

ASSEMBLY BILL

No. 2821

Introduced by Assembly Member Feuer

February 22, 2008

An act to amend, repeal, and add Section 119402 of the Health and Safety Code, relating to drug marketing.

LEGISLATIVE COUNSEL'S DIGEST

AB 2821, as introduced, Feuer. Drug marketing: gifts.

Existing law requires a pharmaceutical company to adopt and update a Comprehensive Compliance Program that is in accordance with a related federal government publication. The Comprehensive Compliance Program is required to include, among other provisions, policies on interactions with health care professionals and limits on gifts and incentives to medical or health professionals. Each pharmaceutical company is required to establish explicitly in its Comprehensive Compliance Program a specific annual dollar limit on gifts, promotional materials, or items, or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional, with certain exemptions.

Existing law also requires a pharmaceutical company to annually declare, in writing, compliance with the Comprehensive Compliance Program. Existing law requires that the pharmaceutical company place its Comprehensive Compliance Program and written acknowledgment of compliance available to the public on its Web site, and provide a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written declaration of compliance may be obtained.

This bill would, effective July 1, 2009, repeal the above-described requirement regarding the establishment of a specific annual dollar limit on gifts, promotional materials, or items, or activities that may be given or provided. It would, instead, prohibit any pharmaceutical company, or agent thereof, from offering or giving a gift, as defined, or combination of gifts that have a total value of more than \$250 to a medical or health professional, except as specified.

The bill would, effective July 1, 2009, require each pharmaceutical company to annually file a report with, and pay a prescribed fee to, the State Department of Public Health that identifies all permitted gifts, financial support, payments, honoraria, or other compensation paid to medical or health professionals during the proceeding year. The department would be required to make the information contained in the reports available to the public, as prescribed.

The bill would establish the Pharmaceutical Gift Disclosure Fund within the State Treasury, into which the fee would be deposited, the moneys of which would be available upon appropriation by the Legislature, to the department.

Vote: majority. Appropriation: no. Fiscal committee: yes.
 State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 119402 of the Health and Safety Code
 2 is amended to read:
 3 119402. (a) Every pharmaceutical company shall adopt a
 4 Comprehensive Compliance Program that is in accordance with
 5 the April 2003 publication “Compliance Program Guidance for
 6 Pharmaceutical Manufacturers,” which was developed by the
 7 United States Department of Health and Human Services Office
 8 of Inspector General (OIG). A pharmaceutical company shall make
 9 conforming changes to its Comprehensive Compliance Program
 10 within six months of any update or revision to the “Compliance
 11 Program Guidance for Pharmaceutical Manufacturers.”
 12 (b) Every pharmaceutical company shall include in its
 13 Comprehensive Compliance Program policies for compliance with
 14 the Pharmaceutical Research and Manufacturers of America
 15 (PhRMA) “Code on Interactions with Health Care Professionals,”
 16 dated July 1, 2002. The pharmaceutical company shall make
 17 conforming changes to its Comprehensive Compliance Program

1 within six months of any update or revision of the “Code on
2 Interactions with Health Care Professionals.”

3 (c) Each pharmaceutical company shall include in its
4 Comprehensive Compliance Program limits on gifts or incentives
5 provided to medical or health professionals, in accordance with
6 this chapter.

7 (d) (1) Each pharmaceutical company shall establish explicitly
8 in its Comprehensive Compliance Program a specific annual dollar
9 limit on gifts, promotional materials, or items or activities that the
10 pharmaceutical company may give or otherwise provide to an
11 individual medical or health care professional in accordance with
12 the “Compliance Program Guidance for Pharmaceutical
13 Manufacturers” and with the “Code on Interactions with Health
14 Care Professionals.”

15 (2) Notwithstanding paragraph (1), drug samples given to
16 physicians and healthcare professionals intended for free
17 distribution to patients, financial support for continuing medical
18 education forums, and financial support for health educational
19 scholarships are exempt from any limits if that support is provided
20 in a manner that conforms to the “Compliance Program Guidance
21 for Pharmaceutical Manufacturers” and the “Code on Interactions
22 with Health Care Professionals.”

23 (3) Payments made for legitimate professional services provided
24 by a health care or medical professional, including, but not limited
25 to, consulting, are exempt from any limits, provided that the
26 payment does not exceed the fair market value of the services
27 rendered, and those payments are provided in a manner that
28 conforms to the “Compliance Program Guidance for
29 Pharmaceutical Manufacturers” and with the “Code on Interactions
30 with Health Care Professionals.”

31 (e) The pharmaceutical company shall annually declare, in
32 writing, that it is in compliance with both its Comprehensive
33 Compliance Program and this chapter. The pharmaceutical
34 company shall make its Comprehensive Compliance Program and
35 its annual written declaration of compliance with the program
36 available to the public on the pharmaceutical company’s Web site
37 and shall also provide a toll-free telephone number where a copy
38 or copies of the Comprehensive Compliance Program and written
39 declaration of compliance may be obtained.

