120th MAINE LEGISLATURE

FIRST REGULAR SESSION-2001

Legislative Document **No. 1167**

S.P. 353 In Senate, February 28, 2001

An Act to Disclose Prescription Drug Marketing Activities.

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

JOY J. O'BRIEN
Secretary of the Senate

Presented by Senator TREAT of Kennebec.
Cosponsored by Representative MAYO of Bath and
Senators: DAGGETT of Kennebec, LONGLEY of Waldo, MARTIN of Aroostook, President MICHAUD of Penobscot, Representatives: KANE of Saco, LEMOINE of Old Orchard Beach, MADORE of Augusta, Speaker SAXL of Portland.

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

Sec. 1. 22 MRSA §258 is enacted to read:

§258. Prescription drug marketing

In order to provide information regarding prescription drugs that may serve the department in its role as a purchaser of prescription drugs and an administrator of prescription drug programs, a manufacturer of prescription drugs shall register information regarding prescription drug marketing activities in this State. As used in this section, unless the context otherwise indicates, "manufacturer" has the same meaning as "manufacturer" or "wholesaler" as defined by Title 32, section 13702, and includes a labeler as defined by section 26812, subsection 2, paragraph C.

1. Annual registration. A manufacturer shall register annually and shall provide the information required in this subsection regarding the representatives of the manufacturer who work within this State and the drug marketing activities of the manufacturer. The manufacturer shall pay an annual registration fee, as required by rule adopted by the department, that must be sufficient to support the work of the department regarding prescription drug marketing. The manufacturer shall report:

A. Data regarding informational, educational and sales presentations provided during the past year to or for persons working in a health care field, including, but not limited to, persons working in health professionals' offices or practices, health care facilities, health benefits administration and insurance carriers, health maintenance organizations, health benefits management organizations, pharmacies and pharmaceutical benefits and management organizations;

B. Data regarding items and services valued at more than $10 including, but not limited to, sponsorships, food, entertainment, gifts or goods, materials bearing corporate or brand advertisements or logos, trips, travel, seminars, remuneration and prescription drug samples provided during the past year at reduced cost or for free within this State to or for persons working in a health care field. The data provided under this paragraph must include fair market value presented in the aggregate in each category of items and services;

C. The names, addresses and telephone numbers of all representatives of the manufacturer who worked within this State during the past year or provided presentations, items

or services listed under paragraph A or B and those who are expected to so work during the coming year. For each person named, the manufacturer shall also provide information on that person's compensation, including the cost of benefits and expense allotments;

D. The cost of all advertising distributed in or originally distributed from this State regarding prescription drugs during the past year. For the purposes of this paragraph, advertising includes radio, television, Internet, magazines, newspapers, direct mail, telephone communications and electronic mail; and

E. For each of the 100 drugs of the manufacturer for which sales in this State were the highest in the prior year, the manufacturer's average wholesale price of the drugs, the lowest price for which the manufacturer sold those drugs in this State during the previous year and any discounts, rebates or other adjustments to cost that applied to sales of those drugs in the previous year.

2. Prescription drug marketing. The Bureau of Medical Services shall administer this section in order to assist the department in its duties as a purchaser of drugs and administrator of prescription drug programs.

A. The bureau shall collect and manage the information required to be provided under subsection 1.

B. With the exception of information protected from disclosure by law, rule or regulation, all information held by the bureau is a public record within the meaning of Title 1, chapter 13.

C. By February 5th each year, the bureau shall report to the Legislature on prescription drug marketing practices and on the cost of prescription drug marketing activities.

3. Required disclosures. Persons making informational, educational or sales presentations subject to the requirements of subsection 1, paragraph A shall disclose in the presentation information regarding pharmaceutical assistance programs operated or participated in by the manufacturer and any potential benefit to the person to whom the presentation is made.

4. Civil violations. The following provisions apply to enforcement of this section by the Attorney General.

A. A person who is employed to make informational, educational or sales presentations within this State on

behalf of a manufacturer who is not registered under subsection 1, paragraph A, or who violates the disclosure rules adopted pursuant to subsection 3, is subject to a civil penalty not to exceed $5,000 per violation, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert witness fees and reasonable attorney's fees, payable to the State.

B. A manufacturer who violates this section or employs or causes a person to violate this section is subject to a civil penalty not to exceed $25,000 per violation, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert witness fees and reasonable attorney's fees, payable to the State.

5. Application. The requirements of this section apply to manufacturers, wholesalers and labelers of prescription drugs subject to the Maine Pharmacy Act.

6. Rules. 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 II-A.

SUMMARY

This bill requires prescription drug manufacturers, wholesalers and labelers to register persons employed by them to make informational, educational and sales presentations in this State. It requires the reporting of information about those activities. It requires reports of the average wholesale price of certain drugs, the lowest prices for which those drugs were sold and any rebates or discounts applicable to those drugs. It requires certain disclosures for persons making informational, educational and sales presentations. The bill charges the Bureau of Medical Services within the Department of Human Services with implementing the law and provides for public access to nonconfidential information and for an annual report. The bill makes a violation of the registration or the disclosure requirements a civil violation enforceable by the Attorney General. The bill authorizes the Department of Human Services to adopt rules as necessary to implement the law.