



Senate

General Assembly

File No. 74

February Session, 2024

Substitute Senate Bill No. 202

Senate, March 21, 2024

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

AN ACT CONCERNING 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:

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2 the general statutes is repealed and the following is substituted in lieu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

4 (a) A licensed manufacturer or licensed wholesaler may sell
5 hypodermic needles and syringes only to the following: (1) To a licensed
6 manufacturer, licensed wholesaler or licensed pharmacy; (2) to [a] an
7 advanced practice registered nurse, dentist, embalmer, optometrist,
8 physician, [dentist,] physician assistant, podiatrist, scientific
9 investigator or veterinarian [, embalmer, podiatrist or scientific
10 investigator] licensed to practice in this state; (3) to a person in charge of
11 a care-giving institution, as defined in section 20-571, incorporated
12 college or scientific institution, but only for use by or in such care-giving
13 institution, college or institution for medical or scientific purposes; (4)

14 to a person in charge of a licensed or registered laboratory, but only for
15 use in that laboratory for scientific and medical purposes; (5) to a farmer
16 but only for use on the farmer's own animals or poultry; (6) to a business
17 authorized in accordance with the regulations adopted under section
18 21a-66 to purchase hypodermic needles and syringes but only for
19 legitimate industrial or medical use within that business; and (7) to a
20 syringe services program established pursuant to section 19a-124.

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22 is repealed and the following is substituted in lieu thereof (*Effective from*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

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

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

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

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

34 (4) "Legend drug" has the same meaning as provided in section 20-
35 571;

36 (5) "Pharmaceutical manufacturer" (A) means a [(A)] (i) person,
37 whether within or without the boundaries of the state of Connecticut,
38 that (I) produces, prepares, cultivates, grows, propagates, compounds,
39 converts or processes a drug, [device or cosmetic,] directly or indirectly,
40 by extraction from substances of natural origin, by means of chemical
41 synthesis or by a combination of extraction and chemical synthesis, or
42 [that] (II) packages, repackages, labels or relabels a drug container under
43 such manufacturer's own trademark or label, or any other trademark or
44 label, [or a drug, device or cosmetic] for the purpose of selling the drug,

45 [device or cosmetic,] or [(B)] (ii) sterile compounding pharmacy, as
46 defined in section 20-633b that dispenses sterile pharmaceuticals
47 without a prescription or a patient-specific medical order intended for
48 use in humans, and (B) includes, but is not limited to, a virtual
49 manufacturer, as defined in section 20-571;

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

52 [(7)] (6) "Pharmaceutical marketing firm" means a pharmaceutical
53 manufacturer that employs or compensates pharmaceutical
54 representatives;

55 [(8)] (7) "Pharmaceutical representative" means any person,
56 including, but not limited to, a sales representative, who markets,
57 promotes or provides information regarding a legend drug for human
58 use to a prescribing practitioner and is employed or compensated by a
59 pharmaceutical manufacturer;

60 [(9)] (8) "Pharmacist" has the same meaning as provided in section 20-
61 571; and

62 [(10)] (9) "Prescribing practitioner" has the same meaning as provided
63 in section 20-571.

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

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

76 this section shall expire annually on June thirtieth.

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

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

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

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

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

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

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

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

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

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

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

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

135 (1) The list price of a legend drug when such pharmaceutical
136 representative provides information concerning [such] the legend drug
137 to [the] such prescribing practitioner or pharmacist based on the dose
138 and quantity of such legend drug as described in the medication

139 package insert; and

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

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

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

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

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

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

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

204 (b) If a practitioner dispenses, administers or prescribes any
205 controlled substance to a patient, the practitioner shall make available
206 to the Department of Consumer Protection, for inspection by the
207 department, records of medical evaluations associated with dispensing,
208 administering or prescribing such controlled substance. Such records
209 shall be confidential and not be subject to disclosure under the Freedom
210 of Information Act, as defined in section 1-200. The department may
211 inspect such records solely for the purpose of investigating any violation
212 or suspected violation, or enforcing any provision, of this chapter or any
213 regulation promulgated under this chapter. Nothing in this subsection
214 shall be construed to require disclosure of any substance abuse
215 treatment record that is protected from disclosure under 42 USC 290dd-
216 2, as amended from time to time, or other applicable federal law.

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

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

234 (B) Notwithstanding the provisions of subparagraph (A) of this
235 subdivision, a prescribing practitioner who is employed by or provides
236 professional services to a hospital shall, prior to designating an

237 authorized agent to review the electronic prescription drug monitoring
 238 program and patient controlled substance prescription information on
 239 behalf of the prescribing practitioner, (i) submit a request to designate
 240 one or more authorized agents for such purposes and a written protocol
 241 for oversight of the authorized agent or agents to the commissioner, in
 242 the form and manner prescribed by the commissioner, and (ii) receive
 243 the commissioner's approval to designate such authorized agent or
 244 agents and of such written protocol. Such written protocol shall
 245 designate either the hospital's medical director, a hospital department
 246 head, who is a prescribing practitioner, or another prescribing
 247 practitioner as the person responsible for ensuring that the authorized
 248 agent's or agents' access to such program and patient controlled
 249 substance prescription information is limited to the purposes described
 250 in this section and occurs in a manner that protects the confidentiality
 251 of information that is accessed through such program. A hospital
 252 medical director, a hospital department head, who is a prescribing
 253 practitioner, or another prescribing practitioner designated as the
 254 person responsible for overseeing an authorized agent's or agents'
 255 access to such program and information in the written protocol
 256 approved by the commissioner may be subject to disciplinary action for
 257 acts of the authorized agent or agents as provided in subsection (a) of
 258 section 21a-322, as amended by this act. The commissioner may inspect
 259 hospital records to determine compliance with written protocols
 260 approved in accordance with this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	21a-65(a)
Sec. 2	<i>from passage</i>	21a-70h
Sec. 3	<i>from passage</i>	21a-70i
Sec. 4	<i>from passage</i>	21a-70j
Sec. 5	<i>from passage</i>	19a-17d
Sec. 6	<i>from passage</i>	21a-70k(a)
Sec. 7	<i>from passage</i>	21a-322
Sec. 8	<i>from passage</i>	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.*

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:** None**Municipal Impact:** None**Explanation**

The bill makes various changes to prescription drug control statutes resulting in no fiscal impact to the state or municipalities.

