The Physician Payment Sunshine Act Final Rule
A Summary Of Key Provisions

COLIN ZICK
Partner
Boston
617 832 1275 direct
czick@foleyhoag.com

PAT CERUNDOLO
Partner
Boston
617 832 1252 direct
pcerundolo@foleyhoag.com

TAD HEUER
Associate
Boston
617 832 1187 direct
theuer@foleyhoag.com

IGOR GORLACH
Associate
Boston
617 832 1715 direct
igorlach@foleyhoag.com

On February 1, 2013, Centers for Medicare and Medicaid Services (CMS) published the long-awaited Physician Payment Sunshine Act (Sunshine Act) Final Rule, implementing Section 1128G of the Social Security Act.[1]

The Sunshine Act (passed in 2010 as part of the Affordable Care Act and summarized here) requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually all payments and other transfers of value to physicians and teaching hospitals.

However, the language of the Sunshine Act left many open questions about its applicability and implementation; CMS issued a proposed rule to address these issues in December 2011 (summarized here) and solicited comment on that rule. After over a year of delay, CMS has issued a Final Rule to address the questions and comments it received.

Most notably, the Final Rule:

- Establishes August 1, 2013 as the starting date for the recording of data and March 31, 2014 as the first deadline for reports;
- Excludes many foreign entities from reporting;
- Excludes certain medical education programs from the disclosure requirements;
- Creates separate reporting and publishing procedures for payments related to research; and
- Excludes from reporting large group meals where recipients are difficult to identify and establishes a reporting process for smaller group meals.

I. Timing

The first reports under the Sunshine Act will cover the period from August 1, 2013 through December 31, 2013. These reports are due by March 31, 2014. There will be no retroactive reporting. CMS plans to release the reported data on a public website by June 30, 2014.

II. Applicability

Applicable Manufacturer

The Final Rule leaves largely unchanged the definition of an "applicable manufacturer"; it remains as an entity operating in the United States that is either:

(1) An entity (not including certain distributors or wholesalers) engaged in the production, preparation,

[1] Part of the Patient Protection and Affordable Care Act of 2010 (ACA). Pub L. No. 111-148. 42 U.S.C. § 1320a–7h.

propagation, compounding, or conversion of a covered product; or

(2) An entity under common ownership with an "applicable manufacturer" that provides assistance or support with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.[2]

However, in response to comments, CMS excluded from this definition certain hospitals, hospital-based pharmacies and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity's own patients.

Foreign Manufacturers

The Final Rule narrows how the Sunshine Act applies to foreign manufacturers by excluding foreign entities that may contribute to the manufacturing process of a covered product, but which have no business presence in the United States.

Common Ownership

While leaving the 5% threshold for "common ownership" unchanged, the Final Rule adds a definition of the other factor in the common ownership test: the provision of "assistance and support." "Assistance and support" is necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. Under this test, an entity that manufactures an active ingredient for drug is providing "assistance and support," but an entity that assists a manufacturer with administrative duties may not be.

Exclusions from Definition of "Applicable Manufacturer"

The Final Rule clarifies that the following are excluded from the definition of applicable manufacturer:

- In-house laboratories,
- Manufacturers of raw material or components (unless in common ownership with an applicable manufacturer),
- Pharmacies,
- Manufacturers who do not manufacture any covered products, do not hold FDA approval for any products, and are not involved in the sale, marketing, or distribution of any covered products, and
- Manufacturers that receive less than 10 percent of total gross revenue from covered products.

CMS also retained its proposed "one product sufficient" interpretation – that having one covered product is sufficient for an applicable manufacturer to be subject to the full disclosure requirements for all of its payments and transfers of value to covered recipients, whether for covered products or not.

Covered Drug, Device, Biological, or Medical Supply

CMS reaffirmed its definition of "covered drug, device, biological, or medical supply" as any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or CHIP, either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system).[3] For drugs and biologicals, the term covers only prescription drugs and biologicals; for devices, the term covers devices that require premarket approval or notification to the FDA.

Covered Recipients

The Sunshine Act defines "covered recipient" as (1) a physician as defined under section 1861(r) of the Social Security Act (for purposes of Medicare), other than a physician employed by an applicable manufacturer, or (2) a teaching hospital.[4]

[2] 42 C.F.R. § 403.902.

[3] 42 C.F.R. § 403.902.

[4] Section 1128G(e)(6) of the Act.

Section 1861(r) defines physicians as doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors, who are legally authorized to practice by the State in which they practice.

The Final Rule reaffirmed the proposed rule's exclusion of non-physician prescribers and employees of applicable manufacturers. However, the definition includes those physicians that do not see patients, so long as the physician is licensed to practice in any State (unless the physician is excluded for other reasons, such as employment by a manufacturer).

Exclusions

In addition to the exclusions enumerated in the initial language of the Sunshine Act, the Final Rule limits the proposed rule's reach by excluding from disclosure the compensation of speakers in certain continuing medical education (CME) programs.[5] Manufacturers need not report compensation for a speaker at a CME program if:

> (1) The event is organized by one of five organizations (the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association),
>
> (2) The applicable manufacturer does not pay the covered recipient speaker directly, and
>
> (3) The applicable 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.

