes.

Sec. 6. (NEW) (*Effective October 1, 2023*) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of sections 4 and 5 of this act concerning the licensing of pharmaceutical representatives. Notwithstanding the requirements of sections 4-168 to 4-172, inclusive, of the general statutes in order to effectuate this section, prior to adopting such regulations, the commissioner may issue policies and procedures to implement the provisions concerning the licensing of pharmaceutical representatives that shall have the force and effect of law. The commissioner shall post all policies and procedures on the department's Internet web site and submit such policies and procedures to the Secretary of the State for posting on the eRegulations System not less than fifteen days prior to the effective date of any policy or procedure. Any such policy or procedure shall no longer be effective upon the earlier of either the adoption of the policy or procedure as a final regulation under section 4-172 of the general statutes or forty-eight months from October 1, 2023, if such regulations have not been submitted to the standing legislative regulation review committee for consideration under section 4-170 of the general statutes.

Sec. 7. (NEW) (*Effective October 1, 2023*) Each pharmaceutical representative engaged in legend drug marketing in this state shall disclose, in writing, to a prescribing practitioner, at the time of each contact with such prescribing practitioner, the following information:

(1) The wholesale acquisition cost of a legend drug when such pharmaceutical representative provides information concerning such legend drug to the prescribing practitioner based on the dose and quantity of such legend drug as described in the medication package insert;

(2) The names of not less than three legend drugs from the same therapeutic class or a similar therapeutic class for the disease or condition that such legend drug being marketed has an indication

approved by the federal Food and Drug Administration; and

(3) Information on the variation efficacy of the legend drug marketed to different racial and ethnic groups, if available.

Sec. 8. (NEW) (*Effective October 1, 2023*) (a) No pharmaceutical representative shall:

(1) Engage in any deceptive or misleading marketing practices of a legend drug, including, but not limited to, concealment, suppression, omission, misrepresentation or misstatement of any material fact;

(2) Use a title or designation of a legend drug that could reasonably mislead a prescribing practitioner or an employee or representative of a prescribing practitioner; or

(3) Transport or provide samples of a legend drug to a prescribing practitioner or an employee or representative of a prescribing practitioner.

(b) Each pharmaceutical representative licensed in this state shall present a copy of such license issued pursuant to section 5 of this act at the time of each visit with a prescribing practitioner or an employee or representative of a prescribing practitioner.

Sec. 9. (*Effective from passage*) Not later than December 24, 2024, the Office of Health Strategy, in consultation with the Insurance Department, shall prepare and submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to insurance. Such report shall include an analysis of pharmacy benefits managers' practices of prescription drug distribution, including, but not limited to, spread pricing arrangements, manufacturing rebates and transparency and an evaluation of prescription drug distribution practices conducted by pharmacy benefits managers in other states. Such report shall provide recommendations (1) to reduce prescription drug costs for consumers, and (2) for the regulation of pharmacy benefits managers in this state.

Sec. 10. Subsection (d) of section 19a-754b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(d) (1) On or before March 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy, in consultation with the Comptroller, Commissioner of Social Services and Commissioner of Public Health, shall prepare a list of not more than ten outpatient prescription drugs that the executive director, in the executive director's discretion, determines are (A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and **[**at least**]** not less than one generic outpatient prescription drug.

[(2) The executive director shall not list any outpatient prescription drug under subdivision (1) of this subsection unless the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, (A) increased by at least (i) twenty per cent during the immediately preceding calendar year, or (ii) fifty per cent during the immediately preceding three calendar years, and (B) was not less than sixty dollars for (i) a thirty-day supply of such drug, or (ii) a course of treatment of such drug lasting less than thirty days.**]**

(2) Prior to publishing the annual list, the executive director shall prepare a preliminary list that includes outpatient prescription drugs the executive director plans to include on such annual list. The executive director shall make such preliminary list available for public comment for not less than thirty days. During the public comment period, any manufacturer of an outpatient prescription drug included on the preliminary list may produce documentation to the executive director to establish that the wholesale acquisition cost of such drug, less all rebates paid to the state for such outpatient prescription drug during the immediately preceding calendar year, does not exceed the limits established in subdivision (3) of this subsection. If such documentation

establishes, to the satisfaction of the executive director, that the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, does not exceed the limits established in subdivision (3) of this subsection, the executive director shall, not later than fifteen days after the closing of the public comment period, remove such drug from the preliminary list before publishing the annual list pursuant to subdivision (1) of this subsection.

(3) The executive director shall not list any outpatient prescription drugs under subdivision (1) or (2) of this subsection unless the wholesale acquisition cost of such outpatient prescription drug (A) increased by not less than sixteen per cent cumulatively during the immediately preceding two calendar years, and (B) was not less than forty dollars for a course of treatment.

[(3)**]** (4) (A) The pharmaceutical manufacturer of an outpatient prescription drug included on a list prepared by the executive director pursuant to subdivision (1) of this subsection shall provide to the office, in a form and manner specified by the executive director, (i) a written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug, and (ii) aggregate, company-level research and development costs and such other capital expenditures that the executive director, in the executive director's discretion, deems relevant for the most recent year for which final audited data are available.

(B) The quality and types of information and data that a pharmaceutical manufacturer submits to the office under this subdivision shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in (i) such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (ii) any other public disclosure.

[(4)**]** (5) The office shall establish a standardized form for reporting information and data pursuant to this subsection after consulting with

pharmaceutical manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the office and pharmaceutical manufacturers.

Sec. 11. Section 19a-508c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(a) As used in this section:

(1) "Affiliated provider" means a provider that is: (A) Employed by a hospital or health system, (B) under a professional services agreement with a hospital or health system that permits such hospital or health system to bill on behalf of such provider, or (C) a clinical faculty member of a medical school, as defined in section 33-182aa, that is affiliated with a hospital or health system in a manner that permits such hospital or health system to bill on behalf of such clinical faculty member;

(2) "Campus" means: (A) The physical area immediately adjacent to a hospital's main buildings and other areas and structures that are not strictly contiguous to the main buildings but are located within two hundred fifty yards of the main buildings, or (B) any other area that has been determined on an individual case basis by the Centers for Medicare and Medicaid Services to be part of a hospital's campus;

(3) "Facility fee" means any fee charged or billed by a hospital or health system for outpatient services provided in a hospital-based facility, regardless of the treatment modality through which such services were provided, that is: (A) Intended to compensate the hospital or health system for the operational expenses of the hospital or health system, and (B) separate and distinct from a professional fee;

(4) "Freestanding emergency department" means a freestanding facility that (A) is structurally separate and distinct from a hospital, (B) provides emergency care, (C) is a department of a hospital licensed under chapter 368v, and (D) has been issued a certificate of need to operate as a freestanding emergency department pursuant to chapter 368z. "Freestanding emergency department" does not include an urgent

care center, as defined in section 19a-493d;

(5) "Health care provider" means an individual, entity, corporation, person or organization, whether for-profit or nonprofit, that furnishes, bills or is paid for health care service delivery in the normal course of business, including, but not limited to, a health system, a hospital, a hospital-based facility, a freestanding emergency department and an urgent care center;

[(4)**]** (6) "Health system" means: (A) A parent corporation of one or more hospitals and any entity affiliated with such parent corporation through ownership, governance, membership or other means, or (B) a hospital and any entity affiliated with such hospital through ownership, governance, membership or other means;

[(5)**]** (7) "Hospital" has the same meaning as provided in section 19a-490;

[(6)**]** (8) "Hospital-based facility" means a facility that is owned or operated, in whole or in part, by a hospital or health system where hospital or professional medical services are provided;

(9) "Medicaid" means the program operated by the Department of Social Services pursuant to section 17b-260 and authorized by Title XIX of the Social Security Act, as amended from time to time;

[(7)**]** (10) "Payer mix" means the proportion of different sources of payment received by a hospital or health system, including, but not limited to, Medicare, Medicaid, other government-provided insurance, private insurance and self-pay patients;

[(8)**]** (11) "Professional fee" means any fee charged or billed by a provider for professional medical services provided in a hospital-based facility;

[(9)**]** (12) "Provider" means an individual, entity, corporation or health care provider, whether for profit or nonprofit, whose primary purpose is to provide professional medical services; and

[(10)**]** (13) "Tagline" means a short statement written in a non-English language that indicates the availability of language assistance services free of charge.

(b) If a hospital or health system charges a facility fee utilizing a current procedural terminology evaluation and management (CPT E/M) code or assessment and management (CPT A/M) code for outpatient services provided at a hospital-based facility where a professional fee is also expected to be charged, the hospital or health system shall provide the patient with a written notice that includes the following information:

(1) That the hospital-based facility is part of a hospital or health system and that the hospital or health system charges a facility fee that is in addition to and separate from the professional fee charged by the provider;

(2) (A) The amount of the patient's potential financial liability, including any facility fee likely to be charged, and, where professional medical services are provided by an affiliated provider, any professional fee likely to be charged, or, if the exact type and extent of the professional medical services needed are not known or the terms of a patient's health insurance coverage are not known with reasonable certainty, an estimate of the patient's financial liability based on typical or average charges for visits to the hospital-based facility, including the facility fee, (B) a statement that the patient's actual financial liability will depend on the professional medical services actually provided to the patient, (C) an explanation that the patient may incur financial liability that is greater than the patient would incur if the professional medical services were not provided by a hospital-based facility, and (D) a telephone number the patient may call for additional information regarding such patient's potential financial liability, including an estimate of the facility fee likely to be charged based on the scheduled professional medical services; and

(3) That a patient covered by a health insurance policy should contact the health insurer for additional information regarding the hospital's or

health system's charges and fees, including the patient's potential financial liability, if any, for such charges and fees.

