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E-ALERT | Health Care

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CMS ISSUES PROPOSED RULE IMPLEMENTING SUNSHINE ACT

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 first in a three-part series regarding the proposed rule, and it summarizes the portion of the rule addressing the reports required to be submitted by manufacturers regarding payments and other transfers of value provided to covered recipients.[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.

TIMING OF REPORTS

The statute requires manufacturers to begin collecting data on January 1, 2012; however, in the proposed rule, CMS states that a final rule will not be published in time for manufacturers to begin collecting the required information on January 1. Thus, CMS will not require manufacturers to begin collecting this information until after the publication of the final rule. CMS is considering an implementation period of 90 days after publication; as a result, manufacturers 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.

RELEVANT DEFINITIONS

- **Applicable Manufacturer.** Under CMS's proposed definition, a manufacturer of a covered drug, device, biological, or medical supply is deemed an "applicable manufacturer" if it sells or distributes at least one covered drug, device, biological, or medical supply in the United States,

[1] The second alert will address 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. The third alert will address 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.

regardless of where the product is produced or where the manufacturer is located or incorporated. The agency proposes to require that all payments or transfers of value made by an applicable manufacturer to a covered recipient be reported, regardless of whether the particular payment or other transfer of value is associated with a covered product. The proposed definition also includes entities that hold Food and Drug Administration (FDA) approval, licensure, or clearance for a covered drug, device, biological, or medical supply, even if such entities contract out the physical manufacturing of the product to another entity.

- **Common Ownership.** Entities are also considered to be "applicable manufacturers" if they are under common ownership with an entity described above, and provide assistance or support to the entity with respect to the production, marketing, promotion, sale, or distribution of a covered product. CMS proposes to define "common ownership" as occurring "when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities" (e.g., parent companies, subsidiaries, brother/sister corporations, etc.). CMS is also considering an alternative interpretation that would limit the common ownership definition to circumstances where "the same individual, individuals, entity, or entities own" five percent or more of total ownership in two or more entities. In any case, if two entities are under common ownership with one another, and both otherwise individually meet the above definition of an applicable manufacturer, then the entities would be required to submit separate reports. But if only one company under common ownership satisfies the definition, and the other company is required to report only because it is under common ownership with the first, then the companies would be permitted to choose whether or not to report jointly.
- **Covered Drug, Device, Biological, or Medical Supply.** CMS proposes to define a "covered drug, device, biological, or medical supply" to limit covered drugs and biologicals to those that can be dispensed only upon a prescription, thus excluding over-the-counter (OTC) drugs and biologicals. Similarly, the definition would limit covered devices and medical supplies to those devices (including medical supplies) that require premarket approval by, or notification to, FDA. As a result, most Class I devices and certain Class II devices would be excluded from the definition. Under this definition, manufacturers who manufacture OTC drugs or biologicals and/or exempt devices in addition to at least one covered drug, device, biological, or medical supply would be required to report all payments or transfers of value to covered recipients, regardless of whether the payment or transfer of value is associated with a covered product.
- **Covered Recipients.** The ACA defines a "covered recipient" as a physician, other than a physician who is an employee of an applicable manufacturer, or a teaching hospital. CMS proposes to define a teaching hospital as an institution that receives Medicare payments for direct or indirect graduate medical education (GME) under section 1886 of the SSA. To enable manufacturers to determine whether a particular hospital meets the definition of a "teaching hospital," CMS would annually publish on its website a list of those hospitals that received payments for GME. The statute requires reports to include each physician's National Provider Identifier (NPI), and specialty. CMS suggests that manufacturers use the National Plan & Provider Enumeration System (NPPES), found on CMS's website, to determine each physician's NPI. To the extent that a physician is not listed in the NPPES NPI registry, the manufacturer would be responsible for obtaining the physician's individual NPI directly from the physician.
- **Payments or Other Transfers of Value.** CMS interprets "payment or other transfer of value" to include payments or transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient; such payments would be required to be reported under the name of the covered recipient. Manufacturers would also be required to report the name of the entity or individual that received the payment at the request of or designated on behalf of the covered recipient. Payments or other transfers of value provided to a physician

through a physician group or practice would also be required to be reported individually under the name of the physician.

CONTENT OF REPORTS

The specific categories of information required to be reported for each payment or transfer of value provided to a covered recipient are set forth in the ACA. In the proposed rule, CMS provides the following information about how some of this information would be required to be reported:

