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Maine Repeals Pharmaceutical Disclosure Requirements Related to Marketing Costs, Drug Pricing, and Clinical Trials

August 15, 2011 | Publications

On July 8, 2011, Governor Paul LePage of Maine signed into law LD 719, "An Act to Make Certain Prescription Drug Disclosure Laws Consistent with Federal Law" ("LD 719"). LD 719 repeals three statutes that require prescription drug manufacturers and labelers to disclose information related to clinical trials, Me. Rev. Stat. Ann. tit. 22, § 2700-A ("§ 2700-A"); marketing costs, Me. Rev. Stat. Ann. tit. 22, § 2698-A ("§ 2698-A"); and drug pricing, Me. Rev. Stat. Ann. tit. 22, § 2698-B ("§ 2698-B"). The repeal becomes effective on September 28, 2011. This Client Alert discusses LD 719.

Summary of LD 719

Clinical Trial Disclosures

LD 719 repeals, in significant part, § 2700-A by striking the clinical trial registration and results reporting requirements that are mandatory for all prescription drug manufacturers and labelers whose products are sold in Maine. Effective September 28, 2011, such drug manufacturers and labelers will no longer be required to register or disclose the results of clinical trials that are not subject to disclosure under federal law.

The Food and Drug Administration Amendments Act of 2007 ("FDAAA") requires clinical investigators and sponsors to register and report results for all "applicable" clinical trials on the National Institutes of Health ("NIH") ClinicalTrials.gov website. Although FDAAA was intended to create uniform clinical trial reporting requirements, the express preemption provision in FDAAA has not been triggered. As a result, industry has been subject to the

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overlapping and partially inconsistent requirements of federal and Maine law.

There are several instances in which Maine's broader reporting obligations require disclosures that are not required by federal law, as well as reporting timelines and administrative provisions that are not wholly consistent with the requirements of FDAAA. Maine's repeal of § 2700-A will reduce regulatory compliance burdens imposed on prescription drug manufacturers, as they will no longer be subject to multiple and potentially conflicting reporting requirements.

Marketing Cost Disclosures

LD 719 also repeals Maine's marketing cost disclosure provision, § 2698-A, effective September 28, 2011. Section 2698-A requires all manufacturers and labelers of prescription drugs dispensed in Maine to report costs related to certain marketing activities conducted in the State including, but not limited to, expenses associated with advertising, marketing, and direct promotion; and food, entertainment, gifts, trips and travel provided to a Maine-licensed health care professional.

Although the repeal of § 2698-A may reduce reporting requirements for prescription drug manufacturers related to Maine, these manufacturers are still subject to other federal and state marketing and disclosure laws.

Actual Price Disclosures

LD 719 further repeals Maine's actual price disclosure statute, § 2698-B, effective September 28, 2011. This statute requires prescription drug manufacturers to disclose, on a quarterly basis, the average manufacturer price ("AMP") and best price ("BP") for all drugs dispensed in Maine that are subject to the Medicaid Drug Rebate Program. Prescription drug manufacturers will no longer be required to submit these price reports to Maine, although federal reporting requirements remain in effect.

Conclusion

Although Maine's repeal of the disclosure requirements described above eliminates potential conflicts with federal reporting requirements and reduces regulatory obligations, manufacturers should review practices for compliance with current federal and state law requirements, as applicable. Regulated entities also should update applicable compliance policies, procedures, work instructions, audit plans, and related processes to reflect the state law change. Manufacturers should determine the potential impact on systems and operations, and adjust accordingly.

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The Epstein Becker Green Client Alert is published by EBG's Health Care and Life Sciences practice to inform health care organizations of all types about significant new legal developments.

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ENDNOTES:

[1]HP 0530, 125th Leg., Reg. Sess., (Me. 2011).

[2]Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, Title VIII § 801 (2007).

[3]The express preemption provision will become effective upon the issuance of final regulations by NIH that expand the clinical trials registry and results data bank. FDAAA § 801(d)(1). The original September 27, 2010 deadline for NIH to promulgate a final rule has since passed and, at this time, NIH has not issued proposed or final regulations.

[4]By way of example, § 2700-A requires the reporting of post hoc analyses of clinical trial data; information pertaining to observational (non-interventional trials); and many bioequivalency and bioavailability studies.

[5]Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002 (2010) ("PPACA"). For an overview of §6002 of PPACA, the Physician Sunshine Act requirements, see showclientalert.aspx?Show=12676.

[6]Currently, seven states — California, Connecticut, Massachusetts, Minnesota, Nevada, Vermont and West Virginia — and the District of Columbia have state marketing and disclosure laws related to pharmaceutical and/or medical device companies. Several other states have similar legislation pending.

[7]The Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, requires drug manufacturers to report AMP and BP to CMS.

Resources

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