PUBLICATION

Physician Payment Sunshine Rule is Finalized [Ober|Kaler]

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The Final Rule implementing the Physician Payment Sunshine Act was announced on February 1st and published in the Federal Register on February 8th. The Final Rule establishes procedures for drug and device manufacturers to submit annual reports to CMS of virtually all payments and other transfers of value to physicians and teaching hospitals – so-called Transparency Reports. The Final Rule also sets procedures for drug and device manufacturers and group purchasing organizations to report ownership interests (if any) held by physicians – so-called Ownership Reports.

The much-anticipated Final Rule contains few surprises for those familiar with the proposed rule, but it does incorporate several adjustments intended to ease the reporting burden. Chief among these changes is the implementation schedule. Entities required to collect and report data under the Sunshine Act will not need to begin collecting data until August 1, 2013 and will not need to make their initial reports until March 31, 2014.

As with so many rules in the health and life sciences space, the devil is in the details (or lack of details). The Final Rule imposes new burdens on drug and device manufacturers as well as GPOs with physician ownership. The regulations provide helpful guidance, but as companies struggle to meet these new burdens, there will be many unanswered questions. The Final Rule also has significant implications for physicians and teaching hospitals whose dealings with drug and device manufacturers and GPOs will be subject to greater public scrutiny.

Reports of Transfers of Value (Transparency Reports)

The Final Rule, mirroring the statute, is primarily divided between descriptions of the reports of payments and other "transfers of value" and reports of physician ownership and investment interests. CMS has elected to require that each type of report be made separately, even though the two types of reports share multiple data points and other similarities. In fact, several defined terms identified in the Transparency Reports section apply to Ownership Reports as well.

Applicable Manufacturer

Manufacturers subject to the reporting requirements are termed *Applicable Manufacturers*. The term is defined broadly to include any entity "operating in the United States" that is "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply" *or is* "under common ownership" with an entity that so manufactures and "provides assistance or support" to the entity with regard to the identified manufacturing tasks. *Common ownership* is defined to include ownership interests of 5 percent or greater. The definition specifically excludes entities which are not operating in the United States, distributors or wholesalers who do not take title to any covered item, and entities which manufacture drugs, devices, biological or medical supplies solely for use by or within the entity itself or by the entity's own patients (such as a compounding pharmacy, so long as certain rules specific to pharmacies are met).

Entities will be considered to *operate in the United States* where they either have a physical location within the United States or are "otherwise conducting activities within the United States or in a territory, possession, or commonwealth of the United States." Notably, the Final Rule specifically provides that entities operating in the

United States may not avoid reporting obligations by passing payments through offshore affiliates or subsidiaries. Such payments would be considered "indirect" but must still be reported.

In general, an Applicable Manufacturer must report ALL transfers of value, including those unrelated to covered products. The Final Rule provides that, in the following limited scenarios, manufacturers need only report transfers related to the specific covered product manufactured:

- Manufacture on behalf of another entity and are not involved in any marketing or distribution of the manufactured product; *or*
- Receive less than 10 percent gross revenue yearly from the manufacture of covered products; *or*
- Function as a separate operating division of an Applicable Manufacturer that does not produce any covered products and do not provide "assistance and support" to divisions that do.

Covered Drug, Device, Biological, or Medical Supply (Covered Product)

In response to public comments, the definition of a *Covered Product* was altered to clarify that a Covered Product "is one for which payment is available under Medicare, Medicaid, or CHIP" *and* which requires a prescription or premarket approval by, or notification to, the FDA. Payment is "available" whether it is made individually for the specific product or as part of a bundled reimbursement payment (such as the hospital inpatient prospective payment system).

Two broad categories of drugs and medical devices were excluded from the definition of Covered Products: (1) over-the-counter (OTC) prescription drugs and (2) medical devices that do not require premarket approval or notification to the FDA. Accordingly, medical device manufacturers that manufacture *only* Class I and certain Class II medical devices or *only* OTC prescription drugs will be exempt from the reporting requirements.