- **Name and Address of Covered Recipient.** The first name, last name, and middle initial, as well as the full street address would be required to be reported for each physician. For teaching hospitals, manufacturers would be required to report only the address included in the CMS-published list of teaching hospitals. For physicians, manufacturers would be required to report the physician's primary practice location, found in NPPES as the "provider business practice location."
- **Specialty and NPI.** When reporting the physician's specialty, manufacturers would be required to use the NPPES "provider taxonomy" and to report only a single specialty for each physician. When reporting the physician's NPI, manufacturers would be required to report the physician's individual NPI, rather than the NPI for any group with which the physician may be associated.
- **Date of Payment.** For payments or transfers of value that are provided over multiple dates, manufacturers would be permitted to report either (1) the total payment on the date of the first payment as a single line item, or (2) each individual payment as a separate line item. CMS is considering whether to require manufacturers to report multiple payments in a single, consistent manner.
- **Associated Product.** Under the proposed rule, when a payment or other transfer of value is "reasonably associated" with a specific drug, device, biological, or medical supply, the name of the specific product would have to be reported.
- **Form of Payment.** CMS does not propose to add any forms of payment beyond those outlined in the statute, and the proposed rule states that each form of payment will be defined by the term's "dictionary definition."
- **Nature of Payment.** CMS proposes to define each statutory nature of payment category by its "dictionary definition." The purpose and manner of the payment or other transfer of value would be factors in determining the nature of a payment. For payments that could fall into more than one category, manufacturers may make "reasonable determinations" about the nature of payment and would report only one category per payment or transfer of value. CMS provides further explanation with respect to several categories of nature of payment, including:
    - **Payments Falling Under Multiple Categories:** Payments or other transfers of value that are associated with multiple categories, such as travel to a meeting under a consulting contract, would be required to be separately reported, but applicable manufacturers would be required to report only a single nature of payment and a single form of payment for each payment or transfer of value. For example, if a physician received meals and travel in association with a consulting fee, the applicable manufacturer would be required to report three separate line items: one for consulting fees, one for meals, and one for travel.
    - **Charitable Contributions:** Charitable contributions to, at the request of, or on behalf of covered recipients by manufacturers would be required to be reported. CMS proposes to define a charitable contribution as any payment or transfer of value made to an

organization with tax-exempt status under the Internal Revenue Code of 1986 that is not more specifically described by one of the other nature or payment categories.

- **Food & Beverage:** Where meals are provided in group settings, manufacturers would be required to report the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake in the meal, but, e.g., the covered recipients' staff do so instead). Offerings of buffet meals, snacks, or coffee at booths at conferences or other similar events where it would be difficult to definitively establish the identities of those present would be exempt from reporting requirements.
- **Research:** All payments or other transfers of value designated as research must be subject to a written agreement and research protocol. CMS distinguishes between "direct research" and "indirect research," which manufacturers would be required to report separately. "Direct research" refers to instances when a research payment or other transfer of value is provided directly to a physician or teaching hospital by an applicable manufacturer or contract research organization (CRO). "Indirect research" refers to instances when a research payment is made to a clinic, hospital (other than a teaching hospital), or institution conducting the research (either by an applicable manufacturer or a CRO), and that organization in turn pays the physician(s) serving as principal investigator(s). When reporting direct and indirect research, manufacturers would be required to report the name and NPI of the physician serving as the principal investigator (PI). Reports of indirect research would also include the name of the entity that received the payment or transfer of value. A research payment or transfer of value to a teaching hospital would be reported as both direct research relative to the teaching hospital and indirect research relative to the physician PI.
- **Direct Compensation for Serving as a Speaker for a Medical Education Program:** CMS proposes that the medical education category be interpreted broadly to encompass all instances in which manufacturers pay physicians to serve as speakers, and not just situations involving "medical education programs." Alternatively, CMS is considering adding another nature of payment category to describe situations when a covered recipient provides speaking services that are outside of medical education programs.
- **Other:** CMS proposes to add another nature of payment category to serve as a catch-all for all payments or other transfers of value that do not fit into one of the listed natures of payment. Any payments or transfers of value that are not specifically excluded and do not fit into another category would be required to be reported with a nature of payment of "other."

- **Exclusions.** CMS proposes that manufacturers use "dictionary definitions" in interpreting the scope of the statutory exclusions but provides clarifications on how it proposes to apply certain exclusions, including:
  - **Transfers of Value Less than $10:** CMS proposes that applicable manufacturers should not be required to report any payments or other transfers of value of less than $10 individually so long as the total annual value of transfers is less than $100. CMS also proposes that all small payments or transfers of value in the same nature of payment category be aggregated as one total amount for that category.
  - **Educational Materials Intended for Patients:** CMS clarifies that the exclusion for educational materials that directly benefit patients or are intended for patient use is limited to "materials" (including, but not limited to, written or electronic materials) and does not include services or other items. The agency is considering whether certain materials provided to covered recipients to educate the covered recipients

themselves—but not actually given to patients (e.g., medical textbooks)—should be interpreted as educational materials that "directly benefit patients."

- **In-kind Items for the Provision of Charity Care**: CMS proposes to define "charity care" as items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay. This exclusion would not cover the provision of in-kind items to a charitable organization for the care of the organization's paying patients, even if the items are used for some non-paying patients.
- **Indirect Payments Through a Third Party**: CMS proposes that the exclusion for transfers of value made indirectly to a covered recipient through a third party would apply only when the applicable manufacturer does not have actual knowledge of, or does not act in deliberate ignorance or reckless disregard of, the identity of the covered recipient.

REPORT SUBMISSION

CMS proposes that manufacturers submit their data electronically in a comma-separated value (CSV) format. Manufacturers would be allowed to submit a document (that would not be publicly posted but presumably subject to release under the Freedom of Information Act) describing assumptions used when categorizing the payments. All manufacturers, regardless of whether they have data to report, would be required to register with CMS. Manufacturers would be required to submit an attestation stating either that all submitted data is correct or that the manufacturer 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,[3] CMS recommends that manufacturers provide the information to covered recipients in advance of submitting it to CMS.

Comments on the proposed rule are due on February 17, 2012. Please contact one of the attorneys listed below if you 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 Doebler	202.662.5271	sdoebler@cov.com
Amalia Fenton	202.662.5445	afenton@cov.com

[3] The review and correction period will be discussed in the second client alert in this series.