(c) If a hospital or health system charges a facility fee without utilizing a current procedural terminology evaluation and management (CPT E/M) code for outpatient services provided at a hospital-based facility, located outside the hospital campus, the hospital or health system shall provide the patient with a written notice that includes the following information:

(1) That the hospital-based facility is part of a hospital or health system and that the hospital or health system charges a facility fee that may be in addition to and separate from the professional fee charged by a provider;

(2) (A) A statement that the patient's actual financial liability will depend on the professional medical services actually provided to the patient, (B) an explanation that the patient may incur financial liability that is greater than the patient would incur if the hospital-based facility was not hospital-based, and (C) a telephone number the patient may call for additional information regarding such patient's potential financial liability, including an estimate of the facility fee likely to be charged based on the scheduled professional medical services; and

(3) That a patient covered by a health insurance policy should contact the health insurer for additional information regarding the hospital's or health system's charges and fees, including the patient's potential financial liability, if any, for such charges and fees.

(d) Each initial billing statement that includes a facility fee shall: (1) Clearly identify the fee as a facility fee that is billed in addition to, or separately from, any professional fee billed by the provider; (2) provide the corresponding Medicare facility fee reimbursement rate for the same service as a comparison or, if there is no corresponding Medicare facility fee for such service, (A) the approximate amount Medicare would have paid the hospital for the facility fee on the billing statement, or (B) the percentage of the hospital's charges that Medicare would have paid the

hospital for the facility fee; (3) include a statement that the facility fee is intended to cover the hospital's or health system's operational expenses; (4) inform the patient that the patient's financial liability may have been less if the services had been provided at a facility not owned or operated by the hospital or health system; and (5) include written notice of the patient's right to request a reduction in the facility fee or any other portion of the bill and a telephone number that the patient may use to request such a reduction without regard to whether such patient qualifies for, or is likely to be granted, any reduction. Not later than October 15, 2022, and annually thereafter, each hospital, health system and hospital-based facility shall submit to the Health Systems Planning Unit of the Office of Health Strategy a sample of a billing statement issued by such hospital, health system or hospital-based facility that complies with the provisions of this subsection and which represents the format of billing statements received by patients. Such billing statement shall not contain patient identifying information.

(e) The written notice described in subsections (b) to (d), inclusive, and (h) to (j), inclusive, of this section shall be in plain language and in a form that may be reasonably understood by a patient who does not possess special knowledge regarding hospital or health system facility fee charges. On and after October 1, 2022, such notices shall include tag lines in at least the top fifteen languages spoken in the state indicating that the notice is available in each of those top fifteen languages. The fifteen languages shall be either the languages in the list published by the Department of Health and Human Services in connection with section 1557 of the Patient Protection and Affordable Care Act, P.L. 111-148, or, as determined by the hospital or health system, the top fifteen languages in the geographic area of the hospital-based facility.

(f) (1) For nonemergency care, if a patient's appointment is scheduled to occur ten or more days after the appointment is made, such written notice shall be sent to the patient by first class mail, encrypted electronic mail or a secure patient Internet portal not less than three days after the appointment is made. If an appointment is scheduled to occur less than ten days after the appointment is made or if the patient arrives without

an appointment, such notice shall be hand-delivered to the patient when the patient arrives at the hospital-based facility.

(2) For emergency care, such written notice shall be provided to the patient as soon as practicable after the patient is stabilized in accordance with the federal Emergency Medical Treatment and Active Labor Act, 42 USC 1395dd, as amended from time to time, or is determined not to have an emergency medical condition and before the patient leaves the hospital-based facility. If the patient is unconscious, under great duress or for any other reason unable to read the notice and understand and act on his or her rights, the notice shall be provided to the patient's representative as soon as practicable.

(g) Subsections (b) to (f), inclusive, and (l) of this section shall not apply if a patient is insured by Medicare or Medicaid or is receiving services under a workers' compensation plan established to provide medical services pursuant to chapter 568.

(h) A hospital-based facility shall prominently display written notice in locations that are readily accessible to and visible by patients, including patient waiting or appointment check-in areas, stating: (1) That the hospital-based facility is part of a hospital or health system, (2) the name of the hospital or health system, and (3) that if the hospital-based facility charges a facility fee, the patient may incur a financial liability greater than the patient would incur if the hospital-based facility was not hospital-based. On and after October 1, 2022, such notices shall include tag lines in at least the top fifteen languages spoken in the state indicating that the notice is available in each of those top fifteen languages. The fifteen languages shall be either the languages in the list published by the Department of Health and Human Services in connection with section 1557 of the Patient Protection and Affordable Care Act, P.L. 111-148, or, as determined by the hospital or health system, the top fifteen languages in the geographic area of the hospital-based facility. Not later than October 1, 2022, and annually thereafter, each hospital-based facility shall submit a copy of the written notice required by this subsection to the Health Systems Planning Unit of the

Office of Health Strategy.

(i) A hospital-based facility shall clearly hold itself out to the public and payers as being hospital-based, including, at a minimum, by stating the name of the hospital or health system in its signage, marketing materials, Internet web sites and stationery.

(j) A hospital-based facility shall, when scheduling services for which a facility fee may be charged, inform the patient (1) that the hospital-based facility is part of a hospital or health system, (2) of the name of the hospital or health system, (3) that the hospital or health system may charge a facility fee in addition to and separate from the professional fee charged by the provider, and (4) of the telephone number the patient may call for additional information regarding such patient's potential financial liability.

(k) (1) If any transaction described in subsection (c) of section 19a-486i, results in the establishment of a hospital-based facility at which facility fees may be billed, the hospital or health system, that is the purchaser in such transaction shall, not later than thirty days after such transaction, provide written notice, by first class mail, of the transaction to each patient served within the three years preceding the date of the transaction by the health care facility that has been purchased as part of such transaction.

(2) Such notice shall include the following information:

(A) A statement that the health care facility is now a hospital-based facility and is part of a hospital or health system, the health care facility's full legal and business name and the date of such facility's acquisition by a hospital or health system;

(B) The name, business address and phone number of the hospital or health system that is the purchaser of the health care facility;

(C) A statement that the hospital-based facility bills, or is likely to bill, patients a facility fee that may be in addition to, and separate from, any professional fee billed by a health care provider at the hospital-based

facility;

(D) (i) A statement that the patient's actual financial liability will depend on the professional medical services actually provided to the patient, and (ii) an explanation that the patient may incur financial liability that is greater than the patient would incur if the hospital-based facility were not a hospital-based facility;

(E) The estimated amount or range of amounts the hospital-based facility may bill for a facility fee or an example of the average facility fee billed at such hospital-based facility for the most common services provided at such hospital-based facility; and

(F) A statement that, prior to seeking services at such hospital-based facility, a patient covered by a health insurance policy should contact the patient's health insurer for additional information regarding the hospital-based facility fees, including the patient's potential financial liability, if any, for such fees.

(3) A copy of the written notice provided to patients in accordance with this subsection shall be filed with the Health Systems Planning Unit of the Office of Health Strategy, established under section 19a-612. Said unit shall post a link to such notice on its Internet web site.

(4) A hospital, health system or hospital-based facility shall not collect a facility fee for services provided at a hospital-based facility that is subject to the provisions of this subsection from the date of the transaction until at least thirty days after the written notice required pursuant to this subsection is mailed to the patient or a copy of such notice is filed with the Health Systems Planning Unit of the Office of Health Strategy, whichever is later. A violation of this subsection shall be considered an unfair trade practice pursuant to section 42-110b.

(5) Not later than July 1, 2023, and annually thereafter, each hospital-based facility that was the subject of a transaction, as described in subsection (c) of section 19a-486i, during the preceding calendar year shall report to the Health Systems Planning Unit of the Office of Health

Strategy the number of patients served by such hospital-based facility in the preceding three years.

(l) (1) A health care provider may only charge, bill for or collect a facility fee for services provided (A) on a hospital's campus, (B) at a facility that includes a hospital emergency department, or (C) at a freestanding emergency department.

[(l)**]** (2) Notwithstanding the provisions of **[**this section, no hospital, health system or hospital-based facility shall**]** subdivision (1) of this subsection, no health care provider shall charge, bill for or collect a facility fee for **[**(1)**]** (A) outpatient **[**health care services that use a current procedural terminology**]** evaluation and management **[**(CPT E/M) code**]** or assessment and management **[**(CPT A/M) code and are provided at a hospital-based facility located off-site from a hospital campus, or (2) outpatient health care services provided at a hospital-based facility located off-site from a hospital campus, received by a patient who is uninsured of more than the Medicare rate**]** services, or (B) any other outpatient diagnostic or imaging service identified by the Office of Health Strategy pursuant to subdivision (3) of this subsection.

(3) The Office of Health Strategy may annually identify outpatient diagnostic and imaging services that may reliably be provided safely and effectively in a setting other than a hospital.

(4) Notwithstanding the provisions of subdivisions (1) to (3), inclusive, of this subsection, in circumstances when an insurance contract that is in effect on July 1, **[**2016**]** 2023, provides reimbursement for facility fees prohibited under the provisions of this section, a hospital or health system may continue to collect reimbursement from the health insurer for such facility fees until the date of expiration, renewal or amendment of such contract, whichever such date is the earliest.

(5) Notwithstanding the provisions of subdivisions (1) to (3), inclusive, of this subsection, to the extent that the Department of Social Services provides reimbursement under Medicaid for facility fees prohibited under the provisions of this section, the John Dempsey

Hospital of The University of Connecticut Health Center and any hospital that is a party to the settlement agreement with the state approved pursuant to special act 19-1 of the December special session may continue to collect reimbursement from said department for such facility fees for dates of service beginning July 1, 2023, and ending June 30, 2026.

(6) A violation of this subsection shall be considered an unfair trade practice pursuant to chapter 735a. **[**The provisions of this subsection shall not apply to a freestanding emergency department. As used in this subsection, "freestanding emergency department" means a freestanding facility that (A) is structurally separate and distinct from a hospital, (B) provides emergency care, (C) is a department of a hospital licensed under chapter 368v, and (D) has been issued a certificate of need to operate as a freestanding emergency department pursuant to chapter 368z.**]**

(m) (1) Each hospital and health system shall report not later than July 1, 2023, and annually thereafter to the executive director of the Office of Health Strategy, on a form prescribed by the executive director, concerning facility fees charged or billed during the preceding calendar year. Such report shall include (A) the name and address of each facility owned or operated by the hospital or health system that provides services for which a facility fee is charged or billed, (B) the number of patient visits at each such facility for which a facility fee was charged or billed, (C) the number, total amount and range of allowable facility fees paid at each such facility disaggregated by payer mix, (D) for each facility, the total amount of facility fees charged and the total amount of revenue received by the hospital or health system derived from facility fees, (E) the total amount of facility fees charged and the total amount of revenue received by the hospital or health system from all facilities derived from facility fees, (F) a description of the ten procedures or services that generated the greatest amount of facility fee gross revenue, disaggregated by current procedural terminology category (CPT) code for each such procedure or service and, for each such procedure or service, patient volume and the total amount of gross and net revenue

received by the hospital or health system derived from facility fees, and (G) the top ten procedures or services for which facility fees are charged based on patient volume and the gross and net revenue received by the hospital or health system for each such procedure or service. For purposes of this subsection, "facility" means a hospital-based facility that is located outside a hospital campus.

