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Client Alert

FDA & Life Sciences Practice Group

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CMS Proposes Changes to Physician Payments Sunshine Act Implementing Regulations

On July 3, 2014, the Centers for Medicare and Medicaid Services (CMS) released four proposed changes for comment to the implementing regulations for the Physician Payments Sunshine Act.[1,2] The proposed changes would amend the final rule CMS published in February 2013, and will be officially published in the *Federal Register* on Friday, July 11, 2014 within a Proposed Rule devoted predominantly to proposed changes to the Medicare physician fee schedule for calendar year 2015.[3]

CMS's proposed changes, if adopted, would take effect for data collection beginning January 1, 2015. The changes would not impact current data collection efforts for the calendar year 2014 reporting period. CMS is soliciting comments from interested stakeholders on its proposed changes. Comments must be received by CMS no later than September 2, 2014.

Brief Background on Sunshine Reporting

Under the Sunshine Act and its implementing regulations, certain pharmaceutical, biologic, and medical device manufacturers must annually report to CMS payments or other transfers of value they furnish to physicians and teaching hospitals (deemed "covered recipients"). The law also requires certain manufacturers and group purchasing organizations ("GPOs") to report ownership or investment interests in their organizations held by physicians.

The proposed changes come on the heels of the June 30 deadline for manufacturers and GPOs to submit their first disclosure reports to CMS that cover the period August 1 to December 31, 2013.[4] CMS is required to aggregate the information manufacturers and GPOs submit and make it publicly available through a searchable website. The agency plans to make the initially reported data publicly available by September 30, 2014.

Summary of Proposed Changes to Sunshine Reporting Requirements

As discussed in more detail below, CMS's proposed changes to the Sunshine reporting requirements include: (1) removing the exclusion for payments to physicians for speaking at certain accredited continuing education programs; (2) requiring manufacturers to report the marketed name of all products

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associated with reported payments or transfers of value (if any); (3) separating out form descriptors used in reporting ownership interests; and (4) removing the definition of "covered device."

1. Removing the exclusion for compensation provided to physicians for speaking at accredited continuing education programs.

CMS proposes to remove the exclusion codified at 42 CFR § 403.908(g), which currently excludes from reporting compensation provided to a physician for speaking at a continuing medical education program, if: (1) the program meets the accreditation requirements and standards for continuing education of one of five listed organizations;[5] (2) the manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program; and (3) the manufacturer does not pay the physician speaker directly.

CMS indicates that its "apparent endorsement or support" of the five organizations listed in the final rule was an "unintended consequence" of the exclusion, and notes that it proposes to delete the exclusion in part because it believes the exclusion is redundant with the exclusion for indirect payments where the manufacturer does not "know" the identity of the physician covered recipient (codified at 42 CFR § 403.904(i)(1)). Notably, CMS states that "[w]hen an applicable manufacturer . . . provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1)." CMS contrasts that situation with those where "an applicable manufacturer conditions its financial sponsorship of a continuing education event on the participation of particular covered recipients, or pays a covered recipient directly for speaking at such an event," noting that payments to physicians in those scenarios are "subject to disclosure."

2. Requiring the reporting of the marketed name for all covered and non-covered drugs, biologicals, devices, and medical supplies associated with a payment or other transfer of value.

Under the current regulations, manufacturers are only required to report the marketed name for covered drugs and biologics that are associated with a payment or other transfer of value. For covered devices and medical supplies associated with a payment or other transfer of value, manufacturers currently have the option of reporting either the marketed name, therapeutic area, or product category. If adopted, the proposed change would require manufacturers to report the marketed name of devices and medical supplies associated with payments or other transfers of value. CMS states that the rationale for the change is to again correct an unintended consequence and to make the reporting requirements consistent.

3. Separating the existing form descriptor for "stock, stock options, or any other ownership interest" into three distinct form descriptors, "stock," "stock options," and "other ownership interest."

CMS proposes this change to enable collection of more specific data from applicable manufacturers. The agency believes such specificity will increase the ease of data aggregation and enhance consumers' use of reported data.

4. Removing the definition of "covered device."

CMS proposes to delete the definition of "covered device" because it believes the definition is redundant in light of the definition of "covered drug, device, biological, or medical supply," which is also codified in the final rule.

Implications of the Proposed Changes

Manufacturers should thoughtfully assess the impact that CMS's proposed changes could have on efforts to collect and report data to CMS, and consider submitting comments to CMS on aspects of the changes that could raise new reporting challenges.

The most significant operational impact of the proposed changes would likely be on companies that manufacture, market, and/or distribute medical devices or medical supplies. Under CMS's proposal, in reporting payments or other transfers of value associated with devices and medical supplies, companies would no longer be able to report products under therapeutic areas or product categories; rather, they would have to report the marketed name of each device or medical supply associated with a particular payment or transfer of value (up to five). This could require significant and expensive upgrades to tracking systems to enable such detailed reporting, and could be especially problematic for companies that manufacture, market, or distribute a large portfolio of devices or medical supplies.

In addition, although the proposed removal of the CME faculty compensation exclusion seems significant, CMS's statements that it interprets the indirect payments exclusion to apply in largely the same circumstances (and that the CME faculty compensation exclusion is therefore redundant) suggest that removing the exclusion may have little practical impact. CMS's statements in that regard (especially if they would be reiterated in the preamble or other documentation accompanying any finalized revisions to the reporting requirements) may in fact have the effect of expanding the circumstances in which manufacturers may reasonably exclude payments furnished to physician speakers of accredited *and non-accredited* continuing education programs. Importantly, however, if CMS would change its view of the application of the indirect payments exclusion to CME activities (which, while not anticipated, could occur at any time *via* sub-regulatory guidance), the removal of the CME faculty compensation exclusion could have a more substantial impact.

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[1] The proposed changes are currently available at the Federal Register Public Inspection Desk, available at http://www.ofr.gov/OFRUpload/OFRData/2014-15948_PI.pdf. The proposals will be officially published in the *Federal Register* on Friday, July 11, 2014.

[2] The Physician Payments Sunshine Act statutory provisions are codified at Social Security Act § 1128G.

[3] 78 Fed. Reg. 9458 (Feb. 8, 2013).

[4] Notably, CMS sent a communication to some manufacturers on June 30 informing them that the agency would not enforce penalties for reporting non-compliance until July 7. The agency has not otherwise publicly announced the one-week extension to the June 30 deadline.

[5] The five organizations listed in the final rule include: (1) the Accreditation Council for Continuing Medical Education; (2) the American Academy of Family Physicians; (3) the American Dental Association's Continuing Education Recognition Program; (4) the American Medical Association; and (5) the American Osteopathic Association.