

1 S.104

2 Introduced by Committee on Health and Welfare

3 Date:

4 Subject: Health; prescription drugs; prescribed products; marketing; gift ban;
5 disclosure

6 Statement of purpose: This bill proposes to make minor and clarifying
7 changes to laws prohibiting most gifts from manufacturers of prescribed
8 products and requiring disclosure of permitted gifts and allowable
9 expenditures. The bill would: (1) specifically authorize manufacturers to
10 conduct blind market research studies and would require related disclosures;
11 (2) exempt from the scope of the gift ban and disclosure laws manufacturers
12 who sell particular categories of over-the-counter products; (3) extend the
13 period for which a manufacturer may lend a medical device from 90 days to
14 120 days and exempt the loans from disclosure if they result in a sale or lease
15 after issuance of a certificate of need; (4) exempt from disclosure prescription
16 drugs provided through a manufacturer's patient assistance program; (5)
17 exempt manufacturers from disclosing the provision of nonprescription
18 products if they do not have any other required disclosures to make; and (6)
19 change the reporting period for required disclosures from the fiscal year to the
20 calendar year and pro rate the related reporting fee.

1 An act relating to modifications to the ban on gifts by manufacturers of
2 prescribed products

3 It is hereby enacted by the General Assembly of the State of Vermont:

4 Sec. 1. 18 V.S.A. § 4631a is amended to read:

5 § 4631a. EXPENDITURES BY MANUFACTURERS OF PRESCRIBED
6 PRODUCTS

7 (a) As used in this section:

8 (1) “Allowable expenditures” means:

9 (A) Payment to the sponsor of a significant educational, medical,
10 scientific, or policy-making conference or seminar, provided:

11 (i) the payment is not made directly to a health care professional
12 or pharmacist;

13 (ii) funding is used solely for bona fide educational purposes,
14 except that the sponsor may, in the sponsor’s discretion, apply some or all of
15 the funding to provide meals and other food for all conference participants; and

16 (iii) all program content is objective, free from industry control,
17 and does not promote specific products.

18 (B) Honoraria and payment of the expenses of a health care
19 professional who serves on the faculty at a bona fide significant educational,
20 medical, scientific, or policy-making conference or seminar, provided:

21 (i) there is an explicit contract with specific deliverables which are
22 restricted to medical issues, not marketing activities; and

1 (ii) consistent with federal law, the content of the presentation,
2 including slides and written materials, is determined by the health care
3 professional.

4 (C) For a bona fide clinical trial:

5 (i) gross compensation for the Vermont location or locations
6 involved;

7 (ii) direct salary support per principal investigator and other health
8 care professionals per year; and

9 (iii) expenses paid on behalf of investigators or other health care
10 professionals paid to review the clinical trial.

11 (D) For a research project that constitutes a systematic investigation,
12 is designed to develop or contribute to general knowledge, and reasonably can
13 be considered to be of significant interest or value to scientists or health care
14 professionals working in the particular field of inquiry:

15 (i) gross compensation;

16 (ii) direct salary support per health care professional; and

17 (iii) expenses paid on behalf of each health care professional.

18 (E) Payment or reimbursement for the reasonable expenses, including
19 travel and lodging-related expenses, necessary for technical training of
20 individual health care professionals on the use of a medical device if the
21 commitment to provide such expenses and the amounts or categories of

1 reasonable expenses to be paid are described in a written agreement between
2 the health care provider and the manufacturer.

3 (F) Royalties and licensing fees paid to health care providers in
4 return for contractual rights to use or purchase a patented or otherwise legally
5 recognized discovery for which the health care provider holds an ownership
6 right.

7 (G) The payment of the reasonable expenses of an individual related
8 to the interview of the individual by a manufacturer of prescribed products in
9 connection with a bona fide employment opportunity.

10 (H) Other research paid at fair market value, as long as the
11 manufacturer on behalf of which the survey or other research is conducted is
12 unaware of the identity of the health care provider receiving expenditures
13 related to the research.

14 (I) Other reasonable fees, payments, subsidies, or other economic
15 benefits provided by a manufacturer of prescribed products at fair market
16 value.

17 (2) "Bona fide clinical trial" means an FDA-reviewed clinical trial that
18 constitutes "research" as that term is defined in 45 C.F.R. § 46.102 and
19 reasonably can be considered to be of interest to scientists or health care
20 professionals working in the particular field of inquiry.