(2) The executive director shall publish the information reported pursuant to subdivision (1) of this subsection, or post a link to such information, on the Internet web site of the Office of Health Strategy.

Sec. 12. Section 19a-653 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(a) Any person or health care facility or institution that is required to file a certificate of need for any of the activities described in section 19a-638, and any person or health care facility or institution that is required to file data or information under any public or special act or under this chapter or sections 19a-486 to 19a-486h, inclusive, or any regulation adopted or order issued under this chapter or said sections, which **[**wilfully**]** fails to seek certificate of need approval for any of the activities described in section 19a-638 or to so file within prescribed time periods, and any person or health care facility or institution that has agreed to fully resolve a certificate of need application through settlement and fails to comply with any term or condition enumerated in the settlement agreement, shall be subject to a civil penalty of up to one thousand dollars a day for each day such person or health care facility or institution conducts any of the described activities without certificate of need approval as required by section 19a-638, **[**or**]** for each day such information is missing, incomplete or inaccurate or for each day any condition of a settlement agreement is not met. Any civil penalty authorized by this section shall be imposed by the Office of Health Strategy in accordance with subsections (b) to (e), inclusive, of this section.

(b) If the Office of Health Strategy has reason to believe that a violation has occurred for which a civil penalty is authorized by

subsection (a) of this section or subsection (e) of section 19a-632, it shall notify the person or health care facility or institution by first-class mail or personal service. The notice shall include: (1) A reference to the sections of the statute, [or] regulation or settlement agreement involved; (2) a short and plain statement of the matters asserted or charged; (3) a statement of the amount of the civil penalty or penalties to be imposed; (4) the initial date of the imposition of the penalty; and (5) a statement of the party's right to a hearing.

(c) The person or health care facility or institution to whom the notice is addressed shall have fifteen business days from the date of mailing of the notice to make written application to the unit to (1) request [(1)] a hearing to contest the imposition of the penalty, [or] (2) request an extension of time to file the required data, or (3) comply with enumerated conditions of an agreed settlement. A failure to make a timely request for a hearing or an extension of time to file the required data or a denial of a request for an extension of time shall result in a final order for the imposition of the penalty. All hearings under this section shall be conducted pursuant to sections 4-176e to 4-184, inclusive. The Office of Health Strategy may grant an extension of time for filing the required data or mitigate or waive the penalty upon such terms and conditions as, in its discretion, it deems proper or necessary upon consideration of any extenuating factors or circumstances.

(d) A final order of the Office of Health Strategy assessing a civil penalty shall be subject to appeal as set forth in section 4-183 after a hearing before the unit pursuant to subsection (c) of this section, except that any such appeal shall be taken to the superior court for the judicial district of New Britain. Such final order shall not be subject to appeal under any other provision of the general statutes. No challenge to any such final order shall be allowed as to any issue which could have been raised by an appeal of an earlier order, denial or other final decision by the office.

(e) If any person or health care facility or institution fails to pay any civil penalty under this section, after the assessment of such penalty has

become final the amount of such penalty may be deducted from payments to such person or health care facility or institution from the Medicaid account.

Sec. 13. Section 19a-639a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(a) An application for a certificate of need shall be filed with the unit in accordance with the provisions of this section and any regulations adopted by the Office of Health Strategy. The application shall address the guidelines and principles set forth in (1) subsection (a) of section 19a-639, and (2) regulations adopted by the department. The applicant shall include with the application a nonrefundable application fee based on the cost of the project. The amount of the fee shall be as follows: (A) One thousand dollars for a project that will cost not greater than fifty thousand dollars; (B) two thousand dollars for a project that will cost greater than fifty thousand dollars but not greater than one hundred thousand dollars; (C) three thousand dollars for a project that will cost greater than one hundred thousand dollars but not greater than five hundred thousand dollars; (D) four thousand dollars for a project that will cost greater than five hundred thousand dollars but not greater than one million dollars; (E) five thousand dollars for a project that will cost greater than one million dollars but not greater than five million dollars; (F) eight thousand dollars for a project that will cost greater than five million dollars but not greater than ten million dollars; and (G) ten thousand dollars for a project that will cost greater than ten million dollars.

(b) Prior to the filing of a certificate of need application, the applicant shall publish notice that an application is to be submitted to the unit **[**in a newspaper having a substantial circulation in the area where the project is to be located**]** <u>on the applicant's Internet web site in a clear and conspicuous location that is easily accessible by members of the public</u>. Such notice shall (1) be published (A) not later than twenty days prior to the date of filing of the certificate of need application, and (B) for not less than three consecutive days, and (2) contain a brief description of

the nature of the project and the street address where the project is to be located. An applicant shall file the certificate of need application with the unit not later than ninety days after publishing notice of the application in accordance with the provisions of this subsection. The unit shall not accept the applicant's certificate of need application for filing unless the application is accompanied by the application fee prescribed in subsection (a) of this section and proof of compliance with the publication requirements prescribed in this subsection.

(c) (1) Not later than five business days after receipt of a properly filed certificate of need application, the unit shall publish notice of the application on its Internet web site. Not later than thirty days after the date of filing of the application, the unit may request such additional information as the unit determines necessary to complete the application. In addition to any information requested by the unit, if the application involves the transfer of ownership of a hospital, as defined in section 19a-639, the applicant shall submit to the unit (A) a plan demonstrating how health care services will be provided by the new hospital for the first three years following the transfer of ownership of the hospital, including any consolidation, reduction, elimination or expansion of existing services or introduction of new services, and (B) the names of persons currently holding a position with the hospital to be purchased or the purchaser, as defined in section 19a-639, as an officer, director, board member or senior manager, whether or not such person is expected to hold a position with the hospital after completion of the transfer of ownership of the hospital and any salary, severance, stock offering or any financial gain, current or deferred, such person is expected to receive as a result of, or in relation to, the transfer of ownership of the hospital.

(2) The applicant shall, not later than sixty days after the date of the unit's request, submit any requested information and any information required under this subsection to the unit. If an applicant fails to submit such information to the unit within the sixty-day period, the unit shall consider the application to have been withdrawn.

(d) Upon determining that an application is complete, the unit shall provide notice of this determination to the applicant and to the public in accordance with regulations adopted by the department. In addition, the unit shall post such notice on its Internet web site. The date on which the unit posts such notice on its Internet web site shall begin the review period. Except as provided in this subsection, (1) the review period for a completed application shall be ninety days from the date on which the unit posts such notice on its Internet web site; and (2) the unit shall issue a decision on a completed application prior to the expiration of the ninety-day review period. The review period for a completed application that involves a transfer of a large group practice, as described in subdivision (3) of subsection (a) of section 19a-638, when the offer was made in response to a request for proposal or similar voluntary offer for sale, shall be sixty days from the date on which the unit posts notice on its Internet web site. Upon request or for good cause shown, the unit may extend the review period for a period of time not to exceed sixty days. If the review period is extended, the unit shall issue a decision on the completed application prior to the expiration of the extended review period. If the unit holds a public hearing concerning a completed application in accordance with subsection (e) or (f) of this section, the unit shall issue a decision on the completed application not later than sixty days after the date the unit closes the public hearing record.

(e) Except as provided in this subsection, the unit shall hold a public hearing on a properly filed and completed certificate of need application if three or more individuals or an individual representing an entity with five or more people submits a request, in writing, that a public hearing be held on the application. For a properly filed and completed certificate of need application involving a transfer of ownership of a large group practice, as described in subdivision (3) of subsection (a) of section 19a-638, when an offer was made in response to a request for proposal or similar voluntary offer for sale, a public hearing shall be held if twenty-five or more individuals or an individual representing twenty-five or more people submits a request, in writing, that a public hearing be held on the application. Any request for a public hearing shall be made to the

unit not later than thirty days after the date the unit determines the application to be complete.

(f) (1) The unit shall hold a public hearing with respect to each certificate of need application filed pursuant to section 19a-638 after December 1, 2015, that concerns any transfer of ownership involving a hospital. Such hearing shall be held in the municipality in which the hospital that is the subject of the application is located.

(2) The unit may hold a public hearing with respect to any certificate of need application submitted under this chapter. The unit shall provide not less than **[**two**]** three weeks' advance notice to the applicant, in writing, and the applicant shall provide not less than two weeks' advance notice to the public by publication **[**in a newspaper having a substantial circulation in the area served by the health care facility or provider**]** on the applicant's Internet web site in a clear and conspicuous location that is easily accessible by members of the public. In conducting its activities under this chapter, the unit may hold hearings with respect to applications of a similar nature at the same time.

(g) The unit may retain an independent consultant with expertise in the specific area of health care that is the subject of a pending application filed by an applicant if the review and analysis of an application cannot reasonably be conducted by the unit without the expertise of an industry analyst or other actuarial consultant. The unit shall submit bills for independent consultant services to the applicant. Such applicant shall pay such bills not later than thirty days after receipt of such bills. Such bills shall be a reasonable amount per application. The provisions of chapter 57, sections 4-212 to 4-219, inclusive, and section 4e-19 shall not apply to any retainer agreement executed pursuant to this subsection.

[(g)**]** (h) The executive director of the Office of Health Strategy may implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulation, provided the executive director holds a public hearing prior to implementing the policies and procedures and posts notice of intent to adopt regulations on the office's Internet web

site and the eRegulations System not later than twenty days after the date of implementation. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted.

