

E-ALERT | Health Care

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CMS ISSUES PROPOSED RULE IMPLEMENTING SUNSHINE ACT: REPORTS REGARDING OWNERSHIP OR INVESTMENT INTERESTS HELD BY PHYSICIANS

On December 19, 2011, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule implementing Section 6002 of the Affordable Care Act (ACA) (Pub. L. 111-148, as amended by Pub. L. 111-152), which requires applicable manufacturers and group purchasing organizations (GPOs) to submit information about certain financial relationships with physicians and teaching hospitals.

This alert is the third in a three-part series regarding the proposed rule, and it summarizes the portion of the rule addressing the reports required to be submitted regarding ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and GPOs.¹

BACKGROUND

Section 6002 of ACA added section 1128G to the Social Security Act (SSA). Section 1128G requires applicable manufacturers and GPOs to report annually to CMS certain information regarding ownership or investment interests held by physicians or their immediate family members in such entities.² CMS is required by statute to publish the reported data on a public website.³

TIMING OF REPORTS

The statute requires manufacturers and GPOs to begin collecting data on January 1, 2012; however, in the proposed rule, CMS states that a final rule will not be published in time for manufacturers and GPOs to begin collecting the required information on January 1. Thus, CMS will not require data collection to begin until after the publication of the final rule. CMS is considering an implementation period of 90 days after publication; as a result, manufacturers and GPOs would be required to collect data for only part of 2012 (the exact portion will depend on the timing of the final rule), which will be reported to CMS by the statutory date of March 31, 2013.

¹ The [first alert](#) addresses the reports required to be submitted by manufacturers regarding payments or other transfers of value to physicians and teaching hospitals. The [second alert](#) addresses how CMS will publish the reported data on a public website and other aspects of the proposed rule, including CMS's comments on the statutory preemption provision.

² Section 1128G also requires applicable manufacturers to report information regarding payments or other transfers of value to covered entities.

³ The [second alert](#) in this series addresses the proposed rule's provisions related to publication of reported data on a public website.

RELEVANT DEFINITIONS

- **Applicable Group Purchasing Organization.** The ACA requires applicable GPOs to submit reports on physician ownership or investment interests. CMS proposes to define “applicable GPOs” as entities that (1) operate in the United States (or a territory, possession or commonwealth of the United States), and (2) purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities, and not solely for use by the purchaser itself. CMS notes that this definition would include not only traditional GPOs but also other entities that purchase covered products for resale or distribution. For example, this definition would include physician owned distributors of covered products but would exclude entities purchasing products for their own use.
- **Physician.** Section 1128G(a)(2) does not exclude from the definition of “physician” employees of applicable manufacturers. As a result, CMS interprets the reporting requirements for GPOs to require reporting of physician ownership and investment interests for any physician, even if the physician is an employee of the applicable manufacturer or GPO.
- **Immediate Family Member.** Under the statute, ownership and investment interests of immediate family members of physicians must also be reported. CMS proposes to define “immediate family member” as a person who is one of the following: (1) a spouse; (2) a natural or adoptive parent, child, or sibling; (3) a stepparent, stepchild, stepbrother, or stepsister; (4) a father-, mother-, daughter-, son-, brother-, or sister-in-law; (5) a grandparent or grandchild; or (6) a spouse of a grandparent or grandchild.
- **Ownership or Investment Interests.** CMS proposes to define an “ownership or investment interest” as one that may be direct or indirect, and through debt, equity, or other means. The term would include stock, stock options, partnership shares, limited liability company memberships, loans, bonds, and other secured financial interests. No exception is made for de minimis ownership or investment interests. *The definition would exclude an ownership or investment interest in a publicly traded security or mutual fund, an interest in a manufacturer or GPO arising from a retirement plan, stock options and convertible securities received as compensation (until exercised), and unsecured loans subordinated to credit facilities.*

CONTENT OF REPORTS

The specific categories of information to be reported for each physician ownership or investment interest are set forth in the ACA. In the proposed rule, CMS provides the following clarification regarding how some of this information should be reported:

- **Physician Owner/Investors.** Manufacturers and GPOs must report the name, address, National Provider Identifier (NPI), and specialty of the physician owner/investor.
- **Immediate Family Members.** In cases where the ownership/investment interest is held by an immediate family member of a physician, the manufacturer or GPO would also be required to report that fact. CMS is also considering requiring reporting of the relationship and/or name of the immediate family member.
- **Payments or Transfers of Value.** In addition to reporting the existence of any physician ownership or investment interest, manufacturers and GPOs must also report any payment or other transfer of value to physicians holding ownership or investment interests. CMS proposes

that manufacturers and GPOs follow the same procedures and include the same data elements as for reporting payments and other transfers of value.⁴

- **Duplicative Reporting.** CMS acknowledges the potential for duplicative reporting because of some overlap in the statutory requirements and proposes that manufacturers submit one file for all payments and transfers of value and another for all physician ownership or investment interests. Manufacturers should report the payments or transfers of value to physician owners/investors (regardless of whether the physician owner is a covered recipient) in the section for all payments and transfers of value but should note that the covered recipient receiving the payment is a physician owner/investor. CMS proposes that if an ownership or investment interest is required to be reported under both sections of the SSA, the manufacturer report the ownership/investment interest only under the reporting requirements for payments or other transfers of value to physicians and teaching hospitals.

REPORT SUBMISSION

CMS proposes that manufacturers and GPOs submit their data electronically in a comma-separated value (CSV) format. All manufacturers and GPOs, regardless of whether they have data to report, would be required to register with CMS. Manufacturers and GPOs would be required to submit an attestation stating either that all submitted data is correct or that the manufacturer or GPO has no reportable information. The proposed rule lists the information to be included in the reports. To decrease the need for corrections during the 45-day review and correction period,⁵ CMS recommends that manufacturers and GPOs provide the information to covered recipients in advance of submitting it to CMS.

CMS intends to audit applicable manufacturers and GPOs and proposes to require applicable manufacturers and GPOs to maintain all books, records, documents, and other materials for a period of at least five years from the date the reported information is published on CMS's website.

Comments on the proposed rule are due on February 17, 2012. Please contact one of the attorneys listed below if you would like assistance in drafting comments or have questions regarding implementation of the disclosure requirements.

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⁴ This information is addressed in the [first client alert](#) in this series.

⁵ The review and correction period is discussed in the [second client alert](#) in this series.