1 (3) “Clinical trial” means any study assessing the safety or efficacy of
2 prescribed products administered alone or in combination with other prescribed
3 products or other therapies, or assessing the relative safety or efficacy of
4 prescribed products in comparison with other prescribed products or other
5 therapies.

6 (4) “Free clinic” means a health care facility operated by a nonprofit
7 private entity that:

8 (A) in providing health care, does not accept reimbursement from
9 any third-party payor, including reimbursement from any insurance policy,
10 health plan, or federal or state health benefits program that is individually
11 determined;

12 (B) in providing health care, either:

13 (i) does not impose charges on patients to whom service is
14 provided; or

15 (ii) imposes charges on patients according to their ability to pay;

16 (C) may accept patients’ voluntary donations for health care service
17 provision; and

18 (D) is licensed or certified to provide health services in accordance
19 with Vermont law.

20 (5) “Gift” means:

21 (A) Anything of value provided to a health care provider for free; or

1 (B) Except as otherwise provided in subdivision (a)(1)(A)(ii) of this
2 section, any payment, food, entertainment, travel, subscription, advance,
3 service, or anything else of value provided to a health care provider, unless:

4 (i) it is an allowable expenditure as defined in subdivision (a)(1)
5 of this section; or

6 (ii) the health care provider reimburses the cost at fair market
7 value.

8 (6) “Health benefit plan administrator” means the person or entity who
9 sets formularies on behalf of an employer or health insurer.

10 (7)(A) “Health care professional” means:

11 (i) a person who is authorized by law to prescribe or to
12 recommend prescribed products, who regularly practices in this state, and who
13 either is licensed by this state to provide or is otherwise lawfully providing
14 health care in this state; or

15 (ii) a partnership or corporation made up of the persons described
16 in subdivision (i) of this subdivision (7)(A); or

17 (iii) an officer, employee, agent, or contractor of a person
18 described in subdivision (i) of this subdivision (7)(A) who is acting in the
19 course and scope of employment, of an agency, or of a contract related to or
20 supportive of the provision of health care to individuals.

1 (B) The term shall not include a person described in subdivision (A)
2 of this subdivision (7) who is employed solely by a manufacturer.

3 (8) “Health care provider” means a health care professional, hospital,
4 nursing home, pharmacist, health benefit plan administrator, or any other
5 person authorized to dispense or purchase for distribution prescribed products
6 in this state. The term does not include a hospital foundation that is organized
7 as a nonprofit entity separate from a hospital.

8 (9) “Manufacturer” means a pharmaceutical, biological product, or
9 medical device manufacturer or any other person who is engaged in the
10 production, preparation, propagation, compounding, processing, marketing,
11 packaging, repacking, distributing, or labeling of prescribed products. The
12 term does not include a wholesale distributor of biological products, a retailer,
13 or a pharmacist licensed under chapter 36 of Title 26. The term also does not
14 include a manufacturer whose only prescribed products are classified as Class I
15 by the U.S. Food and Drug Administration, are exempt from pre-market
16 notification under Section 510(k) of the federal Food, Drug and Cosmetic Act,
17 and are sold over-the-counter without a prescription.

18 (10) “Marketing” shall include promotion, detailing, or any activity that
19 is intended to be used or is used to influence sales or market share or to
20 evaluate the effectiveness of a professional sales force.

1 (11) “Pharmaceutical manufacturer” means any entity which is engaged
2 in the production, preparation, propagation, compounding, conversion, or
3 processing of prescription drugs, whether directly or indirectly by extraction
4 from substances of natural origin, independently by means of chemical
5 synthesis, or by a combination of extraction and chemical synthesis, or any
6 entity engaged in the packaging, repackaging, labeling, relabeling, or
7 distribution of prescription drugs. The term does not include a wholesale
8 distributor of prescription drugs, a retailer, or a pharmacist licensed under
9 chapter 36 of Title 26.

10 (12) “Prescribed product” means a drug or device as defined in section
11 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, a compound
12 drug or drugs, or a biological product as defined in section 351 of the Public
13 Health Service Act, 42 U.S.C. § 262, for human use.

14 (13) “Sample” means a unit of a prescription drug, biological product, or
15 medical device that is not intended to be sold and is intended to promote the
16 sale of the drug, product, or device. The term includes starter packs and
17 coupons or other vouchers that enable an individual to receive a prescribed
18 product free of charge or at a discounted price. The term does not include
19 prescribed products distributed free of charge or at a discounted price pursuant
20 to a manufacturer-sponsored or manufacturer-funded patient assistance
21 program.