Sec. 14. Section 19a-633 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(a) The executive director, or any agent authorized by such executive director to conduct any inquiry, investigation or hearing under the provisions of this chapter, shall have power to administer oaths and take testimony under oath relative to the matter of inquiry or investigation. At any hearing ordered by the unit, the executive director or such agent having authority by law to issue such process may subpoena witnesses and require the production of records, papers and documents pertinent to such inquiry. If any person disobeys such process or, having appeared in obedience thereto, refuses to answer any pertinent question put to such person by the executive director or such executive director's authorized agent or to produce any records and papers pursuant thereto, the executive director or such executive director's agent may apply to the superior court for the judicial district of Hartford or for the judicial district wherein the person resides or wherein the business has been conducted, or to any judge of said court if the same is not in session, setting forth such disobedience to process or refusal to answer, and said court or such judge shall cite such person to appear before said court or such judge to answer such question or to produce such records and papers.

(b) If the executive director or such agent has received information or has a reasonable belief that any person, health care facility or institution has violated or is violating any provision of this chapter, or any regulation or order of the unit, the executive director or such agent may issue a notice pursuant to this section. Such executive director or agent shall notify the person, health care facility or institution against whom such order is issued by first-class mail or personal service. The notice shall include: (1) A reference to the sections of the general statutes, regulations of Connecticut state agencies or orders alleged or believed

to have been violated; (2) a short and plain language statement of the matters asserted or charged; (3) a description of the activity alleged to have violated a statute or regulation identified pursuant to subdivision (1) of this subsection; (4) a statement concerning the right to a hearing of such person, health care facility or institution; and (5) a statement that such person, health care facility or institution may, not later than ten business days after receipt of such notice, make a request for a hearing on the matters asserted, to be sent to the executive director or such agent.

(c) The person, health care facility or institution to whom such notice is provided pursuant to subsection (b) of this section may, not later than ten business days after receipt of the notice, make written application to the Office of Health Strategy to request a hearing to demonstrate that such violation has not occurred, a certificate of need was not required, or each required certificate of need was obtained. A failure to make a timely request for a hearing shall result in the office issuing a cease and desist order. Each hearing held under this subsection shall be conducted as a contested case pursuant to chapter 54.

(d) If the office finds, by a preponderance of the evidence, following a hearing held under subsection (c) of this section that such person, health care facility or institution has violated or is violating any provision of this chapter, or any regulation or order of the unit, the office shall issue a final cease and desist order to such person, health care facility or institution. Such order shall be considered a final decision subject to appeal to the Superior Court in accordance with section 4-183.

(e) Any cease and desist order issued under this section may be enforced by the Attorney General pursuant to section 19a-642.

Sec. 15. Subsection (a) of section 19a-639f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2023*):

(a) The Health Systems Planning Unit of the Office of Health Strategy shall conduct a cost and market impact review in each case where (1) an

application for a certificate of need filed pursuant to section 19a-638 involves the transfer of ownership of a hospital, as defined in section 19a-639, and (2) the purchaser is a hospital, as defined in section 19a-490, whether located within or outside the state **[**, that had net patient revenue for fiscal year 2013 in an amount greater than one billion five hundred million dollars,**]** or a hospital system, as defined in section 19a-486i, whether located within or outside the state, **[**that had net patient revenue for fiscal year 2013 in an amount greater than one billion five hundred million dollars**]** or any person that is organized or operated for profit.

Sec. 16. (NEW) (*Effective October 1, 2023*) (a) For the purposes of this section and sections 17 and 18 of this act:

(1) "Covered drug" means a drug purchased by a 340B covered entity that is subject to the federal pricing requirements set forth in 42 USC 256b, as amended from time to time, or a drug that would be purchased by such covered entity but for the requirements, conditions and exclusions set forth in subsections (b) and (c) of this section or subsection (b) of section 17 of this act.

(2) "340B covered entity" means a provider participating in the federal 340B drug pricing program authorized by 42 USC 256b, as amended from time to time.

(3) "Drug manufacturer" means the following:

(A) An entity described in 42 USC 1396r-8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b; and

(B) A wholesaler described in 42 USC 1396r-8(k)(11) engaged in the distribution of covered drugs for an entity described in 42 USC 1396r-8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b.

(4) "Payer" means a pharmacy benefits manager.

(5) "Pharmacy benefits manager" has the same meaning as provided in section 38a-479aaa of the general statutes and includes a wholly or

partially owned or controlled subsidiary of a pharmacy benefits manager.

(6) "Specified pharmacy" means a pharmacy owned by, or under contract with, a 340B covered entity that is registered with the 340B discount drug purchasing program set forth in 42 USC 256b to dispense covered drugs on behalf of the 340B covered entity, whether in person or by mail.

(b) Any payer shall not impose any requirements, conditions or exclusions that:

(1) Discriminate against a 340B covered entity or a specified pharmacy in connection with dispensing covered drugs; and

(2) Prevent a 340B covered entity from retaining the benefit of discounted pricing for the purchase of covered drugs.

(c) Discrimination prohibited pursuant to subsection (b) of this section includes:

(1) Payment terms, reimbursement methodologies, or other terms and conditions that distinguish between covered drugs and other drugs, account for the availability of discounts under the 340B discount drug purchasing program set forth in 42 USC 256b in determining reimbursement or are less favorable than the payment or purchase terms or reimbursement methodologies for similarly situated entities that are not furnishing or dispensing covered drugs;

(2) Terms or conditions applied to 340B covered entities or specified pharmacies based on the furnishing or dispensing of covered drugs or their status as a 340B covered entity or specified pharmacy, including restrictions or requirements for participating in standard or preferred pharmacy networks or requirements related to the frequency or scope of audits;

(3) Requiring a 340B covered entity or specified pharmacy to identify, either directly or through a third party, covered drugs or covered drug

costs or other information not sought from other drug purchasers;

(4) Refusing to contract with or terminating a contract with a 340B covered entity or specified pharmacy, or otherwise excluding a 340B covered entity or specified pharmacy from a standard or preferred network, on the basis that such entity or pharmacy is a 340B covered entity or a specified pharmacy or for reasons other than those that apply equally to entities or pharmacies that are not 340B covered entities or specified pharmacies;

(5) Refusing to sell covered drugs to a 340B covered entity or specified pharmacy on the basis that such entity or pharmacy is a 340B covered entity or specified pharmacy or for reasons other than those that apply equally to entities or pharmacies that are not 340B covered entities or specified pharmacies;

(6) Retaliation against a 340B covered entity or specified pharmacy based on its exercise of any right or remedy under this section; and

(7) Interfering with an individual's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or via direct delivery, mail or other form of shipment.

(d) This section shall apply to self-insured employee welfare benefit plans, as defined in the federal Employee Retirement Income Security Act of 1974, as amended from time to time, administered through a pharmacy benefits manager.

(e) Notwithstanding any provision of title 38a of the general statutes and chapter 54 of the general statutes, to the extent that any contract provisions contained in a contract between a pharmacy benefits manager and a 340B covered entity entered into, amended or renewed after October 1, 2023, violates subsection (b) or (c) of this section, such contract provisions shall be void and unenforceable.

Sec. 17. (NEW) (*Effective October 1, 2023*) (a) A drug manufacturer shall comply with federal pricing requirements set forth in 42 USC 256b when selling covered drugs to 340B covered entities located in this state

and shall not impose any preconditions, limitations, delays or other barriers to the purchase of covered drugs that are not required under 42 USC 256b.

(b) Preconditions, limitations, delays or other barriers prohibited by subsection (a) of this section include:

(1) Implementation of policies or limitations that restrict the ability of 340B covered entities or specified pharmacies to dispense covered drugs, including restrictions on the number or type of locations through which covered drugs may be dispensed by or on behalf of a 340B covered entity;

(2) Conditioning the sale of covered drugs for 340B covered entities on enrollment with third-party vendors or on the sharing of claims information or other data;

(3) Charging 340B covered entities for covered drugs at amounts above the federal ceiling price, including policies that condition discounts on rebate requests;

(4) Interfering with an individual's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or via direct delivery, mail or other form of shipment;

(5) Delays in shipping covered drugs compared to drugs that are not discounted; and

(6) Retaliation against a 340B covered entity or specified pharmacy based on such entity's or pharmacy's exercise of any right or remedy under this section.

Sec. 18. (NEW) (*Effective October 1, 2023*) (a) A covered entity or the Attorney General may seek a temporary or permanent injunction and such other relief as may be appropriate to enjoin a pharmacy benefits manager or drug manufacturer from continuing to enforce contract provisions that violate the requirements set forth in subsections (b) and (c) of section 16 of this act or subsections (a) and (b) of section 17 of this

act. If the court determines that such violation or violations exist, the court may grant such injunctive relief and such other relief as justice may require and may set a time period within which such pharmacy benefits manager or drug manufacturer shall comply with any such order.

(b) Any appeal taken from any permanent injunction granted under subsection (a) of this section shall not stay the operation of such injunction unless the court is of the opinion that great and irreparable injury will be done by not staying the operation of such injunction.

Sec. 19. Section 19a-649 of the general statutes is amended by adding subsection (d) as follows (*Effective October 1, 2023*):

(NEW) (d) (1) As used in this subsection:

(A) "Ceiling price" means the maximum price a payer may be required to pay as provided in Section 340B(a)(1) of the Public Health Service Act, 42 USC 256b, as amended from time to time;

(B) "Covered outpatient drug" has the same meaning as provided in in Section 340B of the Public Health Service Act, 42 USC 256b, as amended from time to time;

(C) "Federal 340B drug pricing program" means the plan described in Section 340B of the Public Health Service Act, 42 USC 256b, as amended from time to time, that instructs the federal Secretary of Health and Human Services to enter into agreements with any manufacturer of covered outpatient drugs under which the amount paid to any manufacturer by certain statutorily defined covered entities does not exceed the 340B ceiling price;

(D) "Manufacturer" has the same meaning as provided in 42 USC 1396r-8(k)(5), as amended from time to time; and

(E) "Payer" means: (i) Any person, legal entity, governmental body or organization that meets the definition of "eligible organization" as provided in 42 USC 1395mm(b), as amended from time to time, except

for Medicare and Medicaid which purchases covered outpatient drugs under the federal 340B drug pricing program, or (ii) any legal entity whose membership includes not less than one payer or third-party payer.

