



Senate

General Assembly

File No. 542

January Session, 2015

Substitute Senate Bill No. 257

Senate, April 8, 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 REPORTING OF PAYMENTS BY
MANUFACTURERS TO INDEPENDENTLY-PRACTICING ADVANCED
PRACTICE REGISTERED NURSES.**

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

1 Section 1. Section 21a-70f of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective from passage*):

3 (a) For purposes of this section:

4 (1) "Advanced practice registered nurse" means a person licensed
5 pursuant to chapter 378;

6 (2) "Applicable manufacturer" means a manufacturer of a covered
7 drug, device, biological, or medical supply that is operating in the
8 United States, or in a territory, possession, or commonwealth of the
9 United States;

10 (3) "Payment or other transfer of value" means a transfer of anything
11 of value, except (A) a transfer of anything of value that is made

12 indirectly to an advanced practice registered nurse through a third
13 party in connection with an activity or service in the case where the
14 applicable manufacturer is unaware of the identity of the advanced
15 practice registered nurse, or (B) a transfer of anything of value that
16 meets the requirements for exclusion under 42 USC 1320a-7h(e)(10), as
17 amended from time to time;

18 (4) "Covered drug, device, biological, or medical supply" means any
19 drug, biological product, device, or medical supply for which payment
20 is available under subchapter XVIII of chapter 7 of Title 42 of the
21 United States Code or the state Medicaid plan under subchapter XIX or
22 XXI of said chapter or a waiver of such a plan; and

23 (5) "Covered device" means any device for which payment is
24 available under subchapter XVIII of chapter 7 of Title 42 of the United
25 States Code or the state Medicaid plan under subchapter XIX or XXI of
26 said chapter or a waiver of such a plan.

27 (b) (1) Not later than July 1, [2015] 2017, and [quarterly] annually
28 thereafter, an applicable manufacturer that provides a payment or
29 other transfer of value to an advanced practice registered nurse, who is
30 practicing not in collaboration with a physician in the state, in
31 accordance with subsection (b) of section 20-87a, as amended by this
32 act, shall submit to the Commissioner of Consumer Protection, in the
33 form and manner prescribed by the commissioner, the information
34 described in 42 USC 1320a-7h, as amended from time to time, for the
35 preceding calendar year.

36 (2) In determining whether an applicable manufacturer is required
37 to submit information concerning a payment or other transfer of value
38 to an advanced practice registered nurse in accordance with the
39 provisions of this subsection, the applicable manufacturer shall refer to
40 the list of advanced practice registered nurses who are authorized to
41 practice not in collaboration with a physician published by the
42 Commissioner of Public Health on the Department of Public Health's
43 Internet web site in accordance with subsection (b) of section 20-87a, as
44 amended by this act.

45 [(2)] (3) The commissioner may publish such information on the
46 Department of Consumer Protection's Internet web site.

47 (c) An applicable manufacturer that fails to report in accordance
48 with this section shall be assessed a civil penalty in an amount not less
49 than one thousand dollars or more than four thousand dollars for each
50 payment or other transfer of value not reported.

51 Sec. 2. Subsection (b) of section 20-87a of the general statutes is
52 repealed and the following is substituted in lieu thereof (*Effective from*
53 *passage*):

54 (b) (1) Advanced nursing practice is defined as the performance of
55 advanced level nursing practice activities that, by virtue of post-basic
56 specialized education and experience, are appropriate to and may be
57 performed by an advanced practice registered nurse. The advanced
58 practice registered nurse performs acts of diagnosis and treatment of
59 alterations in health status, as described in subsection (a) of this
60 section.

61 (2) An advanced practice registered nurse having been issued a
62 license pursuant to section 20-94a shall, for the first three years after
63 having been issued such license, collaborate with a physician licensed
64 to practice medicine in this state. In all settings, such advanced practice
65 registered nurse may, in collaboration with a physician licensed to
66 practice medicine in this state, prescribe, dispense and administer
67 medical therapeutics and corrective measures and may request, sign
68 for, receive and dispense drugs in the form of professional samples in
69 accordance with sections 20-14c to 20-14e, inclusive, except such
70 advanced practice registered nurse licensed pursuant to section 20-94a
71 and maintaining current certification from the American Association of
72 Nurse Anesthetists who is prescribing and administering medical
73 therapeutics during surgery may only do so if the physician who is
74 medically directing the prescriptive activity is physically present in the
75 institution, clinic or other setting where the surgery is being
76 performed. For purposes of this subdivision, "collaboration" means a
77 mutually agreed upon relationship between such advanced practice

78 registered nurse and a physician who is educated, trained or has
79 relevant experience that is related to the work of such advanced
80 practice registered nurse. The collaboration shall address a reasonable
81 and appropriate level of consultation and referral, coverage for the
82 patient in the absence of such advanced practice registered nurse, a
83 method to review patient outcomes and a method of disclosure of the
84 relationship to the patient. Relative to the exercise of prescriptive
85 authority, the collaboration between such advanced practice registered
86 nurse and a physician shall be in writing and shall address the level of
87 schedule II and III controlled substances that such advanced practice
88 registered nurse may prescribe and provide a method to review
89 patient outcomes, including, but not limited to, the review of medical
90 therapeutics, corrective measures, laboratory tests and other diagnostic
91 procedures that such advanced practice registered nurse may
92 prescribe, dispense and administer.

