

HOUSE BILL NO. 454

IN THE LEGISLATURE OF THE STATE OF ALASKA
TWENTY-FOURTH LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE GUTTENBERG

Introduced: 2/13/06

Referred: Labor and Commerce, Health, Education and Social Services, Finance

A BILL

FOR AN ACT ENTITLED

1 **"An Act relating to prescription drug marketing costs; and providing for an effective**
2 **date."**

3 **BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

4 * **Section 1.** The uncodified law of the State of Alaska is amended by adding a new section
5 to read:

6 FINDINGS. The legislature finds that the reporting of marketing costs for prescription
7 drugs required by this Act will

8 (1) assist the state in its role as a purchaser of prescription drugs and as an
9 administrator of prescription drug programs; and

10 (2) enable the state to determine the scope of prescription drug marketing
11 costs and the effect of marketing on the cost, utilization, and delivery of health care services;
12 and

13 (3) further the role of the state as a guardian of the public interest.

14 * **Sec. 2.** AS 17 is amended by adding a new chapter to read:

1 **Chapter 17.50. Reporting Prescription Drug Marketing Costs.**

2 **Sec. 17.50.010. Reporting required.** A manufacturer or labeler of prescription
3 drugs dispensed in this state who employs, directs, or uses marketing representatives
4 in this state shall report the marketing costs of the manufacturer or labeler in this state
5 as required by this chapter.

6 **Sec. 17.50.020. Manner of reporting.** By July 1 of each year, a covered
7 manufacturer and a covered labeler shall

8 (1) file a report with the department in the form and manner
9 established by the department; and

10 (2) pay a fee set by the department to cover the department's
11 administrative costs of handling the report.

12 **Sec. 17.50.030. Contents of report.** The report required by AS 17.50.020
13 must include the information described under AS 17.50.040

14 (1) as the information relates to marketing activities conducted in this
15 state; and

16 (2) in a form that gives the value, nature, purpose, and recipient of the
17 expense.

18 **Sec. 17.50.040. Information required.** (a) The information in the report
19 required by AS 17.50.020 must include

20 (1) expenses that relate to residents of this state and that are associated
21 with the advertising, direct promotion, or other marketing of prescription drugs
22 through radio, television, magazines, newspapers, direct mail, and telephone
23 communication, except for expenses that are associated with advertising purchased for
24 a national market or a regional market other than this state that includes advertising in
25 the state;

26 (2) expenses that are associated with the advertising, direct promotion,
27 or other marketing of prescription drugs to health care providers in this state; expenses
28 under this paragraph include expenses associated with

29 (A) educational or informational programs, materials, and
30 seminars, and remuneration for promoting or participating in the programs,
31 materials, and seminars, regardless of whether the covered manufacturer or

1 covered labeler provides the sessions, materials, or seminars;

2 (B) food, entertainment, gifts, and other economic benefits
3 provided at less than market value;

4 (C) trips and travel; and

5 (D) product samples, except for samples that are provided for
6 the purpose of free distribution to patients; and

7 (3) the cost, in an aggregated form, of all employees or contractors of
8 the covered manufacturer or covered labeler who directly or indirectly engage in the
9 advertising or promotional activities listed in (1) or (2) of this subsection, including
10 any form of payment to an employee or a contractor; the cost reported under this
11 paragraph must reflect only the portion of the payment to an employee or a contractor
12 that relates to activities in this state or to recipients of the advertising or promotional
13 activities who are residents of or employed in this state.

14 (b) In this section, "health care provider" means a person authorized to
15 provide health care in this state, the person's employees in this state, a health care
16 insurer, a health plan, a pharmacy, a hospital, a nursing facility, and a clinic.

17 **Sec. 17.50.050. Exceptions.** A covered manufacturer or covered labeler is not
18 required to report the following expenses under AS 17.50.040:

19 (1) expenses of \$25 or less;

20 (2) reasonable compensation and reimbursement of expenses in
21 connection with a bona fide clinical trial of a new vaccine, therapy, or treatment; or

22 (3) scholarships and reasonable reimbursement of expenses for
23 attending a significant educational, scientific, or policy-making conference or seminar
24 of a national medical association, a regional medical association, a specialty medical
25 association, or another professional medical association if the recipient of the
26 scholarship or reimbursement is selected by the association sponsoring the conference
27 or seminar.

28 **Sec. 17.50.060. Reports by department.** (a) On or before November 1 of each
29 calendar year, the department shall provide a written report to the attorney general and
30 to the legislature on the prescription drug marketing expenses information received
31 under AS 17.50.020 during the preceding fiscal year. The department shall present the

1 information in an aggregated form.

2 (b) On or before November 1 every two years, the department shall provide a
3 written report to the attorney general and the legislature that analyzes the information
4 submitted to the department during the two previous fiscal years under AS 17.50.020.
5 The department shall include in the report

6 (1) the scope of prescription drug marketing activities in the state;

7 (2) an aggregated form of the expenses reported under AS 17.50.020;

8 (3) the effect of (1) and (2) of this subsection on the cost, utilization,
9 and delivery of health care services in the state; and

10 (4) recommendations for the marketing activities of prescription drug
11 manufacturers and labelers in the state.

12 **Sec. 17.50.070. Confidentiality; public information.** (a) Information
13 submitted to the department under this chapter is confidential and is not a public
14 record under AS 40.25.120.

15 (b) Information compiled in an aggregated form by the department for the
16 purposes of reporting under AS 17.50.060 is a public record under AS 40.25.120,
17 except that compiled information that reveals trade information that is protected by
18 state or federal law is confidential to the extent it reveals the trade information and is
19 not a public record under AS 40.25.120.

20 **Sec. 17.50.080. Penalty.** A covered manufacturer or a covered labeler who
21 knowingly fails to provide a report required by this chapter is subject to a civil penalty
22 of \$1,000.

23 **Sec. 17.50.085. Regulations.** The department shall adopt regulations under
24 AS 44.62 (Administrative Procedure Act) to implement this chapter.

25 **Sec. 17.50.090. Definitions.** In this chapter, unless the context requires
26 otherwise,

27 (1) "aggregated" means gathered into categories without using
28 information that reveals the identity of a specific person;

29 (2) "covered labeler" means a labeler who employs, directs, or uses
30 marketing representatives in this state;

31 (3) "covered manufacturer" means a manufacturer who employs,

1 directs, or uses marketing representatives in this state;

2 (4) "department" means the Department of Health and Social Services;

3 (5) "labeler" means a person who

4 (A) receives prescription drugs from a manufacturer or
5 wholesaler and repackages the drugs for later retail sale; and

6 (B) has a labeler code issued by the United States Food and
7 Drug Administration under 21 C.F.R. 207.20;

8 (6) "manufacturer" means a manufacturer of prescription drugs and
9 includes a subsidiary or an affiliate of a manufacturer;

10 (7) "marketing" means advertising and promotional activities.

11 * **Sec. 3.** The uncodified law of the State of Alaska is amended by adding a new section to
12 read:

13 TRANSITION. (a) The first report required under AS 17.50.060(a), enacted by sec. 2
14 of this Act, is due February 1, 2007.

15 (b) The first report required under AS 17.50.060(b), enacted by sec. 2 of this Act, is
16 due February 1, 2009.

17 * **Sec. 4.** This Act takes effect July 1, 2006.