(2) Not later than January 15, 2024, and annually thereafter, each hospital that participates in the federal 340B drug pricing program shall file the following information in such form and manner prescribed by the unit:

(A) A list of manufacturers from whom the hospital purchased covered outpatient drugs in the immediately preceding year as part of the federal 340B drug pricing program;

(B) A list of covered outpatient drugs, identified by the national drug code number, purchased from each manufacturer identified in subparagraph (A) of this subdivision, categorized by quantity, actual purchase price and ceiling price;

(C) The reimbursement amount by each payer for covered outpatient drugs, categorized by manufacturer, quantity, actual purchase price and ceiling price;

(D) The difference in cost for each covered outpatient drug, identified by such drug's national drug code number, due to the difference in the ceiling price or actual price paid, and the actual price paid by any patient or payer; and

(E) A summary providing how the difference in cost identified in subparagraph (D) of this subdivision was applied for the benefit of the community.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2023*	New section
Sec. 2	*October 1, 2023*	21a-254
Sec. 3	*from passage*	New section

Sec. 4	*October 1, 2023*	New section
Sec. 5	*October 1, 2023*	New section
Sec. 6	*October 1, 2023*	New section
Sec. 7	*October 1, 2023*	New section
Sec. 8	*October 1, 2023*	New section
Sec. 9	*from passage*	New section
Sec. 10	*October 1, 2023*	19a-754b(d)
Sec. 11	*July 1, 2023*	19a-508c
Sec. 12	*October 1, 2023*	19a-653
Sec. 13	*October 1, 2023*	19a-639a
Sec. 14	*October 1, 2023*	19a-633
Sec. 15	*October 1, 2023*	19a-639f(a)
Sec. 16	*October 1, 2023*	New section
Sec. 17	*October 1, 2023*	New section
Sec. 18	*October 1, 2023*	New section
Sec. 19	*October 1, 2023*	19a-649(d)

Statement of Legislative Commissioners:

In Section 2(j)(1), ", as such terms are defined in section 20-571," was inserted after "legend devices" for clarity; in Section 2(j)(17), "or "deprescribing"" was deleted for clarity; in Section 3(a), "for such medical condition" was inserted after "treatments" for clarity; in Section 3(b) "need" was inserted before "not be limited to" and "that are" was inserted before "based" for clarity; Section 4(5) was rewritten for consistency with standard drafting conventions; in Sections 5(b) and (i), "on a form that the commissioner shall provide" was changed to "in a form and manner prescribed by the commissioner" for consistency with standard drafting conventions; in Section 5(f), "department's" was changed to "Department of Consumer Protection's" for clarity; in Section 10(d)(2), "pursuant to subdivision (1) of this subsection" was deleted from the first line for conciseness; in Section 12(b)(1) "statute or regulation or settlement agreement" was changed to "statute, **[**or**]** regulation or settlement agreement", for clarity; and in Section 12(c), ", or (3) comply with enumerated conditions of an agreed settlement" was moved from the second sentence to the first sentence in the subsection, for accuracy and clarity.

PH *Joint Favorable Subst. -LCO*

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 24 $	FY 25 $
Comptroller	GF - Cost	Indeterminate	Indeterminate
Resources of the General Fund	GF - Potential Revenue Gain	At least 1.2 million	At least 1.2 million
Consumer Protection, Dept.	GF - Cost	761,601	516,266
State Comptroller - Fringe Benefits[1]	GF - Cost	79,903	81,900
Office of Health Strategy	GF - Cost	600,000	None
UConn Health Ctr.	GF - Potential Revenue Loss	7.3 million	7.3 million
UConn Health Ctr.	GF - Savings	At least 7 million	At least 7 million

Note: GF=General Fund

Municipal Impact: None

Explanation

Section 1 results in an undetermined cost to the Office of the State Comptroller (OSC) to participate in ArrayRx for the establishment of the Drug Discount Card Program.

Section 2 expands the state's prescription drug monitoring program[2]

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 42.82% of payroll in FY 24.

[2] The Prescription Monitoring Program collects prescription data for Schedule II through Schedule V drugs into a centralized database, the Connecticut Prescription Monitoring and Reporting System (CPMRS), which can then be used by healthcare providers and pharmacists in the active treatment of their patients. The purpose of the CPMRS is to present a complete picture of a patient's controlled substance use, including prescriptions by other providers.

to include legend and non-legend drugs and devices resulting in a cost of $761,601 in FY 24 and $516,266 in FY 25 to the Department of Consumer Protection (DCP), along with corresponding fringe benefit costs of $79,903 in FY 24 and $81,900 in FY 25. To meet the requirements of the bill DCP will have to hire three new employees[3], pay a one-time $250,000 cost to expand the current system, and pay annual ongoing maintenance costs of $325,000 per year.

Section 3 requires DCP, in consultation with UConn's School of Pharmacy, to submit a report detailing a framework to create an academic detailing program for certain medical staff participating in collaborative drug therapy management agreements resulting in no fiscal impact to the state.

Sections 4-8 require pharmaceutical representatives to be licensed by DCP resulting in an estimated annual revenue gain of $1.2 million per year. Approximately 2,200 initial applications are expected for this license and the annual application and renewal fee is $550.

Section 9 results in a cost of $600,000 to the Office of Health Strategy (OHS) in FY 24 to conduct, prepare, and submit a study and corresponding report of pharmacy benefits managers' practices of prescription drug distribution.

Section 10 requires the executive director of the Office of Health Strategy to prepare a preliminary list of outpatient prescription drugs that are deemed a substantial cost to the state or critical to public health, which results in no fiscal impact to the state.

Section 11 prohibits off-campus hospital-based facilities in Connecticut from charging a facility fee in most circumstances. This could result in a significant revenue loss to UConn Health Center beginning in FY 24.

UConn Health has six locations that would be prohibited from

[3] The three new positions consist of a planning analyst, health program assistant, and an office assistant.

charging facility fees unless allowed by a mutually agreed contract. It is estimated that the six facilities collect fees totaling $7.3 million annually.[4] Without contract terms allowing for a facility fee, UConn Health would be unable to collect these fees.

Section 12, which expands OHS's current regulatory authority of the Certificate of Need program, results in a potential revenue gain to the Resources of the General Fund to the extent that OHS imposes civil penalties on health care providers for not complying with the conditions set forth in the bill.

Section 13 allows OHS to retain an independent consultant for a pending Certificate of Need application, at the expense of the applicant, when the agency lacks the subject matter expertise, which results in no fiscal impact to the state.

Section 14 requires the Office of the Attorney General (OAG) to enforce Office of Health Strategy cease and desist orders as needed. This has no fiscal impact as enforcing orders for state agencies is current practice for OAG.

Section 15 expands the requirement of a Cost and Market Impact Review as part of the Certificate of Need application to apply to any hospital or health system acquisition. This does not result in a fiscal impact to the state because the agency already has the resources and expertise to process these applications.

Sections 16-19 regarding 340B entities result in an annual significant savings to the University of Connecticut Health Center. The health center has multiple 340B covered entities, including John Dempsey Hospital, and has not been fully benefiting from the provisions of the 340B program due to manufacturer and pharmacy benefits manager (PBM) practices. The health center estimates that the foregone savings due to these practices has reached approximately $7 million to $9 million annually. It is anticipated that the bill will reduce or eliminate

[4] Excluding facility fees from Medicare and Medicaid, which would continue to be exempted from facility fee limitations.

the practices it prohibits, and consequently result in greater 340B savings to UConn Health Center.

Section 18 allows any entity covered under the bill's provisions, or OAG, to take enforcement action based on the facts of the case and their resources. It also stipulates that if the court determines any violations have occurred, the court may award injunctive relief, or other forms of relief. This has no fiscal impact since there are no fines associated with this provision.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to the number of licenses applied for and inflation.

OLR Bill Analysis

sHB 6669

AN ACT PROTECTING PATIENTS AND PROHIBITING UNNECESSARY HEALTH CARE COSTS.

TABLE OF CONTENTS:

Requires OHS, in consultation with the Insurance Department, to evaluate and report on PBMs' prescription drug distribution practices in Connecticut and other states

§ 10 — DRUGS WITH SUBSTANTIAL COSTS TO THE STATE

Allows a wider range of drugs to be included on OHS's annual list of 10 drugs that are provided at substantial cost to the state, and gives manufacturers the opportunity, following a public comment period, to show that a drug does not meet inclusion criteria

§ 11 — FACILITY FEES

Makes various changes affecting hospital or health system facility fees, such as generally allowing providers to bill these fees only if the services are provided at a hospital campus, hospital emergency department, or freestanding emergency department

§§ 12-15 — CERTIFICATE OF NEED

Makes various changes to the CON program, such as (1) subjecting a person or facility to civil penalties for failing to comply with a settlement agreement; (2) allowing OHS to retain independent expert consultants when necessary in the CON review process; (3) allowing OHS to issue notices for suspected violations of the CON law and, following a hearing, issue cease and desist orders; and (4) expanding the circumstances under which OHS, through an independent consultant, must conduct a cost and market impact review of CON applications for hospital ownership transfers

§§ 16-19 — 340B PROGRAM

Makes various changes affecting participants in the federal 340B drug pricing program, such as (1) prohibiting PBMs from discriminating against 340B covered entities in connection with dispensing covered drugs, (2) requiring drug manufacturers to comply with specified federal pricing requirements when selling covered drugs to these entities, (3) allowing covered entities or the attorney general to seek court relief if a PBM seeks to enforce contract provisions that violate the bill, and (4) requiring hospitals that participate in the 340B program to annually report certain related information to OHS

SUMMARY

A section-by-section analysis follows.

