General Assembly **Substitute Bill No. 202**

*February Session, 2024*

* SB00202GL 030724 *

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

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

Section 1. Subsection (a) of section 21a-65 of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

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

21a-66 to purchase hypodermic needles and syringes but only for legitimate industrial or medical use within that business; and (7) to a syringe services program established pursuant to section 19a-124.

Sec. 2. Section 21a-70h of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

For the purposes of this section and sections 21a-70i to 21a-70k, as amended by this act:

(1) "Commissioner" means the Commissioner of Consumer Protection or the commissioner's authorized representative;

(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 or pharmacist, 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;

(5) "Pharmaceutical manufacturer" (A) means a **[**(A)**]** (i) person, whether within or without the boundaries of the state of Connecticut, that (I) produces, prepares, cultivates, grows, propagates, compounds, converts or processes a drug, **[**device or cosmetic,**]** directly or indirectly, by extraction from substances of natural origin, by means of chemical synthesis or by a combination of extraction and chemical synthesis, or **[**that**]** (II) packages, repackages, labels or relabels a drug container under such manufacturer's own trademark or label, or any other trademark or label, **[**or a drug, device or cosmetic**]** for the purpose of selling the drug, **[**device or cosmetic,**]** or **[**(B)**]** (ii) sterile compounding pharmacy, as defined in section 20-633b that dispenses sterile pharmaceuticals without a prescription or a patient-specific medical order intended for

use in humans, and (B) includes, but is not limited to, a virtual manufacturer, as defined in section 20-571;

**[**(6) "Pharmaceutical manufacturer" includes a virtual manufacturer, as defined in section 20-571;**]**

**[**(7)**]** (6) "Pharmaceutical marketing firm" means a pharmaceutical manufacturer that employs or compensates pharmaceutical representatives;

**[**(8)**]** (7) "Pharmaceutical representative" means any person, including, but not limited to, a sales representative, who markets, promotes or provides information regarding a legend drug for human use to a prescribing practitioner and is employed or compensated by a pharmaceutical manufacturer;

**[**(9)**]** (8) "Pharmacist" has the same meaning as provided in section 20-571; and

**[**(10)**]** (9) "Prescribing practitioner" has the same meaning as provided in section 20-571.

Sec. 3. Section 21a-70i of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) On and after October 1, 2023, a pharmaceutical manufacturer that employs **[**an individual to perform the duties of**]** a pharmaceutical **[**sales**]** representative shall register annually with the department as a pharmaceutical marketing firm, in a form and manner prescribed by the commissioner. No pharmaceutical manufacturer shall authorize an individual to perform **[**such**]** the duties of a pharmaceutical representative on such manufacturer's behalf unless such manufacturer has obtained a pharmaceutical marketing firm registration from the department pursuant to this section. Registrations issued pursuant to this section shall expire annually on June thirtieth.

(b) The nonrefundable fee for registration as a pharmaceutical marketing firm and for annual renewal of such registration shall be one hundred fifty dollars. Any pharmaceutical marketing firm that fails to renew its registration on or before June thirtieth shall pay a late fee of one hundred dollars for each year that such firm did not renew, in addition to the annual renewal fee required under this section.

(c) On the date of its initial registration, and annually thereafter, each pharmaceutical marketing firm shall provide to the department a list of all **[**individuals**]** pharmaceutical representatives employed or compensated by such firm. **[**as a pharmaceutical sales representative.**]** Each pharmaceutical marketing firm shall notify the department, in a form and manner prescribed by the commissioner, of each individual who is no longer employed or compensated as a pharmaceutical **[**sales**]** representative or who was hired or compensated as a pharmaceutical representative after the date on which such firm provided such annual list, not later than two weeks after such individual leaves employment or was hired or otherwise compensated.

(d) The department shall prominently post on its Internet web site the most recent list provided by each pharmaceutical marketing firm pursuant to subsection (c) of this section.

(e) Any person who is not identified to the department pursuant to subsection (c) of this section shall not perform the duties of a pharmaceutical **[**sales**]** representative on behalf of the pharmaceutical marketing firm. **[**for any prescribing practitioner in this state.**]**

(f) Not later than July 1, 2024, and annually thereafter, each pharmaceutical marketing firm shall provide the commissioner with the following information regarding the performance for the previous calendar year of each of its pharmaceutical **[**sales**]** representatives identified to the department pursuant to subsection (c) of this section at any time during the previous calendar year, in a form and manner prescribed by the commissioner:

(1) The aggregate number of contacts such pharmaceutical **[**sales**]** representative had with prescribing practitioners and pharmacists;

(2) The specialty of **[**each**]** such prescribing practitioner and each pharmacist with whom such pharmaceutical **[**sales**]** representative made contact;

(3) Whether product samples, materials or gifts of any value were provided to a prescribing practitioner or such practitioner's staff in a prescribing practitioner's office or to a pharmacist; and

(4) An aggregate report of all free samples, by drug name and strength, in a form and manner prescribed by the commissioner.

(g) The department shall annually **[**analyze the information submitted pursuant to this section and**]** compile a report on the activities of pharmaceutical **[**sales representatives**]** marketing firms in the state. Not later than December **[**1**]** 31, 2024, and annually thereafter, the department shall post such report on its Internet web site and submit such report to the Secretary of the Office of Policy and Management.