Covered Recipients

CMS rejected most comments that sought to narrow the definition of *covered recipients*, generally maintaining the broad statutory definition (any physician, as defined by 42 U.S.C. 1395x, and any teaching hospital). The definition specifically excludes bona fide employees of the Applicable Manufacturer as well as residents (who may or may not be licensed as physicians, depending on their state of practice). *Teaching Hospitals* are defined as facilities which received IME, GME, or psychiatric hospital IME during the most recent year data is available. Teaching Hospitals will be identified by CMS in a published list.

Payments or other Transfers of Value

The Final Rule does not alter the definition of a *payment or other transfer of value* (which is defined to include "a transfer of anything of value") but does provide that a transfer must have discernible economic value, that all taxes, shipping, and other fees should be included in any calculation of value, and that manufacturers are free to include, in their voluntary "assumptions document," an explanation of how values were calculated.

Transparency Report Contents

The specific categories of information required to be reported are set forth in section 1128G of the Social Security Act. The Final Rule, however, provides some insight regarding certain items on the list:

- For payments made over multiple dates, CMS is providing manufacturers the flexibility to report either multiple dates or a single line item for the first date.
- If a payment is not related to any covered product, manufacturers should report "none." If it is related to a non-covered product, they should report "non-covered product." If it is related to both a covered and non-covered product, they should report the covered product by name and *may* report the non-covered product in the fields for associated products. If it is related to more than one covered product, manufacturers may report up to five covered products by name.

- The form of payment and nature of payment requirements have been finalized as proposed. CMS notes that "form of payment" should be the "modality used to transfer value" and "nature of payment" should be the reason the payment was made.
- One form of payment has been divided: "stock, stock options, and other ownership investment interests" are now separated from "dividends, profits, and other returns of investment."
- "Space rental and facilities fees" has been added as a new nature of payment category.
- For meals in group settings, manufacturers should report the per-person cost for each Covered Recipient who actually takes part in the meal.
- An additional nature of payment category has been added for "compensation for serving as faculty or as a speaker for an accredited or certified continuing education event."
- The category "other" has been eliminated from the nature of payment options.
- The Transparency Report may, but is not required to, include an assumptions document providing the assumptions and methodologies used by Applicable Manufacturers to calculate their disclosures. CMS does not *intend* to use the assumption document for prosecution purposes, but notes that it would be available for such use.
- Research payments, in order to be considered research, need only a written agreement or contract *or* a research protocol. The Final Rule, unlike the proposed, does not require both. An unbroken chain of agreements between a manufacturer, a contract research organization (CRO), a site management organization (SMO) and a teaching hospital would be considered a written agreement for this purpose.
- Reporting Research Payments has been streamlined so that each payment is reported once and includes the names of both the entity paid as well as the name(s) of the principal investigator(s).

Exclusions

CMS noted in the Final Rule that it lacked authority to expand the relationships excepted from reporting beyond those provided in the statute. It added some clarifications, however, to the existing categories:

- Existing personal relationships (a gift from one spouse to another, for instance) will not need to be reported.
- Payments or transfers that are each less than $10 *and* collectively amount to less than $100 per year need not be reported. These amounts will remain $10/$100 for the data collected in 2013 but will increase indexed to inflation for 2014 and beyond. Where small payments exceed $100 annually, manufacturers have the option of bundling small payments (in the same nature of payment category) as long as they indicate the method used and report consistently.
- Small items ($10 or less) provided at events that are open to the public (such as conferences) are exempt from reporting entirely, and need not be tracked. Items exceeding $10 in value *do* need to be tracked, even at large scale, open events.
- "Educational materials that directly benefit patients or are intended for patient use" is to be interpreted broadly, but not without limits. The definition has been broadened to include wall hangings and anatomical models that are intended to be used *with* patients, but specifically excludes journals and textbooks that are meant for physician use (even though such use may eventually benefit patients).
- Discounts and rebates need not be reported.
- In-kind items provided for charity care are exempt from reporting. CMS clarified that manufacturers need not track how each item is used, noting that a written agreement that the items will be used only for charity care would be sufficient.
- Product samples remain excluded from the reporting requirement. CMS clarified that devices or evaluation equipment may meet this exception where they are intended for patient use. CMS again noted that, in lieu of tracking how each item is used by the recipient, the parties may enter into a written agreement that the products will be provided to patients.

