

Porzio Pharmaceutical Alert

Maine Department of Health and Human Services Issues Proposed Rules to Govern the Disclosure of Clinical Trials and Pharmaceutical Marketing Expenses

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Introduction

Maine's Department of Health and Human Services (the "Department"), in cooperation with the Governor's Office of Health Policy and Finance and the Office of the Attorney General, has proposed rules addressing the disclosure of clinical trial information¹ and pharmaceutical marketing expenses² by prescription drug manufacturers and labelers.

The Deputy Commissioner of Health for the Department has issued a letter containing the proposed rules and a notice to solicit public comment.

Background

In 2003, Maine passed legislation that requires a manufacturer or labeler of prescription drugs, which "employs, directs or utilizes marketing representatives," to disclose to the Department the costs associated with marketing drugs dispensed within the State. Pursuant to a June 2, 2005 amendment, the legislature postponed all of the filing and reporting deadlines of ME. REV. STAT. ANN. tit. 22, § 2698-A for a one-year period.

Maine passed additional legislation in 2005 that requires a manufacturer or labeler of prescription drugs that must report marketing costs under § 2698-A to also post, on a publicly accessible Internet website, information concerning the clinical trials of prescription drugs

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¹ See ME. REV. STAT. ANN. tit. 22, § 2700-A (clinical trial disclosure law).

² See ME. REV. STAT. ANN. tit. 22, § 2698-A (pharmaceutical marketing costs disclosure law).

advertised in the State.³ In addition, this statute requires manufacturers and labelers to pay a \$1,000 administrative fee to the Department to cover the costs of maintaining links to the publicly accessible website.

A letter issued by Maine’s Governor’s Office in 2005 further clarified that the clinical trial disclosure law equally applies to manufacturers or labelers that employ, direct, or utilize marketing representatives.

Scope of Proposed Rules

The proposed rules contain two sections. The first section describes the required type, content, timing and location of the clinical trial disclosure information. The second section defines the statutory obligations of manufacturers and labelers to prepare an annual report to the Department disclosing marketing costs for prescription drugs in the state.

Section 1, entitled “Prescription Drug Clinical Trial Reporting,” requires that manufacturers and labelers post certain types of information pertaining to covered clinical trials on a publicly funded website. Mandatory disclosures, include, but are not limited to: (1) identifying information consisting of a unique trial number, trial registration date, any secondary IDs, the names of organizations that provided funding for the study, and all sponsors; (2) a description of the study and comparison/control interventions, including pre-specified duration of interventions; (3) inclusion and exclusion criteria; and (4) study type, including whether the trial is randomized, type of masking, type of controls and group assignment. Additionally, manufacturers and labelers must post the results of the clinical trial and provide a citation or link to the periodical in which the trial was published. The section also sets forth the submission schedule for posting all clinical trial information and defines the penalties⁴ for non-compliance with Maine’s clinical trial disclosure law or these rules.

Section 2, styled “Report of Prescription Drug Marketing Costs,” sets forth the content of the annual report and the timeframe for reporting. With respect to the report, manufacturers and labelers must disclose the following information: (1) all expenses associated with educational or informational programs, materials and seminars, including: (a) support for independent or continuing medical education programs; (b) disease management materials provided to health plans; (c) consulting or activities supporting off-label uses of drugs; (d) charitable contributions;

³ Maine’s legislation also contains a provision that prohibits a manufacturer or labeler of prescription drugs or biological products, dispensed in the state of Maine, from circulating a “regulated advertisement” in a manner that would constitute misbranding under federal law. *See* ME. REV. STAT. ANN. tit. 22, § 2700-A(2).

⁴ *See* ME. REV. STAT. ANN. tit. 22, § 2700-A(6). Each day a manufacturer or labeler fails to comply with the clinical trial disclosure requirement may result in fines of no more than ten thousand (\$10,000) dollars for each violation in accordance with Maine’s Unfair Trade Practices Act (ME. REV. STAT. ANN. tit 5 § 205-A).

(e) patient education materials; and (f) market research or other activities; (2) all expenses associated with food, entertainment, or gifts valued at more than twenty-five dollars (\$25) and anything provided to a healthcare 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 and starter kits that will be distributed free of charge to patients. Reports must be filed with the Department by July 1 of each year starting in 2007. In addition, the section authorizes manufacturers to report data in an electronic format “that is satisfactory to the Department.” All reports must be accompanied by an administrative fee of \$1,000 payable to “Treasurer, State of Maine.” The section also sets forth the penalties⁵ for non-compliance with Maine’s marketing expense disclosure law.

Comment Information

The Department has scheduled a public hearing to solicit comments on the proposed rules for Monday, May 15, 2006. To be timely, all comments must be received by 11:59 p.m., on June 1, 2006.⁶

Conclusion

Maine’s proposed clinical trial and marketing expense disclosure rules are amongst the most liberal in the nation, and if adopted, will fundamentally change the way that pharmaceutical companies develop and market new drugs. Whether, and to what extent, Maine’s clinical trial registry will overlap various industry sponsored initiatives to provide the public with similar information remains an open question. Maine’s rules in any case would benefit from a safe harbor provision making clear that publication of a clinical trial in the registry would not be deemed off-label promotion or DTC advertising. The annual reporting requirements for marketing expenses will impose significant accounting costs on manufacturers that likely will be priced into new products. Rather than improving patient health or decreasing the costs of new medicines, such “sunshine” laws will undoubtedly add an additional compliance cost to what is already the world’s most highly regulated industry.

⁵ See ME. REV. STAT. ANN. tit. 22, § 2698-A(8). The Attorney General is authorized to bring a civil action against manufacturers or labelers who violate the disclosure requirement and to seek monetary fines in the amount of one thousand (\$1,000) dollars, plus costs and attorneys’ fees.

⁶ Additional information regarding the hearing schedule and location, as well as the complete text of the proposed rules, is contained in the attached PDF document.