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Transparency Update: Vermont Revises Disclosure Form and Seeks Comment on 2011 Draft Consolidated Disclosure Guide

June 8, 2011

The State of Vermont regulates expenditures and gifts to healthcare professionals and entities by manufacturers of prescribed products (medical device, pharmaceutical, and biological products entities). Such entities with reporting obligations in Vermont should be aware that the Vermont Office of the Attorney General (Vermont) announced several revisions to the FY11 Disclosure Form for Manufacturers of Prescribed Products (reporting period July 1, 2010 to June 30, 2011) and the corresponding database, including a change in the date for the relevant reporting periods for expenditures and samples to April 2012 for the latter half of 2011 (July 1, 2011 to December 31, 2011). Vermont also released draft guidance document and draft example forms for reporting allowable expenditures, gifts, and samples for the 2011 reporting period. Notably, the Vermont Attorney General's Office announced that it will hold a teleconference on June 16, 2011 to obtain feedback and to further discuss these documents. This is an important effort by Vermont to seek input from all stakeholders.

Background

Vermont prohibits manufacturers of prescription drugs, devices, and biologics (collectively, prescribed products) from providing certain types of gifts and payments to healthcare providers and practitioners. In addition, Vermont requires such manufacturers to disclose any allowable gifts and expenditures to the AG office on an annual basis. If a manufacturer fails to disclose the required information, the law allows for the AG office to bring an action for injunctive relief, costs, attorneys' fees, and civil penalties of up to $10,000 for each unlawful disclosure. Recent amendments to the Vermont law changed the reporting period for disclosures of allowable gifts and expenditures and imposed a separate reporting requirement for samples of prescribed products distributed by manufacturers to healthcare providers.

2011 Consolidated Disclosure Guide

The 2011 Consolidated Disclosure Guide addresses the recent amendments to the Vermont reporting law and consolidates guidance with respect to the gift ban, the disclosure of allowable expenditures and gifts, and the sample disclosure requirements (previously, these topics had been addressed in separate documents).

The 2011 Consolidated Disclosure Guide also describes Vermont's nonpreemption position with respect to sample reporting requirements. The federal Sunshine Act expressly provides for the preemption of

state reporting requirements, but includes broad exceptions, including exceptions for state laws requiring the disclosure of information that is "not of the type required to be disclosed" under federal law or requiring reporting to a "Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes."

The 2011 Consolidated Disclosure Guide states that the Vermont Attorney General does not believe Vermont's sample reporting requirements are preempted because they are broader than the federal reporting requirements "in that samples of all prescribed products – not only pharmaceuticals – must be reported" and "starter packs and vouchers, co-pay cards and other items that allow patients access to samples for free or at a discounted price" also must be reported. Nonetheless, the guidance document states that Vermont is willing to exempt pharmaceutical manufacturers from submitting "a duplicate of the information [manufacturers] are required to report to HHS, if [the AG] can obtain state- and recipient-specific information regarding manufacturer distribution of free samples from HHS."

The 2011 Consolidated Disclosure Guide does not discuss Vermont's position concerning potential federal preemption of the other state reporting requirements for gifts and allowable expenditures.

Conference Call

As previously noted, the Vermont Attorney General's Office will hold a teleconference on June 16 to discuss and receive comments on the 2011 Consolidated Disclosure Guide and example reporting forms. The call-in details are provided below.

Date: Thursday, June 16, 2011
Time: 1 p.m. ET
Toll Free: 1.888.757.2790
Pass Code: 134936#

Conclusion

Transparency regulations at the state level continue to expand and evolve for device and pharmaceutical manufacturers, and staying current on various changes will be a significant compliance challenge. State implementation and reporting requirements will eventually coincide with federal sunshine transparency provisions. Under the Patient Protection and Affordable Care Act of 2010, federal regulations must be implemented by October 1, 2011 and draft regulations are expected to be issued by the Centers for Medicare and Medicaid Services this summer. There will be a comment period for the federal regulations.

Links to Vermont Documents

Vermont Attorney General website: http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php

Vermont 2011 Draft Consolidated Disclosure Guide: http://www.atg.state.vt.us/assets/files/2011-06-03%20Draft%20Combined%20Guide.pdf

Vermont AG Memo Discussing the June 16, 2011 Conference Call:
http://www.atg.state.vt.us/assets/files/2011-06-06%20Conference%20Call%20on%20Draft%20Combined%202011%20Guide.pdf

Vermont FY11 Sample Disclosure Form:
http://www.atg.state.vt.us/assets/files/FY11%20Example%20Disclosure%20Form.pdf

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