CMS Issues Proposed Rule Implementing the "Federal Sunshine Law" Reporting Requirements

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The U.S. Centers for Medicare & Medicaid Services (CMS) released a proposed rule implementing the "Sunshine" provisions of the Affordable Care Act (ACA) that requires annual public reporting by certain drug and device manufacturers of payments made by them to physicians and teaching hospitals and of physician ownership interests in such manufacturers. The "Sunshine" provisions of the ACA also require group purchasing organizations to make annual public reports of physician ownership interests in such organizations. CMS is accepting comments on its proposed rule through February 17, 2012.

On December 19, 2011, The U.S. Centers for Medicare & Medicaid Services (CMS) released a proposed rule entitled, "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests" (the Proposed Rule) to implement Section 1128G of the Social Security Act, commonly known as the Federal Sunshine Law, which was enacted as part of the Affordable Care Act.

The Federal Sunshine Law requires annual public reporting by certain drug and device manufacturers of payments made by them to physicians and teaching hospitals and of physician ownership interests in such manufacturers. The law also requires group purchasing organizations (GPOs) to make annual public reports of physician ownership interests in such organizations. While the Federal Sunshine Law preempts corresponding state law reporting requirements, the scope of the federal law is narrower than the states' reporting laws. Therefore, the nature and extent of the preemption is similarly limited.

The goal of the Federal Sunshine Law and the Proposed Rule is to increase transparency of financial relationships between manufacturers and GPOs, on the one hand, and physicians and teaching hospitals, on the other, and of the corresponding potential those interests have for introducing bias into decision-making in clinical care, research and education. CMS estimates that approximately 1,570 entities (inclusive of drug, biologic, device, supply manufactures and GPOs) will be required to make disclosures. As required by statute, CMS proposes to make all the required financial reporting data available online in a searchable and downloadable format so that the public may easily access it.

While CMS recognizes that not all such financial relationships are harmful and that transparency alone will not reduce the occurrence of such relationships or the associated risks, the rationale underlying the Federal Sunshine Law and the Proposed Rule is that the transparency will achieve benefits that outweigh the costs to the affected parties.

CMS is accepting comments on the Proposed Rule through February 17, 2012. A copy of the Proposed Rule is located here.

Reports on Physician Payments and Other Transfers of Value

The Proposed Rule applies the reporting obligations to "applicable manufacturers" that supply and distribute "covered products" in the United States (including U.S. territories, possessions or commonwealths). "Covered products" are "drug, device, biological, or medical supply" products that are covered by Medicare, Medicaid and the Children's Health Insurance Program. In the Proposed Rule, CMS interprets the statutory definition of "applicable manufacturer" to mean an entity that: is engaged in the production, preparation, propagation, compounding or conversion of a covered product; or is under common ownership with such entity and assists such entity in the production or marketing activities of a covered product.

The Federal Sunshine Law and Proposed Rule define "physician" as a medical doctor, doctor of osteopathy, dentist, podiatrist, optometrist or chiropractor who is legally authorized to provide services within the scope of his or her license. In the Proposed Rule, CMS defines "teaching hospital" (which is not defined under the Federal Sunshine Law), as all hospitals receiving direct Medicare Graduate Medical Education (GME) payments or Medicare Indirect Graduate Medical Education (IME) payments. CMS acknowledges that this definition will not include those hospitals with accredited resident programs that do not receive GME or IME payments. The Accreditation Council for Graduate Medical Education (ACGME) estimated that approximately 684 hospitals received GME payments in 2010. CMS is seeking comment on its proposed definition of "teaching hospital."

For each reportable payment or transfer made to a physician or hospital, CMS proposes to require that an applicable manufacturer report the following data elements:

- Recipient name
- Recipient business address
- Recipient specialty (physicians only)
- Recipient National Provider Identifier (NPI) (physicians only)
- Amount of payment
- Date of payment
- Form of payment

- Nature of payment
- Associated covered drug, device, biological or medical supply
- Name of entity paid
- Owner or investor (physicians only- answer to be yes/no)
- Delayed publication (answer to be yes/no)

CMS proposes to require reporting of each payment or transfer as a separate line item, but requests comments on whether lump sum reporting should be permitted.

