§ 4632. Disclosure of allowable expenditures and gifts by manufacturers of prescribed products

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

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

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

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

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

(iv) samples of a prescription drug provided to a health care professional for free distribution to patients.

(B) any allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title to an academic institution or to a professional, educational, or patient organization representing or serving health care providers or consumers, except:

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

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

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

(iv) samples of a prescription drug provided to a health care professional for free distribution to patients.

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

(3) Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require manufacturers of prescribed products to report each allowable expenditure or gift permitted under subdivision 4631a(b)(2) of this title including:

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

(B) the name of the recipient;

(C) the recipient's address;

(D) the recipient's institutional affiliation;

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

(F) the recipient's state board number.

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

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

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

this title.
(5) After issuance of the report required by subdivision (a)(5) of this section, the office of the attorney general shall make all disclosed data used for the report publicly available and searchable through an Internet website.
(6) The office of Vermont health access shall examine the data available from the office of the attorney general for relevant expenditures and determine whether and to what extent prescribing patterns by health care providers of prescribed products reimbursed by Medicaid, VHAP, Dr. Dynasaur, VermontRx, and VPharm may reflect manufacturer influence. The office may select the data most relevant to its analysis. The office shall report its analysis annually to the general assembly and the governor on or before October 1.
(b)(1) Annually on July 1, the office of the attorney general shall collect a $500.00 fee from each manufacturer of prescribed products filing annual disclosures of expenditures greater than zero described in subsection (a) of this section.
(2) Fees collected under this section shall fund collection and analysis of information on activities related to the marketing of prescribed products under sections 4631a and 4632 of Title 18. The fees shall be collected in a special fund assigned to the office.
(c) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer of prescribed products that fails to disclose as required by subsection (a) of this section a civil penalty of no more than $10,000.00 per violation. Each unlawful failure to disclose shall constitute a separate violation.
(d) The terms used in this section shall have the same meanings as they do in section 4631a of this title.

CREDIT(S)
2007, No. 80, § 23, eff. July 1, 2007; 2009, No. 59, § 4, eff. July 1, 2009.