Sec. 4. Section 21a-70j of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

Each pharmaceutical marketing firm that employs or compensates a pharmaceutical representative who is engaged in marketing, promoting or providing information regarding a legend drug **[**marketing**]** for human use in this state shall **[**disclose**]** ensure that such pharmaceutical representative discloses, in writing, to a prescribing practitioner or pharmacist, **[**at the**]** each time **[**of each**]** such pharmaceutical representative makes contact with **[**such**]** the prescribing practitioner or pharmacist: **[**, the following information:**]**

(1) The list price of a legend drug when such pharmaceutical representative provides information concerning **[**such**]** the legend drug to **[**the**]** such prescribing practitioner or pharmacist based on the dose

and quantity of such legend drug as described in the medication package insert; and

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

Sec. 5. Section 19a-17d of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

If a **[**pharmacist or**]** health care professional who is currently licensed or was previously licensed in another state or jurisdiction is subject to automatic reciprocal discipline for a disciplinary action in such state or jurisdiction, such automatic reciprocal discipline shall be automatically rescinded and shall not be entered into the licensing record of the **[**pharmacist or**]** health care professional if the discipline was based solely on the termination of pregnancy under conditions that would not violate the general statutes or the regulations of Connecticut state agencies. The provisions of this section shall not preclude or affect the ability of an agency or board of the state to seek or impose any discipline pursuant to the general statutes against a **[**pharmacist or other**]** health care professional licensed by the state.

Sec. 6. Subsection (a) of section 21a-70k of the 2024 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The commissioner may (1) refuse to authorize the issuance or renewal of a registration to operate as a pharmaceutical marketing firm, (2) revoke, suspend or place conditions on a registration to operate as a pharmaceutical marketing firm, and (3) assess a penalty of up to one thousand dollars for each violation of any provision of section 21a-70i, as amended by this act, or 21a-70j, as amended by this act, or take other action permitted by **[**subdivision (7) of subsection (a) of section 21a-7**]** section 21a-11, if the applicant or holder of the registration fails to comply with the requirements set forth in section 21a-70i, as amended

by this act, or 21a-70j, as amended by this act.

Sec. 7. Section 21a-322 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The **[**commissioner**]** Commissioner of Consumer Protection may suspend, revoke or refuse to renew a registration, place a registration on probation, place conditions on a registration and assess a civil penalty of not more than one thousand dollars per violation of this chapter, for sufficient cause. Any of the following shall be sufficient cause for such action by the commissioner: (1) The furnishing of false or fraudulent information in any application filed under this chapter; (2) conviction of a crime under any state or federal law relating to the registrant's profession, controlled substances or drugs or fraudulent practices, including, but not limited to, fraudulent billing practices; (3) failure to maintain effective controls against diversion of controlled substances into other than duly authorized legitimate medical, scientific, or commercial channels; (4) the suspension, revocation, expiration or surrender of the practitioner's federal controlled substance registration; (5) prescribing, distributing, administering or dispensing a controlled substance in schedules other than those specified in the practitioner's state or federal registration or in violation of any condition placed on the practitioner's registration; (6) suspension, revocation, expiration, surrender or other disciplinary action taken against any professional license or registration held by the practitioner; (7) abuse or excessive use of drugs; (8) possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose; (9) a practitioner's failure to account for disposition of controlled substances as determined by an audit of the receipt and disposition records of said practitioner; (10) failure to keep records of medical evaluations of patients and all controlled substances dispensed, administered or prescribed to patients by a practitioner; (11) failure to establish and implement administrative safeguards for the protection of electronic protected health information pursuant to 45 CFR 164.308, as amended from time to time; and (12)

breach of any such safeguards by a prescribing practitioner's authorized agent.

(b) If a practitioner dispenses, administers or prescribes any controlled substance to a patient, the practitioner shall make available to the Department of Consumer Protection, for inspection by the department, records of medical evaluations associated with dispensing, administering or prescribing such controlled substance. Such records shall be confidential and not be subject to disclosure under the Freedom of Information Act, as defined in section 1-200. The department may inspect such records solely for the purpose of investigating any violation or suspected violation, or enforcing any provision, of this chapter or any regulation promulgated under this chapter. Nothing in this subsection shall be construed to require disclosure of any substance abuse treatment record that is protected from disclosure under 42 USC 290dd-2, as amended from time to time, or other applicable federal law.

Sec. 8. Subparagraphs (A) and (B) of subdivision (10) of subsection (j) of section 21a-254 of the general statutes are repealed and the following is substituted in lieu thereof (*Effective from passage*):

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

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

| This act shall take effect as follows and shall amend the following sections: | | |
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| Section 1 | *from passage* | 21a-65(a) |
| Sec. 2 | *from passage* | 21a-70h |
| Sec. 3 | *from passage* | 21a-70i |
| Sec. 4 | *from passage* | 21a-70j |
| Sec. 5 | *from passage* | 19a-17d |

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| Sec. 6 | *from passage* | 21a-70k(a) |
| Sec. 7 | *from passage* | 21a-322 |
| Sec. 8 | *from passage* | 21a-254(j)(10)(A) and (B) |

***Statement of Legislative Commissioners:***
In Section 7(b), ", as amended from time to time," was added for consistency with standard drafting conventions.

***GL*** *Joint Favorable Subst.*