1 (14) “Significant educational, scientific, or policy-making conference or
2 seminar” means an educational, scientific, or policy-making conference or
3 seminar that:

4 (A) is accredited by the Accreditation Council for Continuing
5 Medical Education or a comparable organization or is presented by an
6 approved sponsor of continuing education, provided that the sponsor is not a
7 manufacturer of prescribed products; and

8 (B) offers continuing education credit, features multiple presenters on
9 scientific research, or is authorized by the sponsor to recommend or make
10 policy.

11 (b)(1) It is unlawful for any manufacturer of a prescribed product or any
12 wholesale distributor of medical devices, or any agent thereof, to offer or give
13 any gift to a health care provider.

14 (2) The prohibition set forth in subdivision (1) of this subsection shall
15 not apply to any of the following:

16 (A) Samples of a prescribed product or reasonable quantities of an
17 over-the-counter drug, nonprescription medical device, or item of
18 nonprescription durable medical equipment, provided to a health care provider
19 for free distribution to patients.

1 (B) The loan of a medical device for a short-term trial period, not to
2 exceed ~~90~~ 120 days, to permit evaluation of a medical device by a health care
3 provider or patient.

4 (C) The provision of reasonable quantities of medical device
5 demonstration or evaluation units to a health care provider to assess the
6 appropriate use and function of the product and determine whether and when
7 to use or recommend the product in the future.

8 (D) The provision, distribution, dissemination, or receipt of
9 peer-reviewed academic, scientific, or clinical articles or journals and other
10 items that serve a genuine educational function provided to a health care
11 provider for the benefit of patients.

12 (E) Scholarship or other support for medical students, residents, and
13 fellows to attend a significant educational, scientific, or policy-making
14 conference or seminar of a national, regional, or specialty medical or other
15 professional association if the recipient of the scholarship or other support is
16 selected by the association.

17 (F) Rebates and discounts for prescribed products provided in the
18 normal course of business.

19 (G) Labels approved by the federal Food and Drug Administration
20 for prescribed products.

1 (H) The provision of free prescription drugs or over-the-counter
2 drugs, medical devices, biological products, medical equipment or supplies, or
3 financial donations to a free clinic.

4 (I) ~~The provision of free prescription drugs to or on behalf of an~~
5 ~~individual through a prescription drug manufacturer's patient assistance~~
6 ~~program.~~ Prescribed products distributed free of charge or at a discounted
7 price pursuant to a manufacturer-sponsored or manufacturer-funded patient
8 assistance program.

9 (J) Fellowship salary support provided to fellows through grants from
10 manufacturers of prescribed products, provided:

11 (i) such grants are applied for by an academic institution or
12 hospital;

13 (ii) the institution or hospital selects the recipient fellows;

14 (iii) the manufacturer imposes no further demands or limits on the
15 institution's, hospital's, or fellow's use of the funds; and

16 (iv) fellowships are not named for a manufacturer and no
17 individual recipient's fellowship is attributed to a particular manufacturer of
18 prescribed products.

19 (K) The provision of coffee or other snacks or refreshments at a
20 booth at a conference or seminar.

1 (c) The attorney general may bring an action in Washington superior court
2 for injunctive relief, costs, and attorney's fees and may impose on a
3 manufacturer that violates this section a civil penalty of no more than
4 \$10,000.00 per violation. Each unlawful gift shall constitute a separate
5 violation.

6 Sec. 2. 18 V.S.A. § 4632 is amended to read:

7 § 4632. DISCLOSURE OF ALLOWABLE EXPENDITURES AND GIFTS
8 BY MANUFACTURERS OF PRESCRIBED PRODUCTS

9 (a)(1)(A) Annually on or before ~~October~~ April 1 of each year, every
10 manufacturer of prescribed products shall disclose to the office of the attorney
11 general for the ~~fiscal preceding calendar year ending the previous June 30th~~ the
12 value, nature, purpose, and recipient information of:

13 ~~(A)~~ any allowable expenditure or gift permitted under subdivision
14 4631a(b)(2) of this title to any health care provider, except:

15 (i) royalties and licensing fees as described in subdivision
16 4631a(a)(1)(F) of this title;

17 (ii) rebates and discounts for prescribed products provided to
18 health care providers in the normal course of business as described in
19 subdivision 4631a(b)(2)(F) of this title;

20 (iii) payments for clinical trials as described in subdivision
21 4631a(a)(1)(C) of this title, which shall be disclosed after the earlier of the date