- Loans of covered devices for a short-term trial remain exempted from reporting, but CMS has clarified that the loan period may not exceed 90 days. Those that do must be reported as having begun on the 91st day.
- Items or services provided pursuant to a contractual warranty remain excluded. CMS has slightly expended this provision to also include items and services provided according to maintenance or service contracts.
- Covered recipient acting as a patient: CMS maintained this exception for transfers made to a covered recipient that is acting as a patient, not as a physician. The Final Rule also clarifies that this exception also applies to a physician who is a subject in a research study (in a non-professional capacity).
- CMS clarified that the exception permitting transfers related to health care services provided to a covered recipient as a result of a self-insured health plan applies also to the covered recipient's family members who also participate in the plan.
- Exceptions for transfers to a covered recipient who is also a non-medical professional (a physician who is also an attorney, for instance) relating solely to the non-medical services of the covered recipient and for transfers made to a covered recipient as payment for services with respect to civil, criminal, or administrative proceedings were both adopted without change.

Indirect Payments and Transfers

CMS acknowledged that manufacturers may have difficulty in determining and reporting indirect payments and transfers that are handled first by a third party and then transferred to the covered recipient. Several commentators were concerned about whether the manufacturer was either aware of the identity of the covered recipient or had control in the selection of the covered recipient. The Final Rule rejects both the awareness and control standards. Instead, the Final Rule adopts a False Claims Act knowledge standard that requires manufacturers to report payments or transfers of value when it “knows” of the covered recipient, i.e., the manufacturer has actual knowledge of a covered recipient, acts in deliberate ignorance of the covered recipient, or acts in a reckless disregard to the truth or falsity of the existence of the covered recipient. CMS explained that manufacturers and GPOs should be familiar with that False Claims Act knowledge standard and should be able to apply it easily.

The Final Rule also clarifies some bright-line examples of reportable and not-reportable indirect payments and transfers. First, manufacturers will be required to report indirect payments when the manufacturer directs that the payment or transfer be made to any covered recipient. Second, payments made to physicians participating in a double-blind market research study conducted by a third party engaged by a manufacturer will not be considered a reportable indirect payment or transfer of value because of the inherent nature of the double-blind study. Third, indirect payments made to covered recipients to conduct CME will not be considered a reportable payment if: (i) the program is appropriately accredited; (ii) the manufacturer does not select the speaker or provide a list of approved speakers for the program; and (iii) the manufacturer does not directly pay the covered recipient. CMS declined to accept threshold exclusions based on whether the manufacturer does not control the selection of the covered recipient by the third party, whether the payment is made to a medical society (or other professional society), or whether the payment is related to Risk Evaluation Mitigation Strategies required by the FDA.

In response to comments from manufacturers, CMS will not require manufacturers to indefinitely monitor their payments to third parties in an attempt to identify indirect payments or other transfers to covered recipients. The Final Rule requires manufacturers to report those indirect payments or transfers to a covered recipient during the reporting year and up to the end of the following second calendar quarter.

Delayed Publication of Research Payments and Clinical Investigations

The Final Rule essentially adopts the provisions of the proposed rule with regard to delayed publication of payments for research and/or clinical investigation. All payments that are related to research related to *new*

products will be granted a delay. Generic products will be considered “new products,” including drugs receiving approval under an Abbreviated New Drug Application or devices seeking approval under the 501(k) process. Payments related to new applications of existing products will be granted a delay *only* where the research does not meet the definition of a clinical investigation. *Clinical investigation* has been defined broadly to mean Phases I through IV clinical research for drugs and biologicals and approval trials for devices. Finally, CMS clarified that a payment can only be granted delayed publication where it meets the definition of *research* – including the requirement that it include *either* a written agreement or a written research protocol (though CMS does not intend that manufacturers provide these materials to CMS for verification).