93 (3) An advanced practice registered nurse having (A) been issued a
94 license pursuant to section 20-94a, (B) maintained such license for a
95 period of not less than three years, and (C) engaged in the performance
96 of advanced practice level nursing activities in collaboration with a
97 physician for a period of not less than three years and not less than two
98 thousand hours in accordance with the provisions of subdivision (2) of
99 this subsection, may, thereafter, alone or in collaboration with a
100 physician or another health care provider licensed to practice in this
101 state: (i) Perform the acts of diagnosis and treatment of alterations in
102 health status, as described in subsection (a) of this section; and (ii)
103 prescribe, dispense and administer medical therapeutics and corrective
104 measures and dispense drugs in the form of professional samples as
105 described in subdivision (2) of this subsection in all settings. Any
106 advanced practice registered nurse electing to practice not in
107 collaboration with a physician in accordance with the provisions of
108 this subdivision shall maintain documentation of having engaged in
109 the performance of advanced practice level nursing activities in
110 collaboration with a physician for a period of not less than three years
111 and not less than two thousand hours. Such advanced practice
112 registered nurse shall maintain such documentation for a period of not

113 less than three years after completing such requirements and shall
 114 submit such documentation to the Department of Public Health for
 115 inspection not later than forty-five days after a request made by the
 116 department for such documentation. Any such advanced practice
 117 registered nurse shall submit written notice to the Commissioner of
 118 Public Health of his or her intention to practice without collaboration
 119 with a physician after completing the requirements described in this
 120 subdivision and prior to beginning such practice. Not later than
 121 December first, annually, the Commissioner of Public Health shall
 122 publish on the department's Internet web site a list of such advanced
 123 practice registered nurses who are authorized to practice not in
 124 collaboration with a physician.

125 (4) An advanced practice registered nurse licensed under the
 126 provisions of this chapter may make the determination and
 127 pronouncement of death of a patient, provided the advanced practice
 128 registered nurse attests to such pronouncement on the certificate of
 129 death and signs the certificate of death not later than twenty-four
 130 hours after the pronouncement.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	21a-70f
Sec. 2	<i>from passage</i>	20-87a(b)

Statement of Legislative Commissioners:

In section 1(a)(2) and 2(b)(4) "without collaboration" was changed to "not in collaboration" for internal consistency.

PH *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 results in no fiscal impact to the state as it is procedural in nature.

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

OLR Bill Analysis**sSB 257*****AN ACT CONCERNING REPORTING OF PAYMENTS BY MANUFACTURERS TO INDEPENDENTLY-PRACTICING ADVANCED PRACTICE REGISTERED NURSES.*****SUMMARY:**

Legislation enacted last year requires manufacturers of covered drugs, devices, biologicals, and medical supplies to report to the Department of Consumer Protection (DCP) on payments or other transfers of value they make to advanced practice registered nurses (APRNs) practicing in Connecticut (see BACKGROUND).

This bill:

1. extends, by two years, the due date for the first report, from July 1, 2015 to July 1, 2017; makes the reports due annually rather than quarterly; and specifies that the reports cover the previous calendar year;
2. specifies that the reporting requirement applies only to payments made to APRNs practicing not in collaboration with a physician (i.e., independently) (see BACKGROUND);
3. requires the Department of Public Health, by December 1 annually, to maintain on its website a list of APRNs authorized to practice independently, which the manufacturers must use when determining whether they need to report to DCP; and
4. excludes from the reporting requirement the same payments excluded under the federal law on reporting payments to physicians.

EFFECTIVE DATE: Upon passage

MANUFACTURER REPORTING REQUIREMENT FOR PAYMENTS TO APRNS***Exceptions to Reporting Requirement***

Under existing law, the reporting requirement does not apply to transfers made indirectly to an APRN through a third party, in connection with an activity or service in which the manufacturer is unaware of the APRN's identity.

The bill further excludes those payments that are excluded under the federal law that requires these manufacturers to report on payments or transfers of value to physicians or teaching hospitals (42 USC § 1320a-7h(e)(10)). The federal law is known as the Physician Payments Sunshine Act.

Thus, the bill excludes the following from the reporting requirement:

1. transfers valued at under \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the recipient by the manufacturer during the calendar year exceeds \$100, adjusted for inflation after 2012 (the 2015 thresholds are \$10.21 and \$102.07);
2. product samples intended for patient use and not intended for sale;
3. educational material that directly benefits patients or is intended for them;
4. loans of a device for a short-term trial period, up to 90 days, to allow the recipient to evaluate the device;
5. items or services provided under a contractual warranty, including device replacement, where the warranty terms are set forth in the purchase or lease agreement;
6. transfers made when the recipient is a patient and not acting in his or her professional capacity;

7. discounts, including rebates;
8. in-kind items used for providing charity care;
9. dividends or other profit distributions from, or ownership or investment interests in, a publicly traded security and mutual fund;
10. for manufacturers who offer self-insured plans, payments for health care to employees under the plan;
11. for recipients also licensed as non-medical professionals, payments to them solely for those other professional services; and
12. payments solely for the recipient's services with respect to a civil or criminal action or an administrative proceeding.

BACKGROUND

Reporting of Manufacturer Payments to APRNs

By law, the reporting requirement applies to manufacturers of drugs, devices, biological products, or medical supplies covered by (1) Medicare or (2) the state Medicaid or Children's Health Insurance Program plan, including a plan waiver. These manufacturers must report the same information required by the Physician Payments Sunshine Act. Among other things, the reports must include the (1) recipient's name and business address, (2) amount and date of the payment or other transfer of value, and (3) form and nature of the payment or transfer.

A manufacturer required to report that fails to do so is subject to a civil penalty of \$1,000 to \$4,000 for each payment or transfer not reported.

Independently-Practicing APRNs

By law, as of July 1, 2014, APRNs may practice independently if they have been licensed and practicing in collaboration with a physician for at least three years and 2,000 hours. APRNs who seek to

practice without this collaboration must notify the public health commissioner of their intention to do so.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 28 Nay 0 (03/25/2015)