1 of the approval or clearance of the prescribed product by the Food and Drug
2 Administration for the use for which the clinical trial is being conducted or ~~two~~
3 four calendar years after the date the payment was made. For a clinical trial
4 for which disclosure is delayed under this subdivision (iii), the manufacturer
5 shall identify to the attorney general the clinical trial, the start date, and the
6 web link to the clinical trial registration on the national clinical trials registry;

7 (iv) interview expenses as described in subdivision 4631a(a)(1)(G)
8 of this title; ~~and~~

9 (v) coffee or other snacks or refreshments at a booth at a
10 conference or seminar;

11 (vi) loans of medical devices for short-term trial periods pursuant
12 to subdivision 4631a(b)(2)(B) of this title, provided the loan results in the
13 purchase, lease, or other comparable arrangement of the medical device after
14 issuance of a certificate of need pursuant to chapter 221, subchapter 5 of this
15 title; and

16 (vii) prescribed products distributed free of charge or at a
17 discounted price pursuant to a manufacturer-sponsored or manufacturer-funded
18 patient assistance program.

19 (B) Annually on or before April 1 of each year, every manufacturer
20 of prescribed products shall disclose to the office of the attorney general for the
21 preceding calendar year:

1 (i) if the manufacturer is reporting other allowable expenditures or
2 permitted gifts pursuant to subdivision (a)(1)(A) of this section, the product,
3 dosage, number of units, and recipient information of over-the-counter drugs,
4 nonprescription medical devices, and items of nonprescription durable medical
5 equipment provided to a health care provider for free distribution to patients
6 pursuant to subdivision 4631a(b)(2)(A) of this title.

7 (ii) for each research activity described in subdivision
8 4631a(a)(1)(H) of this title, the number of health care providers participating in
9 the research, the total amount paid to the entity conducting the research, and, if
10 a product is distributed as part of the research, the product name, dosage, and
11 number of units distributed.

12 (C) Annually on or before April 1 of each year, every manufacturer
13 of prescribed products shall disclose to the office of the attorney general for the
14 preceding calendar year the value, nature, purpose, and recipient information
15 of any allowable expenditure or gift to an academic institution, to a nonprofit
16 hospital foundation, or to a professional, educational, or patient organization
17 representing or serving health care providers or consumers located in or
18 providing services in Vermont, except:

19 (i) royalties and licensing fees as described in subdivision
20 4631a(a)(1)(F) of this title;

1 (ii) rebates and discounts for prescribed products provided in the
2 normal course of business as described in subdivision 4631a(b)(2)(F) of this
3 title; and

4 (iii) payments for clinical trials as described in subdivision
5 4631a(a)(1)(C) of this title, which shall be disclosed after the earlier of the date
6 of the approval or clearance of the prescribed product by the Food and Drug
7 Administration for the use for which the clinical trial is being conducted or ~~two~~
8 four calendar years after the date the payment was made. For a clinical trial
9 for which disclosure is delayed under this subdivision (iii), the manufacturer
10 shall identify to the attorney general the clinical trial, the start date, and the
11 web link to the clinical trial registration on the national clinical trials registry.

12 (2)(A)(i) Subject to the provisions of subdivision (B) of this subdivision
13 (a)(2) and to the extent allowed under federal law, annually on or before
14 April 1 of each year beginning in 2012, each manufacturer of prescribed
15 products shall disclose to the office of the attorney general all ~~free~~ samples of
16 prescribed products provided to health care providers during the preceding
17 calendar year, identifying for each sample the product, recipient, number of
18 units, and dosage.

19 (ii) The office of the attorney general may contract with academic
20 researchers to release to such researchers data relating to manufacturer
21 distribution of ~~free~~ samples, subject to confidentiality provisions and without

1 including the names or license numbers of individual recipients, for analysis
2 and aggregated public reporting.

3 (iii) Any public reporting of manufacturer distribution of ~~free~~
4 samples shall not include information that allows for the identification of
5 individual recipients of samples or connects individual recipients with the
6 monetary value of the samples provided.

7 (B) Subdivision (A) of this subdivision (a)(2) shall not apply to
8 samples of prescription drugs required to be reported under Sec. 6004 of the
9 Patient Protection and Affordable Care Act of 2010, Public Law 111-148, as
10 amended by the Health Care and Education Reconciliation Act of 2010, Public
11 Law 111-152, if as of January 1, 2011, the office of the attorney general has
12 determined that the U.S. Department of Health and Human Services will
13 collect and report state- and recipient-specific information regarding
14 manufacturer distribution of ~~free~~ samples of such prescription drugs.

