121st MAINE LEGISLATURE

FIRST REGULAR SESSION-2003

Legislative Document **No. 254**

H.P. 209 House of Representatives, January 23, 2003

An Act To Require Full Disclosure of Prescription Drug Marketing Costs

Reference to the Committee on Health and Human Services suggested and ordered printed.

Millicent M. MacFarland

MILLICENT M. MacFARLAND
Clerk

Presented by Representative KANE of Saco.
Cosponsored by Senator TREAT of Kennebec and
Representatives: CUMMINGS of Portland, FISCHER of Presque Isle, LEMOINE of Old Orchard Beach, NORBERT of Portland, O'NEIL of Saco, SIMPSON of Auburn, TWOMEY of Biddeford, Senator: MAYO of Sagadahoc.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §2699 is enacted to read:

§2699. Marketing costs

A manufacturer or labeler of prescription drugs dispensed in this State that employs, directs or utilizes marketing representatives in this State shall report marketing costs for prescription drugs in this State as provided in this section.

1. Purposes. Marketing costs for prescription drugs in this State must be reported to the department for the purposes of assisting this State in its role as a purchaser of prescription drugs and an administrator of prescription drug programs, enabling this State to determine the scope of prescription drug marketing costs and their effect on the cost, utilization and delivery of health care services and furthering the role of this State as guardian of the public interest.

2. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" has the same meaning as provided in section 2697, subsection 1.

B. "Manufacturer" has the same meaning as provided in section 2697, subsection 1.

C. "Marketing" means advertising and promotional activities, including, but not limited to, the activities described in subsection 4.

3. Manner of reporting. By July 1st each year a manufacturer or labeler of prescription drugs that directly or indirectly distributes prescription drugs for dispensation to residents of this State shall file a report with the department in the form and manner provided by the department. The report must be accompanied by payment of a fee, as set by the department in rule, to support the work of the department under this section.

4. Content of annual report by manufacturer or labeler. The annual report filed under subsection 3 must include the following information as it pertains to marketing activities conducted within this State in a form that provides the value, nature, purpose and recipient of the expense:

A. All expenses associated with advertising, marketing and direct promotion of prescription drugs through radio,

television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this State;

B. With regard to all persons and entities licensed to provide health care in this State, including health care professionals and persons employed by them in this State, carriers licensed under Title 24 or Title 24-A, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics and other entities licensed to provide health care under this Title, the following information:

(1) All expenses associated with educational or informational programs, materials and seminars and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;

(2) All expenses associated with food, entertainment, gifts valued at more than $25 and anything provided to a health care professional for less than market value;

(3) All expenses associated with trips and travel; and

(4) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and

C. The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs A and B, including all forms of payment to those employees. The cost reported under this paragraph must reflect only that portion of payment to employees or contractors that pertains to activities within this State or to recipients of the advertising or promotional activities who are residents of or are employed in this State.

5. Exceptions. The following marketing expenses are not subject to the requirements of this section:

A. Expenses of $25 or less;

B. Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment; and

C. Scholarships and reimbursement of expenses for attending a significant educational, scientific or policy-making conference or seminar of a national, regional or specialty

medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

6. Department reports. By November 30th each year, the department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses to the Legislature and the Attorney General. By January 1, 2005 and every 2 years after that date, the department shall provide a report to the Legislature and the Attorney General, providing information in aggregate form, containing an analysis of the data submitted to the department, including the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization and delivery of health care services and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

7. Confidentiality; public information. Notwithstanding any provision of law to the contrary, information submitted to the department pursuant to this section is confidential and is not a public record as defined in Title 1, section 402, subsection 3. Data compiled in aggregate form by the department for the purposes of reporting required by this section is a public record as defined in Title 1, section 402, subsection 3, as long as it does not reveal trade information that is protected by state or federal law.

8. Penalty. This section may be enforced in a civil action brought by the Attorney General. A manufacturer or labeler that fails to provide a report as required by this section commits a civil violation for which a fine of $10,000 plus costs and attorney's fees may be adjudged.

9. Rulemaking. The department shall adopt rules to implement this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Effective date. This Act takes effect January 1, 2004.

SUMMARY

This bill requires prescription drug manufacturers and labelers whose drugs are dispensed to state residents to file annual reports with the Department of Human Services regarding their expenses for marketing their drugs. The bill requires the department to file an annual report with the Legislature and the Attorney General regarding the information filed and a biennial

report that contains analysis of information and recommendations. The bill continues the confidentiality of trade information that is protected under state and federal law. The bill provides for a fine of $10,000 for failure to report as required. The bill provides for rulemaking by the department and contains an effective date of January 1, 2004.