2010 Volume 2

www.ober.com

IN THIS ISSUE

Physician Payment Sunshine Act

By: Susan A. Turner

The Patient Protection and Affordable Health Care Act (H.R. 3590) signed into law in March 2010 includes the Physician Payment Sunshine Act (section 6002) (PPSA), which requires pharmaceutical, medical device, biological, and medical supply manufacturers to report to Health and Human Services (HHS) any "payment or other transfer of value" to physicians and teaching hospitals. The first reports will be due March 31, 2013 for the calendar year 2012 reporting period.

The report must include information about the amount of the payment, the date on which the payment was made, the form of payment, and the nature of the payment (e.g., gift, consulting fees, entertainment). The PPSA specifically excludes certain transfers of value from this disclosure requirement.

Preemption of State Laws

The Physician Payment Sunshine Act will, to a certain extent, preempt state disclosure laws. Several states, including California, the District of Columbia, Massachusetts, Vermont, and West Virginia, have laws which require pharmaceutical and/or medical device manufacturers to report various types of spending. Effective January 1, 2012, the PPSA will preempt any state law that requires a manufacturer to disclose the type of information covered by the federal PPSA.

The PPSA therefore will not preempt any state law that requires the disclosure of the type of information that is *not covered* by the act, *or* information that is *expressly excluded* from disclosure by the act. The PPSA also does not preempt state laws which require the disclosure of information by any person or entity other than an applicable manufacturer or a covered recipient. Finally, the PPSA does not preempt any state law concerning the reporting of information to federal, state, or local governmental agencies "for public health surveillance, investigation, or other public health purposes or health oversight purposes."

One of the main categories of information that is not covered by the PPSA is direct-to-consumer advertising expenses and marketing costs. State laws which require disclosure of this type of spending therefore will not be preempted. Accordingly, companies will need to continue reporting this type of information to state authorities if required to do so by state law.

The PPSA also expressly excludes certain types of payments from its disclosure requirements. Under the PPSA, manufacturers are not required to disclose information concerning the following types of payments or transfers:

1. A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100, subject to increase each year using the consumer price index

2. Product samples that are not intended to be sold and are intended for patient use

3. Educational materials that directly benefit patients or are intended for patient use

4. The loan of a medical device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient

5. Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device

6. A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient

7. Discounts (including rebates)

8. In-kind items used for the provision of charity care

9. A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund

10. In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan

11. In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional

12. In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding

State laws which require the disclosure of information pertaining to these types of payments are not preempted by the PPSA and companies are required to continue reporting such payments to state authorities if required to do so by state law. There is one exception. The PPSA does preempt state laws which require disclosures similar to that described in item 1 above.

Application to Particular States

To ensure compliance with both federal and state disclosure laws, companies will need to be aware of both federal law and the state disclosure laws in each state in which they operate. West Virginia and the District of Columbia both have reporting statutes that apply exclusively to pharmaceutical manufacturers and labelers.

West Virginia Code §5A-3C-13

Under West Virginia Code §5A-3C-13, all manufacturers and labelers of prescription drugs dispensed in the state that employ or use marking representatives must report aggregate advertising costs associated with the promotion and advertising of prescriptions to residents of West Virginia. Because these advertising costs are a type of "transfer of value" that is not covered by the PPSA, pharmaceutical companies which operate in West Virginia are required to continue reporting this information to the state council.

District of Columbia Code §48-833

Under District of Columbia Code §48-833.01, all manufacturers and labelers of prescription drugs dispensed in the District that employ or use marketing representatives must report marketing costs for prescription drugs in the District. Parts of § 48-833 overlap with the disclosure requirements in the PPSA and therefore portions of the District's disclosure law will be preempted.

First, several sections of the District's law will not be preempted by the new federal legislation. Pharmaceutical manufacturers still will be required to report expenses associated with advertising, marketing, and direct promotion of prescription drugs to District residents. Additionally, pharmaceutical manufacturers must continue reporting the aggregate cost of employees and contractors engaged in advertising and promotional activities within the District.

Second, because certain sections of the District's current reporting law requires disclosure of the type of information covered by the PPSA, these sections will be preempted by the new federal legislation. As of January 1, 2012, pharmaceutical manufacturers operating in the District will no longer be required to report the following types of information:

- With regard to transfers of value to persons and entities licensed to provide health care in the District, as long as they are classified as covered entities under the PPSA

- All expenses associated with educational or informational programs
- All expenses associated with food, entertainment, gifts valued at more than $25, and anything provided to health care professionals for less than market value
- All expenses associated with trips and travel
- All expenses associated with product samples, except samples that will be distributed free of charge to patients

Pharmaceutical manufacturers dispensing prescription drugs in the District soon will need to report these types of payments only to the federal government.

Points for Consideration

Because the Physician Payment Sunshine Act does not go into effect until January 1, 2012, manufacturers have some time to figure out how exactly this new law will affect them. Companies should keep in mind that the states in which they operate may have pending and proposed physician payment disclosure legislation which may take effect in the interim.