The Out Years**State Impact:** None**Municipal Impact:** None

OLR Bill Analysis**sSB 202*****AN ACT CONCERNING THE DEPARTMENT OF CONSUMER PROTECTION'S RECOMMENDATIONS REGARDING PRESCRIPTION DRUG CONTROL.*****SUMMARY**

This bill allows the direct sale of hypodermic needles to certain health care professionals and amends certain provisions on pharmacists, pharmaceutical marketing firms and representatives, and controlled substances.

The bill authorizes licensed manufacturers and wholesalers to sell hypodermic needles and syringes directly to licensed advanced practice registered nurses, optometrists, and physician assistants, in addition to the other professions and groups already covered by existing law.

The bill eliminates the requirement for the Department of Consumer Protection (DCP) to analyze the information submitted to it while compiling a report on the activities of pharmaceutical marketing firms.

Among other changes regarding these firms, the bill requires each pharmaceutical marketing firm that employs or compensates pharmaceutical representatives to ensure that each representative discloses to prescribing practitioners and pharmacists certain information, such as the drug price, each time they contact them about legend drugs. Under current law, this is the responsibility of the pharmaceutical representatives themselves.

The bill eliminates an overlapping prohibition on automatic reciprocal discipline of pharmacists who assist in the termination of a pregnancy. Under existing law automatic reciprocal discipline of a pharmacist must be automatically rescinded if the other state's

discipline was solely for the termination of a pregnancy under conditions that would not violate Connecticut law.

The bill requires a person permitted to distribute or dispense controlled substances in Connecticut to make certain medical evaluation records available to DCP for inspection for the purpose of enforcing existing law. It does not require the disclosure of any substance abuse treatment record that is protected from disclosure under federal law.

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

EFFECTIVE DATE: Upon passage

§ 1 — HYPODERMIC NEEDLES AND SYRINGES

Under existing law, licensed manufacturers and wholesalers are permitted to sell hypodermic needles and syringes directly to licensed physicians, dentists, veterinarians, embalmers, podiatrists, and scientific investigators, in addition to certain other people and entities.

The bill also authorizes licensed manufacturers and wholesalers to sell these items directly to licensed advanced practice registered nurses, optometrists, and physician assistants.

§§ 2-4 & 6 — PHARMACEUTICAL MARKETING FIRMS

Under existing law, pharmaceutical marketing firms that employ pharmaceutical representatives must annually give DCP (1) a list of all pharmaceutical representatives they employ and (2) certain information about these representatives' activities.

The bill specifies that a "pharmaceutical marketing firm" includes entities that compensate pharmaceutical representatives, not just those who employ them as under current law. Existing law already defines a "pharmaceutical representative" as someone, including a sales representative, who markets, promotes, or provides information on legend drugs to prescribing practitioners and is employed or compensated by a pharmaceutical manufacturer.

The bill specifically requires firms to include people compensated as

pharmaceutical representatives, not just employed, by the firm in the list of pharmaceutical representatives that they are required to submit annually to DCP, and makes related conforming changes.

The bill eliminates the requirement that DCP analyze the information submitted to it while compiling an annual report on the activities of pharmaceutical marketing firms. The bill also delays, from December 1 to December 31, 2024, the due date for DCP to post the first report online and submit it to the Office of Policy and Management.

The bill requires each pharmaceutical marketing firm that employs or compensates pharmaceutical representatives to ensure that each representative discloses to prescribing practitioners and pharmacists certain information each time they make contact about legend drugs. Under current law, this requirement is the responsibility of the individual pharmaceutical representatives. That information is:

1. the drug's list price; and
2. the variation efficacy of the drug marketed to different racial and ethnic groups, if it is available.

§ 5 — AUTOMATIC RECIPROCAL DISCIPLINE OF PHARMACISTS

The bill eliminates an overlapping prohibition on automatic reciprocal discipline of pharmacists who were disciplined in another state solely for assisting in the termination of a pregnancy.

Two 2023 laws enacted similar provisions providing that such a pharmacist must not be subject to automatic reciprocal discipline in Connecticut based on another jurisdiction's discipline solely for the termination of a pregnancy that would not violate Connecticut law. The bill eliminates one of these overlapping provisions and keeps the other.

§ 7 — INSPECTION OF MEDICAL EVALUATION RECORDS ASSOCIATED WITH CONTROLLED SUBSTANCES

The bill requires a person licensed, registered, or otherwise permitted to distribute or dispense controlled substances in Connecticut to make medical evaluation records associated with the dispensing,

administering, or prescribing of controlled substances available to DCP for inspection. These medical evaluation records are confidential and are not subject to disclosure under the Freedom of Information Act. DCP is limited to inspecting these records only when they are investigating, or conducting an enforcement action, of a violation or suspected violation, relating to the registration of controlled substances.

The bill does not require the disclosure of any substance abuse treatment record that is protected from disclosure under federal law.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute

Yea 22 Nay 0 (03/07/2024)