EFFECTIVE DATE: Various, see below

§ 1 — DRUG DISCOUNT CARD PROGRAM

Requires the state comptroller to establish a Drug Discount Card Program for state residents and allows him to join with other states or a regional consortium to pool prescription drug purchasing power

This bill requires the state comptroller to establish the Drug Discount Card Program and make it available to all state residents. Through this program, the comptroller may cooperate with other U.S. states and territories or regional consortia to pool prescription drug purchasing power to do the following:

1. lower prescription drug costs;
2. negotiate discounts with drug manufacturers;
3. centralize drug purchasing; and
4. establish volume discount contracting (i.e., a negotiated drug purchase in a large quantity for a lower cost).

The bill requires the comptroller to adopt regulations to implement the program, including establishing program criteria and procedures. Regardless of the Uniform Administrative Procedure Act's (UAPA) regulation adoption process, in order to carry out the bill's purposes, the comptroller must issue policies and procedures to implement the program before adopting regulations. He must do so by January 1, 2024, and these policies and procedures have the force and effect of law.

The bill requires the comptroller, at least 15 days before the policies and procedures take effect, to post them on the comptroller's website and submit them to the Secretary of the State (SOTS) to be posted on the eRegulations system. A policy or procedure is no longer effective once the final regulation is adopted or, if the regulations have not been submitted to the Regulation Review Committee, on July 1, 2027, whichever occurs earlier.

EFFECTIVE DATE: October 1, 2023

§ 2 — PRESCRIPTION DRUG MONITORING PROGRAM EXPANSION

Expands the state's prescription drug monitoring program to include not just controlled substances but other prescription drugs, non-prescription drugs, and medical devices; makes related changes to the program, including (1) temporarily reducing the required reporting frequency for pharmacies and other dispensers and (2) adding to the information they must report

Under current law, the state's prescription drug monitoring program collects prescription data on most controlled substances into a centralized online database to prevent improper or illegal drug use or improper prescribing. Pharmacies and other dispensers must report certain information for inclusion in the database, such as the dispensing date, dispenser identification and prescription number, and certain patient identification data.

The bill expands the program to include other legend (i.e., prescription) drugs, non-legend drugs, and legend and non-legend devices. It also expands the program's statutory purposes to include improving prescribers' ability to identify medications that should be discontinued, deprescribed, or modified in the patient's best interest.

Additionally, the bill requires the program to collect transaction information for covered products that have been electronically deprescribed and sent to licensed pharmacies and nonresident pharmacies (i.e., an out-of-state pharmacy that ships prescription products into the state).

The bill makes several conforming changes to expand the program's scope to include all dispensed drugs and devices (legend and non-legend). In most respects, the bill extends current law's provisions to these other types of drugs and devices, such as:

1. excluding product samples dispensed by physicians and products dispensed to hospital inpatients;

2. procedures for prescribers to designate authorized agents, and pharmacists to designate pharmacy technicians, to review program information on their behalf; and

3. required Department of Consumer Protection (DCP) regulations.

The bill also generally extends to these other products current provisions on the confidentiality and allowable disclosures of program information (other than certain provisions that concern research on opioid abuse or controlled substance overdoses).

However, the bill does not extend to these other products current requirements for prescribing practitioners or their authorized agents to (1) review a patient's records in the program before prescribing more than a 72-hour supply of a controlled substance and (2) periodically review patient records on a specified schedule when prescribing controlled substances for continuous or prolonged treatment.

As described below, the bill also (1) temporarily reduces the required reporting frequency for pharmacies and other dispensers and (2) adds to the information they must report.

EFFECTIVE DATE: October 1, 2023

Reporting Frequency and Information

Current law requires pharmacists and most other dispensers to report to the program, in a DCP-approved electronic format, by the next business day after dispensing a covered drug. If the program is not operational, they must report by the next business day (i.e., the next day that the pharmacy is open) after regaining access to the program.

The bill gives pharmacists and most other dispensers more time to report to the program from October 1, 2023 (when these provisions take effect), through June 30, 2024. During that period, it requires them to report not less than weekly, in an electronic format or another DCP-approved format if the pharmacy does not maintain electronic records. Starting July 1, 2024, the bill reverts back to the current deadlines as described above (i.e., the next business day unless the program is not operational).

As under current law, the bill requires, both before and after July 1, 2024, that (1) veterinarians report at least weekly and (2) pharmacists and other dispensers report diabetes-related drugs and devices at least

daily. (The current program already reaches beyond controlled substances to include diabetes-related products.)

From October 1, 2023, through June 30, 2024, the bill specifically expands the program's scope to include drugs or devices dispensed by prescribing practitioners instead of just pharmacies as under current law. Starting October 1, 2023, it also adds the following to the information that must be reported: (1) prescribing practitioner's national provider identification number and (2) date the prescription (until June 30, 2024) or drug or device (starting July 1, 2024) was delivered to the patient.

§ 3 — ACADEMIC DETAILING PROGRAM FRAMEWORK

Requires the DCP commissioner, in consultation with UConn's School of Pharmacy, to submit a report that may include a framework to create an academic detailing program for physicians, APRNs, and pharmacists participating in collaborative drug therapy management agreements

The bill requires the DCP commissioner, in consultation with UConn's School of Pharmacy, to report to the Public Health Committee by January 1, 2025. The report may include a framework for establishing an academic detailing program for physicians, advanced practice registered nurses (APRNs), and pharmacists who participate in collaborative drug therapy management agreements (see *Background*). The bill defines "academic detailing" as the process of (1) identifying the best evidence-based practices for a particular medical condition and appropriate treatments and (2) giving this information to prescribing practitioners and qualified pharmacists participating in collaborative drug therapy management agreements to advance patient care.

Under the bill, the report must provide recommendations to ensure that these agreements' participants are aware of cost-effective treatments for patients based on current practice. It may include suggestions for cost-effective implementation and evaluation of an academic detailing program.

EFFECTIVE DATE: Upon passage

Background — Collaborative Drug Therapy Management Agreements

By law, certain pharmacists may enter into written protocol-based collaborative drug therapy agreements with physicians or APRNs (providers) to manage a patient's drug therapy and medical devices. These agreements can authorize a pharmacist to implement, continue, modify, discontinue, or deprescribe a drug therapy the provider prescribes; take similar actions for medical devices (except they may not modify them); order associated lab tests; and administer drugs. The agreements may include guideline-directed management rather than be patient-specific (CGS § 20-631).

§§ 4-8 — PHARMACEUTICAL REPRESENTATIVES

Requires pharmaceutical representatives to be licensed by DCP; establishes reporting requirements for licensees; allows DCP to adopt implementing regulations; requires these representatives to disclose certain information to prescribers when marketing prescription drugs, such as the wholesale acquisition cost; and prohibits them from taking certain actions, such as providing drug samples

The bill requires pharmaceutical representatives to be licensed by DCP and makes several related changes.

Under the bill, a "pharmaceutical representative" is anyone, such as a sales representative or medical science liaison, who markets, promotes, or gives legend drug information to prescribing practitioners and is employed or compensated by a pharmaceutical manufacturer.

A "pharmaceutical manufacturer" is anyone (including a virtual manufacturer) who directly or indirectly produces, prepares, cultivates, grows, propagates, compounds, converts, or processes controlled substances by natural substance extraction, chemical synthesis, or a combination, or packages or repackages controlled substance containers under the person's own name, trademark, or label to sell it.

Generally, existing law defines "virtual manufacturer" as anyone who (1) manufactures drugs, devices, or cosmetics for which the person owns certain rights through a contract with a manufacturing organization, but (2) is not involved in the physical manufacturing and does not physically possess the items at any time (CGS § 20-571).

EFFECTIVE DATE: October 1, 2023

Licensure Application and Renewals (§ 5(b)-(e))

The bill requires anyone seeking licensure as a pharmaceutical representative to (1) apply to DCP on a commissioner-provided form, (2) pay a nonrefundable $550 application fee, and (3) submit evidence of completing five hours of professional education requirements (see below). The commissioner must issue a license to anyone who meets these requirements.

Licenses may be renewed annually by June 30. The renewal fee is also $550, and renewal applicants must certify that they have met the bill's continuing education requirements.

The bill requires licensees to inform the commissioner within five business days after changing their name, address, or other licensure contact information.

Professional Education (§ 5(f)-(h))

The bill requires licensure or renewal applicants, before applying, to provide satisfactory evidence to the commissioner of having completed at least five hours of continuing professional education. This must include training in ethical standards, health equity, whistleblower protections, pharmaceutical marketing laws and regulations, and any other commissioner-approved training published on DCP's website. Applicants and licensees must (1) keep records of completing this training for at least three years after doing so and (2) give the records to DCP upon request.

Under the bill, continuing professional education training programs are subject to the commissioner's review and approval. The commissioner must publish a list of approved programs on the department's website.

Programs must meet the following standards:

1. they may not be provided by the applicant's or licensee's

employer;

2. they may not be funded by entities in the pharmaceutical industry or a third party paid by them; and

3. the provider must disclose any conflicts of interests, such as personal conflicts of interest that would interfere or prevent the provider from conducting the training honestly, objectively, and effectively.

Annual Reporting Requirement (§ 5(i))

The bill requires pharmaceutical representatives to annually report specified information to DCP for the previous calendar year, on a commissioner-prescribed form. They must report when renewing their license, or by July 31 if not renewing it. The reports must include:

1. the total number of contacts (see below) the licensee had with prescribing practitioners;

2. the names and specialties of these prescribing practitioners;

3. the location and length of each contact;

4. the name and a description of each legend drug marketed to each contact;

5. a description of each gift, voucher, coupon, or other compensation of any value given to prescribing practitioners or staff in their offices; and

6. any other information the commissioner requests.

For this purpose, a "contact" is any in-person, phone, email, text, or other electronic communication between a pharmaceutical representative and a prescribing practitioner to promote or provide information about a legend drug.

Disciplinary Actions (§ 5(j))

The bill allows the DCP commissioner to revoke, suspend, or annul a

pharmaceutical representative's license, after notice and a hearing, if the commissioner determines that the licensee (1) obtained the license by fraud or misrepresentation or (2) violated the provisions above or related implementing regulations.

Regulations and Policies and Procedures (§ 6)

The bill allows the DCP commissioner to adopt regulations implementing these licensure provisions. It also allows the commissioner, regardless of the UAPA's regulation adoption process, to issue policies and procedures before adopting regulations. These policies and procedures have the force and effect of law.

