

E-ALERT | Health Care

December 30, 2011

CMS ISSUES PROPOSED RULE IMPLEMENTING SUNSHINE ACT: REVIEW, CORRECTION, AND PUBLICATION OF DATA ON PUBLIC WEBSITE

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 second in a three-part series regarding the proposed rule, and it summarizes the portion of the rule addressing how CMS will publish the data on a public website, as well as several other issues related to reports regarding payments made by manufacturers to physicians and teaching hospitals.¹

BACKGROUND

Section 6002 of ACA added section 1128G to the Social Security Act (SSA). Section 1128G requires applicable manufacturers of drugs, devices, biologicals, or medical supplies for which coverage is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals.² CMS is required by statute to publish the reported data on a public website.

45-DAY REVIEW PERIOD

Under the ACA, manufacturers and GPOs, as well as covered recipients and physician owners/investors have 45 days to review the data submitted to CMS by manufacturers and GPOs before the data are made publicly available. To decrease the need for corrections during the 45-day review and correction period, CMS recommends (but does not require) that manufacturers provide the information to covered recipients in advance of submitting it to CMS. Once the data have been submitted and aggregated by CMS, the agency plans to notify all manufacturers, GPOs, covered recipients, and physician owners/investors about the procedures for review. In the proposed rule, CMS provides the following information regarding their plans for these procedures:

- **Notification of Procedures for Review.** Covered recipients would have the opportunity—but would not be required—to register with CMS to ensure they receive communications about the processes for review. CMS also proposes to notify physicians and teaching hospitals through the

¹ The [first alert](#) addresses the reports required to be submitted by manufacturers regarding payments and other transfers of value provided to covered recipients. The third alert addresses reporting requirements regarding ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and GPOs.

² Section 1128G also requires applicable manufacturers and GPOs to report certain information regarding the ownership or investment interests held by physicians or their immediate family members in such entities.

agency's list-serves and by posting the information publicly. CMS is considering requiring manufacturers and GPOs to collect and report whether the covered recipient, or physician owner/investor would like to be notified by U.S. mail or email of the process for review.

- **Dispute Resolution.** CMS proposes that in the event of a dispute over the reported data, covered recipients and physician owners/investors would be able to request from CMS the contact information for a specific manufacturer or GPO, but it would be the responsibility of the covered recipient or physician owner/investor to resolve the dispute. At least one of the entities involved would be required to report the dispute and its resolution to CMS by the end of the 45-day review period. If the dispute cannot be resolved, the data would be identified as contradictory and both the original submission from the manufacturer or GPO, and the modified information provided by the covered recipient or physician owner/investor would appear on the publicly available website. The data provided by the covered recipient or physician owner/investor would be used for aggregated totals when a dispute cannot be resolved.
- **Correction of Errors.** CMS proposes that the 45-day review period be the primary opportunity to correct errors or contest the data submitted to CMS. After the 45-day review period has passed, none of the parties could further amend the data for that calendar year. The parties could continue to notify CMS regarding any errors or omissions, but these changes would not be made until the data is refreshed for the following reporting year.

PUBLICATION OF DATA

The ACA requires CMS to publish, on a publicly available website, the data reported by manufacturers and GPOs for calendar year 2012 by September 30, 2013, and by June 30 for each year thereafter. The public website must be searchable, understandable, downloadable, and easily aggregated on various levels. CMS proposes to include the following information on payment and other transfers of value on the public website:

- Applicable manufacturer name;
- Covered recipient name, specialty (physician only), and business street address (practice location);
- Amount (in U.S. dollars), date, form, and of payment or other transfer of value;
- Name of the covered drug, device, biological, or medical supply, when applicable; and
- Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly.

CMS proposes to publish the following information for physician ownership and investment interests:

- Applicable manufacturer or GPO name;
- Physician owner name, specialty, and business street address, as well as whether the ownership or investment interest is held by the physician or an immediate family member of the physician;
- Dollar amount invested, as well as value and terms of each ownership or investment interest; and
- Any payment or other transfer of value provided to the physician owner, including the amount (in U.S. dollars), date, form, and nature of the payment or transfer of value, as well as the name of the covered drug, device, biological, or medical supply (as applicable).

CMS also proposes that the website include information on any enforcement activities taken under the statute for the previous year, background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals, and publication of information on payments or other transfers of value that were granted delayed publication (described below). In addition, the website would clearly state that disclosure of a payment or other transfer of value on the website does not indicate either that the transfer was legitimate or that there was a conflict of interest or any wrongdoing.

DELAYED PUBLICATION

The ACA provides for delayed publication of payments or other transfers of value from manufacturers to covered recipients made pursuant to product research or development agreements or clinical investigations. CMS provides the following guidance on delayed publication:

- **Procedure.** CMS proposes that manufacturers be required to indicate on their reports whether or not a payment or other transfer of value is eligible for a delay in publication. Such payments would be required to be reported each year and updated as necessary, with an indication that publication should remain delayed. Following FDA approval, licensure, or clearance, manufacturers would be required to indicate in their next annual submission that the publication should no longer be delayed.
- **Written Agreement Required.** Delayed publication would be available only for payments or other transfers of value provided in the context of bona fide research or investigation activities, which, if made public, would damage the manufacturers' competitive and/or proprietary interests. CMS would therefore require that the research or development agreement include a written statement or contract between the manufacturer and covered recipient, as well as a written research protocol. Eligible clinical investigations would be limited to those memorialized in a written research protocol.
- **Scope of Eligible Research or Investigation Activities.** CMS proposes to allow delayed publication with respect to research on or development of a new drug, device, biological, or medical supply or a new application of an existing product. In the context of clinical investigations, however, delayed publication would be permitted only for a new drug, device, biological, or medical supply.

PENALTIES

The ACA authorizes the imposition of civil monetary penalties (CMPs) of not less than \$1,000, up to \$10,000, with a cap of \$150,000 per annual submission, for failure to report each transfer of value or interest as required. These penalties are multiplied tenfold, with an annual cap of \$1,000,000, for knowing failures to report. Outside the 45-day period prior to publication, any additions or oversights would be considered late and thus subject to penalties. CMS intends to audit manufacturers and GPOs and proposes to require that manufacturers and GPOs 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.

RELATION TO STATE LAWS

The ACA preempts all state and local laws requiring reporting of the same type of information required under section 1128G(a). State or local government reporting requirements are not preempted if the information is being collected by a federal, state, or local governmental agency for public health purposes. This exception does not apply to reporting requirements related to payments

or other transfers of value included in section 1128G of the SSA. States and local governments may require reporting of other information, including types of information excluded under the statute, except that reports of payments that fall below the statute's minimum thresholds (\$10 for individuals, or \$100 in aggregate) may not be required by states.

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.

Erika Lietzan	202.662.5165	elietzan@cov.com
Anna Kraus	202.662.5320	akraus@cov.com
Demetrios Kouzoukas	202.662.5057	dkouzoukas@cov.com
Stefanie Doeblner	202.662.5271	sdoeblner@cov.com
Amalia Fenton	202.662.5445	afenton@cov.com

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