A manufacturer is expected to obtain the applicable physician's NPI and specialty from the National Plan & Provider Enumeration System (NPPES) that CMS maintains as a public website that includes a database of NPIs. The NPI Registry is available here.

CMS proposes to use 14 separate categories for the nature of the payment that are identified in the Federal Sunshine Law, including such categories as consulting fees, honoraria, entertainment, food, education and research.

The Federal Sunshine Law addresses reporting of indirect as well as direct payments. It does not require applicable manufactures to report payments or other transfers of value made *indirectly* (*i.e.*, through a third-party) when the applicable manufacturer is *unaware* that the ultimate third-party is a physician. However, if an applicable manufacturer is *aware* that any payment or other transfer of value will be indirectly provided to a physician, it must report the transaction. The Proposed Rule uses the False Claims Act definition of "knowingly" as the standard for testing whether an applicable manufacturer was "aware" of the recipient of an indirect transfer of value.

The Proposed Rule explicitly identifies indirect research payments as one category of indirect payments. Indirect research payments are defined as:

Payments or other transfers of value provided by an applicable manufacturer (including through a contract research organization or similar entity) to a clinic, hospital, or other institution conducting the research, and that clinic, hospital, or other institution conducting the research in turn pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s).

Reports of indirect research payments must be made individually under the name(s) and NPI(s) (if applicable) of principal investigator(s) and, when the payment is made to a teaching hospital, they must also be reported as a direct research payment to the teaching hospital. CMS proposes that indirect and direct research payments made to a

particular physician be aggregated and reported as the entire payment made to a physician or applicable research institution. Nonetheless, to avoid misleading information about the nature and amount of payments reported under a principal investigator's NPI, CMS notes that it will not include indirect research payments reported under the physician/principal investigator's name/NPI as part of publically available aggregate payments to the physician. Instead, CMS will report the research payment amount separately. However, CMS concedes that the reporting of research payments to physicians might still be misleading to the public because of the nature of research payments generally.

As permitted by the Federal Sunshine Law, the Proposed Rule also permits manufacturers to delay release (but not reporting) of certain payments and transfers related to product research and development and clinical investigations, in order to maintain the confidentiality of proprietary information relating to development of new drugs, devices, biologics and medical supplies. CMS acknowledges that the reporting of research payments presents many challenges and specifically requests comments in that regard.

The Federal Sunshine Law and the Proposed Rule exclude 13 total categories of payments and transfers from its reporting requirements, such as product samples, items or services provided under contractual warranty, discounts (including rebates) and payments for the provision of health care services to employees of a manufacturer under a self-insured plan.

Reports on Physician Ownership and Investment Interests

Under the Federal Sunshine Law and the Proposed Rule, applicable manufacturers (defined above) and applicable GPOs (defined below) are required to report any ownership or investment interest by a physician or a physician's immediate family member. The Federal Sunshine Law and the Proposed Rule define "applicable GPO" as an entity that "purchases, arranges for or negotiates the purchase of a covered drug, device, biological or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States." In the Proposed Rule, CMS excludes from the definition of applicable GPO "entities that buy covered drugs, devices, biologicals or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians)." CMS clarifies that it intends to capture GPOs (inclusive of physician-owned entities) that purchase covered drugs, devices, biologicals or medical supplies for resale or distribution. CMS is seeking comment on its proposed definition of applicable GPO.

CMS does not propose a minimum ownership or investment threshold (*e.g.,* 5 percent), but specifically seeks comments on whether a minimum reporting threshold would be appropriate. Per the Federal Sunshine Law, CMS would require reporting of the following elements about the physician owner or investor:

- Name
- Business address
- Specialty (physicians only)
- NPI (physicians only)
- Interest held by immediate family member (answer to be yes/no)
- Dollar amount invested
- Value of interest
- Terms of interest

If the ownership or investment interest is held by an immediate family member, CMS is considering requiring reporting of the family member's name and relationship to the physician. CMS requests comments on this approach.