Ownership Reports

Physician Ownership Reports

The Sunshine Act requires Applicable Manufacturers and Applicable Group Purchasing Organizations (GPO) to report direct and indirect ownership and investment interests of physicians and the immediate family members of physicians. CMS acknowledged relying on existing Stark law definitions for many of the key terms and definitions for Ownership Reports. As mentioned above, many of the key definitions for Ownership Reports are included under the discussion of Transparency Reports. For example, an Applicable Manufacturer is defined the same for both rules, although an Applicable Manufacturer has to make separate Transparency and Ownership Reports.

Group Purchasing Organizations

GPOs are required to submit reports on physicians, and their immediate family members, who own an interest in the GPO. CMS defined an *Applicable Group Purchasing Organization* to include any entity that (1) operates in the United States, or a territory or commonwealth of the United States, and (2) “purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.” CMS explained that the intent of the rule is to include those entities that purchase goods and devices for resale to others and for distribution to groups of individuals or other entities. CMS also explained that this definition includes physician-owned distributors (PODs) of those items. However, a GPO that does not have ownership held by a physician or an immediate family member of a physician does not have to report to CMS.

CMS declined to expand the definition of *Applicable GPO* to include other entities, which should result in fewer GPOs reporting to CMS. For example, CMS excluded group purchasing entities that purchase covered products only for use by commonly owned entities, such as those sometimes found in hospital health systems. CMS also limited Applicable GPOs to only those organizations that purchase for a group. In response to other comments, CMS agreed that an Applicable GPO would not include “rare and circumstantial resale” of products in response to drug shortages.

As a general rule, Applicable GPOs are not required to report payments to physicians. However, Applicable GPOs must report payments and transfers of value to those physicians who have ownership or investment interests. Applicable GPOs report this information as part of their Ownership Report requirement, using the same reporting requirements as Applicable Manufactures use for Transparency Reports.

Immediate Family Members and Ownership or Investment Interests

The Final Rule's definition of *immediate family members* is identical to the list of immediate family members found in the Stark law regulations: a physician's spouse, parents, children, siblings, stepparents, stepsiblings, in-laws, grandparents, spouses of grandparents and grandchildren. Both natural and adoptive family members are included as immediate family members.

Similarly, the Final Rule's definition of *ownership or investment interests* is similar to the traditional Stark law definition. Stock, stock options (as equity), partnership shares, limited liability company memberships or units, loans, bonds and other financial instruments that are secured with an entity's property or revenue are all included as an ownership or investment interest. Also like Stark, an interest held in an employer-based retirement plan, unsecured loans, stock options received as compensation, and publicly traded securities are excluded from the definition of ownership or investment interests and need not be reported.

Stock options pose a more vexing question for manufacturers and GPOs. Some stock options will be considered ownership or investment interests and should be reported in the Ownership Report. Other stock options could be considered payments or transfers of value and should be reported under the Transparency Report. Still other stock options might not need to be reported until exercised.

CMS acknowledged in the Final Rule that GPOs and manufacturers could have some difficulty identifying, or knowing, the immediate family members of physicians. The Final Rule does not require physicians to disclose to GPOs, manufacturers or CMS their immediate family members.

Similar to its treatment of indirect payments, CMS acknowledged that reporting entities that do not have "knowledge" of the ownership interests of a physician (or immediate family member of the physician) are not required to report the ownership interest. The Final Rule again uses the False Claims Act knowledge standard. Thus, GPOs and manufacturers should make reasonable inquiries to attempt to identify immediate family members of physicians.

Reporting, Public Display and Dispute Resolution

The Basics

The initial Transparency Reports and Ownership Reports will be due by March 31, 2014. Subsequent reports will be due by the 90th day of each new calendar year. Reporting entities will be permitted (and encouraged) to submit reports before that time. CMS will publish the reporting data within 90 days of data submission. Entities required to submit a Transparency Report or an Ownership Report will be required to register within the first 90 days of the calendar year and provide two points of contact to CMS.

An authorized representative for the reporting entity must provide an attestation of the accuracy of the report. The attestation should be signed by the chief executive officer, chief financial officer or chief compliance officer. CMS expects a new attestation for each annual report and an additional attestation any time data is changed or updated.