1 (f) This section shall become ~~operative on July 1, 2005~~
2 *inoperative on July 1, 2009, and, as of January 1, 2010, is*
3 *repealed, unless a later enacted statute that is enacted before*
4 *January 1, 2010, deletes or extends the date on which it becomes*
5 *inoperative and is repealed.*

6 SEC. 2. Section 119402 is added to the Health and Safety Code,
7 to read:

8 119402. (a) Every pharmaceutical company shall adopt a
9 Comprehensive Compliance Program that is in accordance with
10 the April 2003 publication “Compliance Program Guidance for
11 Pharmaceutical Manufacturers,” which was developed by the
12 United States Department of Health and Human Services Office
13 of Inspector General (OIG). A pharmaceutical company shall make
14 conforming changes to its Comprehensive Compliance Program
15 within six months of any update or revision to the “Compliance
16 Program Guidance for Pharmaceutical Manufacturers.”

17 (b) Every pharmaceutical company shall include in its
18 Comprehensive Compliance Program policies for compliance with
19 the Pharmaceutical Research and Manufacturers of America
20 (PhRMA) “Code on Interactions with Health Care Professionals,”
21 dated July 1, 2002. The pharmaceutical company shall make
22 conforming changes to its Comprehensive Compliance Program
23 within six months of any update or revision of the “Code on
24 Interactions with Health Care Professionals.”

25 (c) The pharmaceutical company shall annually declare, in
26 writing, that it is in compliance with both its Comprehensive
27 Compliance Program and this chapter. The pharmaceutical
28 company shall make its Comprehensive Compliance Program and
29 its annual written declaration of compliance with the program
30 available to the public on the pharmaceutical company’s Web site
31 and shall also provide a toll-free telephone number where a copy
32 or copies of the Comprehensive Compliance Program and written
33 declaration of compliance may be obtained.

34 (d) (1) No pharmaceutical company, or any agent thereof, may
35 offer or give within a calendar year any gift or combination of gifts
36 that have a total value of more than two hundred fifty dollars (\$250)
37 to a medical or health professional. Except as provided in paragraph
38 (2), a gift shall include a payment, food, entertainment, travel,
39 subscription, or any other item of value, under consideration of
40 equal or greater value is provided by the recipient to the donor.

1 The amount of any difference between the market value of a gift
2 and any consideration provided by the recipient shall be used to
3 determine the value of the gift for purposes of this section.

4 (2) As used in this section, “gift” does not include any of the
5 following:

6 (A) Drug samples provided to a prescriber for free distribution
7 to patients.

8 (B) Financial support for continuing medical education forums,
9 and financial support for health educational scholarships, if that
10 support is provided in a manner that conforms to the “Compliance
11 Program Guidance for Pharmaceutical Manufacturers” and the
12 “Code on Interactions with Health Care Professionals.”

13 (C) Reasonable honoraria and payment of the reasonable
14 expenses of a medical or health professional who serves on the
15 faculty at a professional or educational conference or meeting.

16 (D) Payments made for legitimate professional services provided
17 by a health care or medical professional, including, but not limited
18 to, consulting, provided that the payment does not exceed the fair
19 market value of the services rendered, and those payments are
20 provided in a manner that conforms to the “Compliance Program
21 Guidance for Pharmaceutical Manufacturers” and with the “Code
22 on Interactions with Health Care Professionals.”

23 (E) Publications and educational materials.

24 (F) Salaries or other benefits paid to employees.

25 (e) (1) Each pharmaceutical company shall annually file with
26 the State Department of Health Care Services a report, in a form
27 and on the date prescribed by the department, that identifies the
28 nature and value of all gifts, as well as all financial support,
29 payments, honoraria, or other compensation described in
30 subparagraphs (B) to (D), inclusive, of paragraph (2) of subdivision
31 (d), with a value of at least fifty dollars (\$50) paid to a medical or
32 health professional in the state during the preceding calendar year.
33 The report shall also identify the first and last name of the recipient
34 and his or her business address.

35 (2) The reports described in this subdivision shall be public
36 records available and open to the public for inspection. The State
37 Department of Health Care Services, not later than December 31,
38 2010, shall provide access to all information contained in the
39 reports by means of an online database.

- 1 (3) The State Department of Health Care Services shall not be
- 2 liable for any damages arising from the inaccuracy of information
- 3 provided in the reports filed pursuant to this subdivision.
- 4 (f) Each pharmaceutical company shall, along with the report
- 5 filed pursuant to subdivision (c), pay a disclosure fee to the
- 6 department in an amount determined by the department to not
- 7 exceed the costs of administering this section. All fees collected
- 8 pursuant to this section shall be deposited in the Pharmaceutical
- 9 Gift Disclosure Fund, which is hereby established in the State
- 10 Treasury, and shall become available to the department, upon
- 11 appropriation by the Legislature, for the purposes of this section,
- 12 including the development and maintenance of the online database.
- 13 Notwithstanding Section 16305.7 of the Government Code, interest
- 14 and dividends earned on money in the fund shall accrue to the
- 15 fund.
- 16 (g) This section shall become operative on July 1, 2009.