



Senate

General Assembly

File No. 495

January Session, 2015

Substitute Senate Bill No. 998

Senate, April 7, 2015

The Committee on Public Health reported through SEN. GERRATANA of the 6th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING PRESCRIPTION DRUGS.

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

1 Section 1. Section 21a-90 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2015*):

3 (a) For the purposes of this section:

4 (1) "Counterfeit drug or device" means a drug, as defined in section
5 21a-92, or a "device", as defined in section 21a-92, or the container or
6 labeling of which, that without authorization, bears the trademark,
7 trade name or other identifying mark, imprint, number or device, or
8 any likeness thereof, of a manufacturer, distributor or dispenser other
9 than the person or persons who in fact manufactured, distributed or
10 dispensed such drug or device and that thereby falsely purports or is
11 represented to be the drug or device of, or to have been distributed by,
12 such other manufacturer, distributor or dispenser; and

13 (2) "Department" means the Department of Consumer Protection.

14 (b) No person shall knowingly import or reimport into the state,
15 purchase for resale, sell, offer for sale, dispense, as defined in section
16 20-571, or deliver in any manner a counterfeit drug or device.

17 (c) The department shall conduct any necessary investigation
18 regarding possible violations of this section. In connection with any
19 such investigation, the commissioner, or the commissioner's
20 authorized agent, may administer oaths, issue subpoenas, compel
21 testimony and order the production of books, records and documents.
22 If any person refuses to appear, to testify or to produce any book,
23 record or document when so ordered, a judge of the Superior Court
24 may make such order as may be appropriate to aid in the enforcement
25 of this section.

26 (d) The commissioner may conduct hearings regarding violations of
27 this section. Such hearings shall be conducted in accordance with
28 chapter 54. In connection with any such hearing, the commissioner
29 may administer oaths, issue subpoenas, compel testimony and order
30 the production of books, records and documents. If any person refuses
31 to appear, testify or produce any book, record or document when so
32 ordered, a judge of the Superior Court may make such order as may be
33 appropriate to aid in the enforcement of this section.

34 (e) For any violation of this section, the commissioner may:

35 (1) Suspend, revoke, refuse to renew, or place on probationary
36 status a license or registration issued by the department;

37 (2) Assess a civil penalty of not more than one thousand dollars per
38 violation;

39 (3) Issue an appropriate order to any person found to be in violation
40 of this section to provide for the immediate discontinuance of the
41 violation; and

42 (4) Issue an appropriate order to any person found to be in violation
43 of this section, requiring the person to make restitution for any damage
44 caused by the violation.

45 (f) The commissioner may adopt regulations, in accordance with
46 chapter 54, to implement the provisions of this section.

47 (g) Any person who violates any provision of this section shall be
48 fined not more than ten thousand dollars or imprisoned not more than
49 one year, or both, for each violation.

50 Sec. 2. (NEW) (*Effective October 1, 2015*) Any prescribing practitioner,
51 as defined in section 20-14c of the general statutes, who violates the
52 provisions of subsection (b) of section 21a-90 of the general statutes, as
53 amended by this act, shall be subject to disciplinary action pursuant to
54 section 19a-17 of the general statutes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2015</i>	21a-90
Sec. 2	<i>October 1, 2015</i>	New section

Statement of Legislative Commissioners:

In Section 2, ", as amended by this act," was added for consistency with standard drafting conventions.

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

The bill results in no cost to the state as few enforcement actions for violations of the provisions of subsection (b) of section 21a-90 of the general statutes, as amended by the bill are anticipated within the Department of Consumer Protection.

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

OLR Bill Analysis**sSB 998*****AN ACT CONCERNING PRESCRIPTION DRUGS.*****SUMMARY:**

This bill expands current prohibitions concerning counterfeit drugs and devices to include knowingly dispensing, importing, or reimporting into the state such drugs or devices. The law already prohibits knowingly purchasing for resale, selling, offering for sale, or delivering these items.

By law, a “counterfeit drug or device” is a drug or device, or its container or label that, without authorization, (1) bears the trademark, trade name, or other identifying mark, imprint, number or device, or likeness of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance and (2) falsely claims or represents the drug or substance to have been distributed by the other manufacturer, distributor, or dispenser.

The bill subjects violators to both criminal and civil penalties, including, for each violation, a maximum (1) criminal fine of \$10,000, one year imprisonment, or both, or (2) civil fine of \$1,000. It also allows the Department of Consumer Protection (DCP) commissioner to investigate and take various disciplinary actions (see BACKGROUND).

The bill also provides that any prescribing practitioner who takes any of the bill’s or current law’s prohibited actions, is subject to certain Department of Public Health (DPH) disciplinary actions, including a maximum civil fine of \$25,000 (see BACKGROUND).

EFFECTIVE DATE: October 1, 2015

BACKGROUND***Disciplinary Actions***

DCP. By law, DCP can take the following actions against anyone who knowingly violates the counterfeit drug or device law:

1. suspend, revoke, refuse to renew, or place on probation a DCP license or registration;
2. assess up to a \$1,000 civil penalty for each violation;
3. issue a cease and desist order; or
4. issue an order of restitution (CGS § 21a-90).

DPH. By law, DPH can take, among others, the following disciplinary actions:

1. suspending or revoking the person's DPH certification,
2. issuing a letter of reprimand to or censuring the person,
3. placing him or her on probation,
4. assessing a civil penalty of up to \$ 25,000, or
5. taking summary action against the violator's DPH certification if the person has been found guilty of a state or federal felony or is subject to disciplinary action in another jurisdiction (CGS § 19a-17).

COMMITTEE ACTION

Public Health Committee

Joint Favorable

Yea 27 Nay 0 (03/23/2015)