At least 15 days before the policies and procedures take effect, the commissioner must post them on DCP's website and submit them to SOTS for posting on the eRegulations system. A policy or procedure is no longer effective once the final regulation is adopted or, if the regulations have not been submitted to the Regulation Review Committee, on October 1, 2027, whichever occurs earlier.

Required Disclosures to Prescribers (§ 7)

The bill requires pharmaceutical representatives marketing legend drugs in Connecticut to disclose certain written information to prescribing practitioners at the time of each contact with them. Specifically, they must disclose the following information related to these drugs:

1. the drug's wholesale acquisition cost, based on its dose and quantity as described in the medication package insert;

2. the names of at least three drugs from the same, or a similar, therapeutic class for the disease or condition for which the marketed drug has federal Food and Drug Administration approval; and

3. information, if available, on whether the drug's effectiveness varies for different racial and ethnic groups.

Prohibited Actions; License Presentation (§ 8)

The bill prohibits pharmaceutical representatives from the following actions in relation to legend drugs:

1. engaging in any deceptive or misleading marketing practices, such as concealing, suppressing, omitting, misrepresenting, or misstating any material fact;

2. using a drug title or designation that could reasonably mislead prescribing practitioners or their employees or representatives; or

3. transporting or giving drug samples to prescribing practitioners or their employees or representatives.

The bill also requires pharmaceutical representatives to present a copy of their license at each visit to these people.

§ 9 — OHS STUDY OF PHARMACY BENEFIT MANAGERS

Requires OHS, in consultation with the Insurance Department, to evaluate and report on PBMs' prescription drug distribution practices in Connecticut and other states

The bill requires the Office of Health Strategy (OHS), in consultation with the Insurance Department, to report to the Insurance and Real Estate Committee by December 24, 2024.

The report must include (1) an analysis of pharmacy benefit managers' (PBMs) prescription drug distribution practices, including spread pricing arrangements, manufacturing rebates, and transparency and (2) an evaluation of PBMs' prescription drug distribution practices in other states. It must make recommendations to reduce consumers' prescription drug costs and regulate in-state PBMs.

EFFECTIVE DATE: Upon passage

Background — Related Bill

sSB 1159 (File 347), reported favorably by the Insurance and Real Estate Committee, requires the Insurance Department to report on similar subjects.

§ 10 — DRUGS WITH SUBSTANTIAL COSTS TO THE STATE

Allows a wider range of drugs to be included on OHS's annual list of 10 drugs that are provided at substantial cost to the state, and gives manufacturers the opportunity, following a public comment period, to show that a drug does not meet inclusion criteria

Existing law requires OHS, in consultation with the comptroller and the commissioners of public health and social services, to annually identify up to 10 outpatient prescription drugs that are provided at substantial state cost, considering their net cost, or critical to public health. Manufacturers of identified drugs must give OHS certain information on the (1) factors that led to an increase in the drug's wholesale acquisition cost and (2) company's research and development costs and other capital costs.

Current law establishes certain parameters for what drugs may be included on this list, requiring both a minimum (1) cost increase percentage over prior years and (2) total cost for a specified supply or course of treatment. As shown in the table below, the bill lowers the minimum required cost increase and total cost that qualifies for inclusion.

Table: Minimum Requirements for List of Outpatient Prescription Drugs

	Current Law	***The Bill***
Cost Increase	At least 20% over the prior year or 50% over the prior three years	At least 16% cumulatively during the prior two years
Cost for Course of Treatment	At least $60 for a 30-day supply or shorter course of treatment	At least $40 for a course of treatment of unspecified duration

Under current law, the drugs are evaluated based on their wholesale acquisition cost, minus all associated rebates paid to the state during the prior year. Presumably, these rebates are still factored in under the bill.

The bill requires the OHS executive director, before publishing the annual list, to prepare a preliminary list and make it available for public comment for at least 30 days. During that period, the manufacturer of any drug on the preliminary list may give OHS documentation showing that the drug's wholesale acquisition cost, less all rebates paid to the

state for it during the prior calendar year, did not exceed the bill's limits shown in the table above. If this documentation establishes this to the executive director's satisfaction, then she must remove the drug from the list before publishing the annual list. She must remove it within 15 days after the comment period closes.

EFFECTIVE DATE: October 1, 2023

§ 11 — FACILITY FEES

Makes various changes affecting hospital or health system facility fees, such as generally allowing providers to bill these fees only if the services are provided at a hospital campus, hospital emergency department, or freestanding emergency department

Current law limits when hospitals, health systems, and hospital-based facilities may charge facility fees for outpatient services provided off-site from a hospital campus. The bill makes various changes to these provisions, such as further limiting the locations where health care providers may charge facility fees and the procedures for which they charge them.

EFFECTIVE DATE: July 1, 2023

Definitions

Under current law, a "facility fee" is any fee a hospital or health system charges or bills for outpatient hospital services provided in a hospital-based facility that is (1) intended to compensate the hospital or health system for its operational expenses and (2) separate and distinct from the provider's professional fee. The bill specifies that this applies regardless of the treatment modality of the services.

For its facility fee provisions, the bill defines "health care provider" as an individual or entity, whether for-profit or nonprofit, that provides, bills for, or is paid for delivering health care services in the normal course of business, such as a hospital, health system, hospital-based facility, freestanding emergency department, and urgent care center.

These definitions apply to facility fee limits as well as other related provisions in existing law on patient notification requirements, billing statements, reporting, and related matters.

Facility Fee Limits

The bill allows health care providers to charge, bill for, or collect facility fees only for services provided (1) on a hospital's campus, (2) at a facility that includes a hospital emergency department, or (3) at freestanding emergency departments. The bill specifies that urgent care centers licensed as outpatient clinics are not freestanding emergency departments (which are part of licensed hospitals).

It prohibits health care providers from charging, billing for, or collecting facility fees for outpatient evaluation and management or assessment and management services. Current law has a generally similar limitation for hospitals, health systems, and hospital-based facilities for these services provided offsite from a hospital campus.

The bill allows OHS to annually identify outpatient diagnostic and imaging services that may reliably be provided safely and effectively in a non-hospital setting. It prohibits health care providers from charging, billing for, or collecting facility fees for these identified services.

The bill also subjects freestanding emergency departments to the above limits, removing an exemption from current law.

It removes a current limitation on hospitals, health systems, or hospital-based facilities charging more than the Medicare rate for outpatient services provided offsite from a hospital campus.

Despite the above limits, it allows hospitals or health systems to continue to collect insurance reimbursement for otherwise-prohibited facility fees if an insurance contract in effect on July 1, 2023, reimburses these fees. They may continue to do so until the earlier of the contract's expiration, renewal, or amendment.

Additionally, the bill allows certain hospitals to continue to collect Medicaid reimbursement for otherwise-prohibited facility fees, to the extent the Department of Social Services reimburses for them. They may do so for service dates from July 1, 2023, through June 20, 2026. This applies to (1) the John Dempsey Hospital at UConn Health Center and

(2) any hospital that is a party to the settlement agreement with the state approved under Special Act 19-1, December Special Session (DSS) (see *Background*).

As under current law, (1) the bill's facility fee limits do not apply to Medicare and Medicaid patients or those receiving services under a workers' compensation plan and (2) a provider that violates these fee prohibitions has committed an unfair trade practice (see *Background*).

Background — 2019 Settlement Agreement

SA 19-1, DSS, approved a settlement agreement between the state and the Connecticut Hospital Association and its member hospitals. The settlement resolved a dispute related to the state's hospital user fee (i.e., hospital provider tax). Generally, the hospitals alleged that they had received inadequate Medicaid supplement payments back from the state in comparison to their tax assessments.

Among other things, the settlement (1) refunded certain tax revenue to the hospitals; (2) reduced the amount of revenue to be collected from the "second hospital user fee" (i.e., the tax on inpatient and outpatient hospital services beginning July 1, 2017); and (3) increased Medicaid payments to hospitals for the covered period.

Background — Connecticut Unfair Trade Practices Act (CUTPA)

By law, CUTPA prohibits businesses from engaging in unfair and deceptive acts or practices. It allows the DCP commissioner to issue regulations defining an unfair trade practice, investigate complaints, issue cease and desist orders, order restitution in cases involving less than $10,000, enter into consent agreements, ask the attorney general to seek injunctive relief, and accept voluntary statements of compliance. It also allows individuals to sue. Courts may issue restraining orders; award actual and punitive damages, costs, and reasonable attorney's fees; and impose civil penalties of up to $5,000 for willful violations and up to $25,000 for a restraining order violation.

§§ 12-15 — CERTIFICATE OF NEED

Makes various changes to the CON program, such as (1) subjecting a person or facility to civil penalties for failing to comply with a settlement agreement; (2) allowing OHS to retain independent expert consultants when necessary in the CON review process; (3) allowing OHS to issue notices for suspected violations of the CON law and, following a hearing, issue cease and desist orders; and (4) expanding the circumstances under which OHS, through an independent consultant, must conduct a cost and market impact review of CON applications for hospital ownership transfers

Generally, existing law requires certain health care facilities to apply for and receive a certificate of need (CON) from OHS's Health Systems Planning Unit when proposing to (1) establish a new facility or provide new services, (2) change ownership, (3) purchase or acquire certain equipment, or (4) terminate certain services. The bill makes various changes to this process, primarily concerning OHS's enforcement authority and hiring of experts to assist in the CON review process.

EFFECTIVE DATE: October 1, 2023

Civil Penalties (§ 12)

Current law imposes a civil penalty of up to $1,000 per day for any person, health care facility, or institution (hereinafter, "person or facility") who willfully fails to (1) seek CON approval when required or (2) timely file required data or information under the CON law, other laws (such as those on nonprofit hospital conversions or various required filings with OHS), and related regulations and orders. The bill eliminates the current condition that the failure must be willful for the penalty to apply.

It also extends the penalty to any person or facility that has agreed to resolve a CON application through a settlement and fails to comply with any of the agreement's terms or conditions. It extends existing procedures (and related deadlines) to these penalties, such as prior notice, the right to a hearing, and the right to appeal. It similarly extends an existing provision that makes the failure to pay the penalty after the final assessment potentially lead to a deduction in Medicaid payments.