III. Report Contents

Under the Act, applicable manufacturers must report both the form and the nature of each payment or transfer of value. In response to numerous comments pointing to the unique nature of research payments, the Final Rule establishes a separate process for reporting payments and transfers of value under the "research" category. CMS also removed the "other" payment reporting category, clarified food and beverage reporting, and modified the nature of payments categories to accommodate the reporting of CME.

Research

CMS adopted the definition of "research" from the Public Health Service Act: "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development."[6] The definition includes pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations. The definition also captures unbroken chains of agreements, which link the applicable manufacturer with the covered recipient, where applicable manufacturers use other entities such as contract research organizations (CROs) or site management organizations (SMOs) to manage their clinical research activities.

Unlike the proposed rule, the Final Rule does not distinguish between direct and indirect research payments. Instead, it requires that a single research payment be reported once, and include the name of the entity receiving the payment, the total amount, the name of the study, the name of the covered product, and the name of the principal investigator. The Final Rule grants a delay in publication—for four years or until FDA approval—to all payments or transfers of value made pursuant to a research agreement for research related to new products. However, payments related to research on new applications

[5] 42 C.F.R. § 403.904(g)(1)(i)-(iii).
[6] 42 C.F.R. § 50.603.

of existing products will be granted a delay only if the research does not meet the definition of "clinical investigation" (which includes Phases I through IV clinical research for drugs and biologicals, and approval trials for devices).

In the Final Rule, CMS reconsidered the requirements for CME programs and their reporting:

- Compensation for speaking and serving as a faculty in certain CME programs is now excluded from the disclosure requirements.[7]
- Compensation for speaking or serving as faculty in non-excluded (but accredited or certified) CME programs must be reported under a newly-created category.[8]

CMS created a separate reportable category for speaking engagements at unaccredited and non-certified continuing education events.[9] CMS also clarified that payments or other transfers of value for non-CME speaking engagements fall under the "compensation for services other than consulting" category.[10]

Meals

The Final Rule also provides new details on the required tracking and reporting of meals. For meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), the Final Rule requires applicable manufacturers to report the per person cost (not the per covered recipient cost) of the food or beverage for each covered recipient who actually partakes in the meals. If the per-person cost exceeds the minimum threshold amount, then the applicable manufacturer must report the food or beverage value for each covered recipient who actually consumed food or beverage in the group meal. These same reporting methodologies apply where the food was merely dropped off at the covered recipient's office.

IV. Physician Ownership and Investment Interests

The Final Rule elaborates on—but does not significantly modify—the physician ownership and investment interest section of the proposed rule. Each applicable manufacturer and GPO must report separately all physicians (and their immediate family members) who have ownership or investment interests in the applicable manufacturer or GPO.[11] Applicable manufacturers must also report separately the payments and transfers of value made to physicians or their immediate families who have ownership or investment interests in the applicable manufacturer. Under the Final Rule, the requirement extends to any physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO.

V. Enforcement

The Sunshine Act authorizes the imposition of civil monetary penalties (CMPs) for failures to report required information on a timely basis in accordance with the regulations.[12] An applicable manufacturer or applicable GPO will be subject to a CMP of $1,000-$10,000 for each payment or other transfer of value, or ownership or investment interest not reported as required for a total maximum of $150,000. The CMPs are higher for knowing failure to submit required information in a timely manner: $10,000-$100,000 per instance, up to a maximum CMP of $1,000,000.

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[7] 42 C.F.R. § 403.904(g)(1)(i)-(iii).
[8] 42 C.F.R. § 403.904(e)(2)(xv).
[9] 42 C.F.R. § 403.904(e)(xiv).
[10] 42 C.F.R. § 403.904(e)(2)(ii).
[11] 42 C.F.R. § 403.906.
[12] Section 1128G(b) of the Act.

The Final Rule reaffirmed the requirement that an authorized representative from each applicable manufacturer and applicable GPO must submit a signed attestation from the CEO, CFO, or CCO certifying the timeliness, accuracy, and completeness of the data submitted to the best of the signer's knowledge and belief.[13]

The Final Rule lists several factors that will be considered when an agency determines the amount of civil monetary penalties.[14] These include:

- The duration of the failure to report,
- The amount in question,
- The level of culpability,
- The nature and amount of information reported in error, and
- The degree of diligence exercised in correcting the error.

VI. Comment Request on the Collection of Information

Following the publication of the Final Rule, CMS published a suggestion for a data collection system where the agency would provide manufacturers and GPOs with data templates to populate throughout the year. Revisions to the templates would be announced 90 days prior to first day of data collection for the next reporting year.

CMS is now seeking comments on the data collection proposal as to:

- The necessity and utility of the proposed information collection for the proper performance of the agency's functions;
- The accuracy of the estimated burden;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- The use of automated collection techniques or other forms of information technology to minimize the information collection burden.

[13] 42 C.F.R. § 403.908(e).

[14] 42 C.F.R. § 403.912(d).