



General Assembly

February Session, 2024

Raised Bill No. 202

LCO No. 1642



Referred to Committee on GENERAL LAW

Introduced by:
(GL)

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2 the general statutes is repealed and the following is substituted in lieu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22 is repealed and the following is substituted in lieu thereof (*Effective from*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 (II) [that] 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 a legend
129 drug [marketing] in this state shall [disclose] ensure that such
130 pharmaceutical representative discloses, in writing, to a prescribing
131 practitioner or pharmacist, [at the] each time [of each] such
132 pharmaceutical representative makes contact with [such] the
133 prescribing practitioner or pharmacist; [, the following information:]

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

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

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

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142 is repealed and the following is substituted in lieu thereof (*Effective from*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

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148 rescinded and shall not be entered into the licensing record of the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

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

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

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

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

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

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

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

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

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

To: (1) Allow a licensed manufacturer or wholesaler to sell a hypodermic needle or syringe to an advanced practice registered nurse, optometrist or physician assistant; (2) redefine "commissioner", "pharmaceutical manufacturer" and "pharmaceutical marketing firm" for the purposes of various statutes concerning pharmaceutical marketing; (3) eliminate a requirement that the Department of Consumer Protection annually analyze certain information submitted to the department concerning pharmaceutical marketing; (4) extend the date by which the department is required to submit an annual report concerning pharmaceutical marketing; (5) eliminate an overlapping prohibition concerning automatic reciprocal discipline of pharmacists; (6) modify the actions the Commissioner of Consumer Protection may take following a violation of certain statutes concerning pharmaceutical marketing; (7) require certain practitioners that dispense, administer or prescribe controlled substances to make certain records available to the department; and (8) make minor, technical and conforming changes to various statutes concerning prescription drug control.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]