Application Notice (§ 13(b))

The bill eliminates the requirement that a CON applicant file prior notice in a newspaper with substantial circulation in the area. Instead, it

requires the applicant to file this notice on its website, in a clear and conspicuous location that is easily accessed by the public.

As under existing law, the notice must (1) briefly describe the project, (2) list its proposed location, and (3) be published for at least three consecutive days and no later than 20 days before filing the CON application.

Public Hearing Notice (§ 13(f))

Existing law requires the Health Systems Planning Unit to hold a public hearing for CON applications in certain circumstances; the unit has the discretion to hold hearings in other cases. The bill increases, from two to three weeks, the minimum required prior written notice that the unit must give to the applicant.

It eliminates a requirement that the unit publish a newspaper notice, and instead requires the applicant to publish notice on its website in a clear and conspicuous location easily accessed by the public. As under current law, this public notice must be made at least two weeks before the hearing.

Independent Consultants (§ 13(g))

Under the bill, if the unit cannot reasonably review and analyze a CON application without the expertise of an industry analyst or other actuarial consultant, it may retain an independent consultant for assistance. The consultant must have expertise in the specific health care area under review.

If the unit retains a consultant, it must bill the applicant for the person's services, and the applicant must pay within 30 days after receipt. These bills must be a reasonable amount per application.

The bill specifies that these retainer agreements are not subject to specified existing laws on (1) the Department of Administrative Services, (2) consultant and personal service agreements, and (3) methods for awarding state contracts.

Cease and Desist Orders (§ 14)

The bill allows the OHS executive director, or her agent, to issue a notice to any person or facility if she or her agent has received information or reasonably believes that the person or facility has violated or is violating the CON law, other related laws, or the unit's regulations or orders.

The executive director or agent must notify the person or facility by first-class mail or personal service. The notice must include the following:

1. a reference to the laws, regulations, or orders allegedly violated;
2. a short and plain language statement of the matter;
3. a description of the activity alleged to have violated a law or regulation; and
4. a statement on the person's or facility's right to a hearing and the deadline and manner to request one.

Under the bill, the person or facility has 10 business days after receiving the violation notice to request a hearing. To do so, they must apply in writing to the OHS executive director or her agent. At the hearing, the person or facility may attempt to demonstrate that (1) the violation did not occur, (2) a CON was not required, or (3) the required CON was obtained. The hearing must be conducted as a contested case proceeding under the UAPA.

OHS must issue a cease and desist order if (1) the person or facility does not request a hearing by the deadline or (2) after the hearing, OHS finds, by a preponderance of the evidence, that the violation occurred or is occurring. The order is a final decision and may be appealed to Superior Court under the UAPA. The attorney general may go to court to enforce the order.

Cost and Market Impact Review of Hospital Transfers (§ 15)

The bill expands the circumstances under which OHS's Health

Systems Planning Unit must conduct a cost and market impact review of CON applications that propose to transfer a hospital's ownership. It requires this review in all cases when the purchaser is a hospital or health system (in-state or otherwise), rather than only when the purchaser had net patient revenue exceeding $1.5 billion in FY 13 as under current law.

Existing law also requires this review in all CON applications to transfer a hospital's ownership to a for-profit purchaser.

By law, the unit must retain an independent consultant to conduct the review at the purchaser's expense (up to $200,000). The unit must complete a preliminary report and then, after giving the transacting parties time to respond, a final report. After the review, the unit must refer its final report to the attorney general for investigation if a transacting party currently or, after the transfer, will likely (1) have a dominant market share and (2) charge prices, or have health status adjusted total medical expenses, that are materially higher than the median for similar providers in the market.

§§ 16-19 — 340B PROGRAM

Makes various changes affecting participants in the federal 340B drug pricing program, such as (1) prohibiting PBMs from discriminating against 340B covered entities in connection with dispensing covered drugs, (2) requiring drug manufacturers to comply with specified federal pricing requirements when selling covered drugs to these entities, (3) allowing covered entities or the attorney general to seek court relief if a PBM seeks to enforce contract provisions that violate the bill, and (4) requiring hospitals that participate in the 340B program to annually report certain related information to OHS

Section 340B of the federal Public Health Service Act (i.e., the 340B Drug Pricing Program) requires drug manufacturers participating in Medicaid to sell certain outpatient prescription drugs ("covered drugs") at discounted prices to health care organizations that care for uninsured and low-income patients. These organizations include federally qualified health centers, children's hospitals, hospitals that serve a disproportionate number of low-income patients, and other safety net providers ("340B covered entities").

The bill prohibits pharmacy benefit managers (PBMs) from (1)

discriminating in certain ways against 340B covered entities or their specified pharmacies in connection with dispensing covered drugs and (2) preventing the 340B covered entities from keeping the benefit of the covered drugs' discounted prices. It applies to all PBMs and their subsidiaries.

The bill specifically requires certain drug manufacturers (including wholesalers) to comply with federal 340B pricing and sales requirements when selling covered drugs to 340B covered entities in Connecticut. It also prohibits them from imposing a precondition, limitation, delay, or other barrier to purchasing covered drugs beyond those required by federal law.

The above provisions on covered drugs apply to those that a 340B covered entity (1) purchases under the program and that are subject to the program's pricing requirements or (2) would purchase except for the prohibited conduct.

The bill allows covered entities, or the attorney general, to seek an injunction or other court relief to prevent PBMs or drug manufacturers from enforcing contract provisions that violate the bill's restrictions.

Lastly, the bill requires hospitals that participate in the 340B program to annually file certain related information with OHS's Health Systems Planning Unit.

EFFECTIVE DATE: October 1, 2023

Activities Constituting Discrimination by PBMs (§ 16)

The bill prohibits PBMs from imposing requirements, conditions, or exclusions that (1) discriminate against 340B covered entities or their specified pharmacies in connection with dispensing covered drugs and (2) prevent covered entities from keeping the benefit of the discounted pricing. ("Specified pharmacies" are those that the 340B covered entity owns or contracts with and that dispense drugs on the entity's behalf under the program, whether in person or by mail.)

For these purposes, discrimination includes the following:

1. payment terms, reimbursement methodologies, or other terms or conditions that (a) distinguish between covered and non-covered drugs, (b) consider the availability of 340B program discounts when determining reimbursement, or (c) are less favorable than the payment or purchase terms or reimbursement methods for similarly situated entities that are not furnishing or dispensing covered drugs;

2. terms or conditions for 340B covered entities or specified pharmacies based on their (a) furnishing or dispensing covered drugs or (b) status as a 340B covered entity or specified pharmacy, including restrictions or requirements for participating in certain pharmacy networks or audit frequency or scope;

3. requiring 340B covered entities or their specified pharmacies to (a) identify covered drugs or their costs or (b) provide information not sought from other drug purchasers;

4. refusing to contract, or ending a contract, with a 340B covered entity or specified pharmacy, or excluding either from a network, because of its status as a 340B covered entity or specified pharmacy or for any reasons other than those that apply equally to non-340B covered entities and pharmacies;

5. refusing to sell covered drugs to a 340B covered entity or specified pharmacy because of its status as such, or for reasons that do not apply equally to other entities and pharmacies;

6. retaliating against a 340B covered entity or specified pharmacy because it avails itself of a right or remedy under these provisions; and

7. interfering with a person's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or by direct delivery, mail, or other shipment method.

The bill specifies that these provisions apply to PBM-administered self-insured employee welfare benefit plans under the federal Employee Retirement Income Security Act.

For contracts between PBMs and 340B covered entities, the bill makes any contract provisions that violate the above restrictions void and unenforceable. This applies to contracts entered into, amended, or renewed after October 1, 2023, and despite the existing insurance laws and UAPA.

Prohibitions on Drug Manufacturers and Wholesalers (§ 17)

The bill specifically prohibits drug manufacturers subject to the 340B program's pricing rules, and their wholesalers, from imposing preconditions, limitations, delays, or other barriers on 340B covered entities purchasing covered drugs, unless they are required by federal law. The bill specifies that prohibited conduct includes the following:

1. implementing policies or limitations restricting 340B covered entities' or specified pharmacies' ability to dispense covered drugs, including restricting the number or type of locations that may dispense them;

2. conditioning the sale of covered drugs for 340B covered entities on enrollment with third-party vendors or sharing claims or other data;

3. charging 340B covered entities for covered drugs more than the federal ceiling price, including conditioning discounts on rebate requests;

4. interfering with a person's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or by direct delivery, mail, or other shipment method;

5. delaying covered drug shipments compared to non-discounted drugs; and

6. retaliating against a 340B covered entity or specified pharmacy

because it avails itself of a right or remedy under these provisions.

Injunction or Other Court Relief (§ 18)

The bill allows a covered entity or the attorney general to go to court seeking a temporary or permanent injunction and other appropriate relief to prevent a PBM or drug manufacturer (including a wholesaler) from continuing to enforce contract provisions that violate the bill. The bill allows a court, if it finds such a violation, to grant injunctive relief and other relief that justice may require. The court may set deadlines for compliance.

In these cases, if the PBM or manufacturer appeals, the injunction remains in effect unless the court determines that this would lead to great and irreparable injury.

Hospital Reporting (§ 19)

Starting by January 15, 2024, the bill requires hospitals participating in the 340B program to file certain information with the Health Systems Planning Unit, in a way set by the unit. This includes the following:

1. a list of manufacturers from whom the hospital purchased covered outpatient drugs under the program in the prior year;

2. a list of these drugs purchased from each manufacturer, identified by national drug code (NDC) number and categorized by quantity, actual purchase price, and ceiling price;

3. the reimbursement amount by each payer (other than Medicaid and Medicare) for these drugs, categorized by manufacturer, quantity, actual purchase price, and ceiling price;

4. the cost difference for each of these drugs (identified by NDC number) due to the difference in the ceiling price or actual price paid and the patient's or payer's actual price paid; and

5. a summary of how this cost difference was applied for the community's benefit.

COMMITTEE ACTION

Public Health Committee

Joint Favorable
Yea 25 Nay 12 (03/20/2023)