15 (3) Annually on ~~July~~ January 1, each manufacturer of prescribed
16 products also shall disclose to the office of the attorney general the name and
17 address of the individual responsible for the manufacturer's compliance with
18 the provisions of this section.

19 (4) Disclosure shall be made on a form and in a manner prescribed by
20 the office of the attorney general and shall require manufacturers of prescribed

1 products to report each allowable expenditure or gift permitted under
2 subdivision 4631a(b)(2) of this title including:

3 (A) except as otherwise provided in subdivision (a)(2) of this section,
4 the value, nature, and purpose of each allowable expenditure, and gift
5 permitted under subdivision 4631a(b)(2) of this title according to specific
6 categories identified by the office of the attorney general;

7 (B) the name of the recipient;

8 (C) the recipient's address;

9 (D) the recipient's institutional affiliation;

10 (E) prescribed product or products being marketed, if any; and

11 (F) the recipient's state board number or, in the case of an institution,
12 foundation, or organization, the federal tax identification number or the
13 identification number assigned by the attorney general.

14 (5) The office of the attorney general shall report annually on the
15 disclosures made under this section to the general assembly and the governor
16 on or before ~~April~~ October 1. The report shall include:

17 (A) Information on allowable expenditures and permitted gifts
18 required to be disclosed under this section, which shall be presented in both
19 aggregate form and by selected types of health care providers or individual
20 health care providers, as prioritized each year by the office. In accordance

1 with subdivision (2)(A) of this subsection, information on samples of
2 prescribed products shall be presented in aggregate form.

3 (B) Information on violations and enforcement actions brought
4 pursuant to this section and section 4631a of this title.

5 (6) After issuance of the report required by subdivision (5) of this
6 subsection and except as otherwise provided in subdivision (2)(A)(~~i~~) of this
7 subsection, the office of the attorney general shall make all disclosed data used
8 for the report publicly available and searchable through an Internet website.

9 (7) The department of Vermont health access shall examine the data
10 available from the office of the attorney general for relevant expenditures and
11 determine whether and to what extent prescribing patterns by health care
12 providers of prescribed products reimbursed by Medicaid, VHAP, Dr.
13 Dynasaur, VermontRx, and VPharm may reflect manufacturer influence. The
14 department may select the data most relevant to its analysis. The department
15 shall report its analysis annually to the general assembly and the governor on
16 or before ~~October 1~~ March 1.

17 (b)(1) ~~Annually on July 1~~ Beginning January 1, 2013 and annually
18 thereafter, the office of the attorney general shall collect a \$500.00 fee from
19 each manufacturer of prescribed products filing annual disclosures of
20 expenditures greater than zero described in subsection (a) of this section.

1 (2) Fees collected under this section shall fund collection and analysis of
2 information on activities related to the marketing of prescribed products under
3 section 4631a of this title and under this section. The fees shall be collected in
4 a special fund assigned to the office.

5 (c) The attorney general may bring an action in Washington superior court
6 for injunctive relief, costs, and attorney's fees, and to impose on a
7 manufacturer of prescribed products that fails to disclose as required by
8 subsection (a) of this section a civil penalty of no more than \$10,000.00 per
9 violation. Each unlawful failure to disclose shall constitute a separate
10 violation.

11 (d) The terms used in this section shall have the same meanings as they do
12 in section 4631a of this title.

13 Sec. 3. REPORTING FEES

14 (a) Notwithstanding the provisions of 18 V.S.A. § 4632(b)(1), on July 1,
15 2011, the office of the attorney general shall collect a \$500.00 fee from each
16 manufacturer of prescribed products filing annual disclosures of expenditures
17 greater than zero described in 18 V.S.A. § 4632(a) for the fiscal year ending
18 June 30, 2011.

19 (b) Notwithstanding the provisions of 18 V.S.A. § 4632(b)(1), on
20 January 1, 2012, the office of the attorney general shall collect a \$250.00 fee
21 from each manufacturer of prescribed products filing disclosures of

1 expenditures greater than zero described in 18 V.S.A. § 4632(a) for the
2 six-month period from July 1, 2011 through December 31, 2011.

3 Sec. 4. EFFECTIVE DATES

4 This act shall take effect on July 1, 2011, except that, in Sec. 2, the
5 amendments to 18 V.S.A. § 4632(a)(1)(B) shall take effect on January 1, 2012.