Connecticut Law Tribune
May 30, 2013
An ALM Publication

Shining The Light On Physician Payment Sunshine Act

Law requires pharmaceutical firms to disclose gifts to physicians, hospitals

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For many years, there have been raucous debates about the implications of medical device, pharmaceutical and other medical products companies providing payments or gifts to physicians and hospitals. While there have been sporadic attempts at both the state and federal level to address such payments and gifts through reporting and disclosure laws, a national approach was not established until the Physician Payment Sunshine Act was promulgated in 2010, which sets forth comprehensive disclosure and reporting rules applicable to many participants in the health care and bioscience sectors.

The Centers for Medicare and Medicaid Services (CMS) recently issued final regulations to implement the Sunshine Act's reporting and transparency requirements. The law requires certain manufacturers of drugs, devices, biologicals or medical supplies to report to CMS certain payments or transfers of value (collectively referred to as "payments") to physicians and teaching hospitals — everything from consulting arrangements to bagels. (The law also requires certain manufacturers and group purchasing organizations to report ownership and investment interests which are not discussed herein.)

Applicable manufacturers must begin to collect the required data on August 1, 2013 and report the data to CMS by March 31, 2014. Thereafter, reports must be submitted to CMS by the 90th day of each calendar year. Accordingly, manufacturers should be implementing processes to collect, store and report the required information. To assist such manufacturers, we have prepared the following FAQs:

Who needs to report payments? "Applicable manufacturers" that make any type of payments to a physician or teaching hospital are required to report. "Applicable manufacturers" are entities that "engage in the production, preparation, propagation, compounding, or conversion of" drugs and biologicals that require a prescription; or medical devices and supplies that require premarket approval by, or notification to, the Food and Drug Administration (each a "covered product"). Payment for a drug, biological, device or medical supply must be available under Medicare, Medicaid or the Children's Health Insurance Program in order for it to be a covered product.

The obligation to report also applies to entities "under common ownership" with applicable manufacturers, when the entity provides "assistance and support" to the applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product. "Under common ownership" refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more of two entities, including parent corporations, direct and indirect subsidiaries and brother/sister corporations. An entity provides "assistance and support" when it provides services necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product.


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What payments need to be reported? Any payment to a physician (other than a resident or a physician who is an employee of an applicable manufacturer) or teaching hospital (each a "covered recipient"); or any payment to other individuals or entities to be passed through to a physician.

Does the Sunshine Act require reporting on all payments to covered recipients or only payments particular to covered products? An applicable manufacturer must report all payments to covered recipients, unless one of the following exceptions applies:

- If an applicable manufacturer does not manufacture a covered product except

pursuant to a written agreement to manufacture the covered product for another entity, does not hold the FDA approval, licensure or clearance for the product and is not involved in the sale, marketing or distribution of the product, then the manufacturer is only required to report payments related to the covered product it manufactures.

- The act permits applicable manufacturers with less than 10 percent of total (gross) revenues from covered products during the previous fiscal year to report only payments specifically related to covered products.

We have separate operating divisions that do not produce any covered products. Must these divisions report all payments to covered recipients? Separate operating divisions of applicable manufacturers that produce only non-covered products and which do not qualify as applicable manufacturers themselves under the common ownership rules are required to report only payments that are related to a covered product.

If I am considered an "applicable manufacturer" and have made a payment to a covered recipient, what kind of information must I report to CMS? An applicable manufacturer must report the name and business address for the recipient; specialty, National Provider Identifier and at least one state professional license number of physician recipients; amount and date of payment; information regarding ownership or investment interests of the recipient; name of product (if payment is related to a specific product); form of payment (e.g., cash); and nature of payment broken down by category (e.g., contingency fee, honoraria, research, gift, entertainment, food); and name of entity paid.

Are there any payments that do not need to be reported? Yes, certain payments do not need to be reported, including, but not limited to: for calendar year 2013, payments of less than $10 (except when the total annual value of payments provided to a covered recipient exceeds $100); product samples that are not intended to be sold and are intended for patient use; educational materials that directly benefit patients or are intended for patient use; discounts, including rebates; and in-kind items used for the provision of charity care.

What is the procedure for submitting reports to CMS? Applicable manufacturers with reportable payments must register with CMS and submit the required reports to CMS electronically. CMS encourages (but does not require) applicable manufacturers to include an assumptions document, explaining the assumptions made and methodologies used when reporting payments. The reports must include an attestation by the CEO or another company officer that the information reported is timely, accurate and complete.

What are the potential penalties for failure to report? The Sunshine Act establishes two penalty tiers based upon one's knowledge or lack thereof. If an applicable manufacturer fails to submit the required information in a timely, accurate or complete manner, the applicable manufacturer may be subject to a civil monetary penalty of at least $1,000, but no more than $10,000, for each unreported payment. The maximum total monetary penalty with respect to each annual submission for failure to report is $150,000. Penalties for a knowing failure to submit required information include at least $10,000, but no more than $100,000, for each knowingly and unreported payment. The maximum total penalty with respect to each annual submission for a knowing failure to report is $1,000,000.

May CMS audit manufacturers for compliance with the reporting requirements? Yes, CMS may audit or inspect applicable manufacturers for compliance with the reporting requirements. Applicable manufacturers must maintain all supporting documentation sufficient to enable such audits for at least five years from the date the payment is published by CMS.

Am I still subject to additional reporting requirements imposed by state law requiring disclosure of the same type of information? No. The Sunshine Act preempts state laws requiring disclosure of similar types of information by applicable manufacturers. States may still require reporting of information for payments not reported to CMS. ■

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