45-Day Review, Dispute Resolution and Public Display

After submission of a Transparency Report or an Ownership Report, Applicable Manufacturers, Applicable GPOs, covered recipients and physician owners and investors will have 45 days to review and provide corrections to CMS. During this period, the reporting information will not be disclosed to the public. If the information is not disputed, the reporting information will be disclosed to the public after the end of the 45-day period.

To assist physicians and teaching hospitals to identify disclosures, the Final Rule requires CMS to give notice to physicians and teaching hospitals annually using an online notification process and CMS's listserves. Physicians and teaching hospitals will also be able to register with CMS to receive electronic notification of the review period.

If an Applicable Manufacturer, Applicable GPO, covered recipient or physician owner or investor has corrective information, they will have a 15-day dispute resolution period to negotiate and resolve the dispute. If the dispute is resolved within the dispute resolution period, Applicable Manufacturers and Applicable GPOs can update the data and provide a new attestation during the 15-day period. If the dispute is not resolved within the dispute resolution period, CMS will release the original information without change but will note that the information provided was disputed by the covered recipient or physician.

Physicians and teaching hospitals should register with CMS in advance of next year's reporting period to take full advantage of the 45-day review period and the 15-day dispute resolution period. If a physician or teaching hospital receives electronic notification and raises the dispute early in the 45-day review period, the two sides will have until the full 60-day period expires before CMS begins the process to release the information.

If a dispute is resolved after the end of the dispute resolution period, the reporting entities will update the data and provide a new attestation. The Final Rule explains that any update received after the end of the dispute resolution period will not be automatically updated. CMS explained that it will update the database at least annually but refused to commit to making more updates.

The Proposed Rule considered whether CMS should take an active role in managing any disputes between Applicable Manufacturers, Applicable GPOs, covered recipients and physicians. In the Final Rule CMS declined invitations from numerous commentators to do so.

Registration and Pre-submission Review Not Required

CMS considered requiring manufacturers and GPOs that have no reportable payments, transfers of value, or ownership or investment interests to register with CMS. The Final Rule explains that manufacturers and GPOs should not register if they have nothing to report.

CMS also proposed requiring Applicable GPOs and Manufacturers to have a pre-submission review period. This period would have required the reporting entities to share reporting information with the applicable covered recipient or physician owner or investor. The Final Rule does not include this provision.

Penalties and Document Retention

The Final Rule includes substantial penalties for failing to timely, accurately, or completely report required information. The fines can be as high as $1,150,000 per Applicable Manufacturer or Applicable GPO, per each annual submission. CMS has indicated that errors corrected during the review and correction period will not be subject to penalties as long as the original submission was made in good faith. Correcting errors or omissions after the review and correction period, however, may result in penalties.

The Final Rule also imposes new document retention requirements. Applicable Manufacturers and Applicable GPOs are required to maintain all books, contracts, records, documents, and other evidence to support payments disclosed under the Final Rule to be maintained for a period of five years from the date the payment or other transfer of value is made available to the public by CMS.

Comments

The Final Rule completes the initial round of implementing regulations for the Sunshine Act that started in December 2011 with the proposed rule. Its publication means that manufacturers and GPOs will need to comply with the Sunshine Act provisions of the Affordable Care Act.

CMS wisely decided to delay the effective date of information collection activities to August 1, 2013. This allows the industry some time to implement policies and procedures to meet the reporting deadline. For many entities, it will be difficult to get the necessary systems in place in time. To meet the initial reporting deadline of March 31, 2014, entities will have to work quickly.

Whether a physician has received an ownership or investment interest or a payment or transfer of value will present some initial challenges, particular with options and other quasi-ownership / quasi-compensation interests. Similarly, the rules for reporting indirect payments and for determining when the manufacturer has knowledge of an indirect covered recipient will be difficult to implement initially. Reporting entities that may have these types of issues should begin to address them well in advance of the March 31, 2014 reporting deadline.

Physicians and teaching hospitals should expect to receive inquiries from manufacturers and GPOs confirming their receipt of payments, transfers of value, and ownership and investment interests. All covered recipients should register with CMS to receive electronic notification of the data dispute review period so that both reporting entities and covered recipients have ample time to make corrections before the inaccurate or incomplete information is made public.