CMS also proposes to require that any payment or transfer by an applicable GPO to a physician with an ownership or investment interest (or another entity or individual at the request of or designation by such physician) be reported in the same manner as required for payments or transfers to physicians by applicable manufacturers.

Submission and Review Period

The Federal Sunshine Law requires reporting on March 31, 2013 of payments/transfers and ownership/investment interests for calendar year 2012, and on the 90th calendar day of each subsequent year. However, CMS requests comments as to whether this reporting date is feasible given the expected release of the final rule during 2012.

Similarly, although the Federal Sunshine Law requires that applicable manufacturers and GPOs begin collecting reportable information on January 1, 2012, data collection will not be required to begin until after the publication of the final rule due to the delayed release of the Proposed Rule and the corresponding delayed publication of the final rule. CMS proposes to require manufacturers and GPOs to register with CMS prior to submission of required information and is seeking comments on whether to require all manufacturers and GPOs to register, or only those that will have information to report.

The Federal Sunshine Law also requires CMS to provide a 45-day period during which reporting entities, physicians and teaching hospitals may review the data submitted for errors prior to its release to the public. CMS would also permit review of both the current and previous year data during the 45-day review process. If a physician or

physician owner/investor disputes the data submitted by the applicable manufacture or applicable GPO, the physician or physician owner/investor is obligated to directly contact the applicable manufacturer or applicable GPO to reconcile any disputes. If the dispute is not resolved within the 45-day review period, and if at least one party notifies CMS of the dispute, CMS will report both versions of the disputed information on the public website. While CMS states in the preamble that its role should not include arbitrating disputes between applicable manufactures or applicable GPOs, and physicians or physician owners or investors, it is developing a process to streamline and automate the dispute reporting process.

Penalties

As required by the Federal Sunshine Law, the Proposed Rule imposes civil monetary penalties (CMPs) for failures to report required information of between $1,000 and $10,000 for each payment/transfer or ownership/investment interest that is not appropriately reported, up to an annual maximum of $150,000. For "knowingly" (as defined for purposes of the federal False Claims Act) failing to report, the penalty for each payment/transfer or ownership/investment interest escalates to between $10,000 and $100,000, up to an annual maximum of $1,000,000.

Preemption

As under the Federal Sunshine Law, the Proposed Rule mandates preemption of any statute or regulation of a state or political subdivision of a state that requires an applicable manufacturer to disclose or report the same information. Nonetheless, the preemption is limited in scope and does not apply to state laws or regulations that require reporting of different information, reporting involving entities other than an applicable manufacturer and physician or teaching hospitals as defined in the Proposed Rule, or reporting to a federal, state or local governmental agency for various public health purposes and investigations.

Costs

CMS estimates that compliance with the reporting requirements by large manufacturers will require an average of 10 Full-Time Equivalents (FTE), with the average for all manufacturers being 1.74 FTEs in the first year and 1.3 FTEs in subsequent years. Compliance with GPO reporting obligations are expected to require between 5 and 25 percent of an FTE, depending on the size of the GPO, with an average of 10 percent in year 1 and 7.5 percent in subsequent years. CMS estimates that compliance by physicians will require between a few minutes and 10 to 20 hours to review and dispute submitted data and that teaching hospitals will require between three and 60 hours to review and dispute submitted data.

Next Steps

Although CMS has delayed the initial January 1, 2012 start date for data collection, each entity covered by the Federal Sunshine Law should continue to work diligently to finalize and implement its compliance plan to ensure that it is ready to collect and submit data once the required collection and reporting dates are finalized. In particular, physicians and teaching hospitals impacted by the rule, especially those physicians and teaching hospitals that also receive research payments, will need internal record keeping procedures that will ensure a reliable record upon which to compare and potentially challenge data being submitted for the public's view. Finally, any compliance plan must take into account provisions of State sunshine laws that will survive the limited scope of preemption by the Federal Sunshine Law and possible legislative changes made by the States to address the Federal preemption provisions.