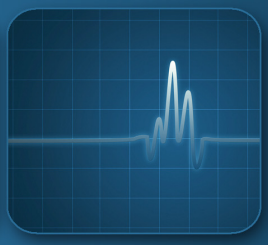
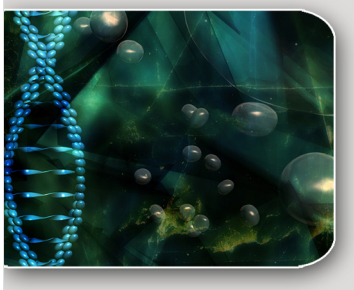
Polsinelli Shughart


HEALTH CARE LAW IN THE NEWS

March 2013



Physician Payment Sunshine Act Final Rule Released

Executive Summary

On February 8, 2012, the Centers for Medicare and Medicaid Services ("CMS") published a final rule ("Rule") for what is commonly referred to as the Physician Payment Sunshine Act ("Act"), which was passed as Section 6002 of the Affordable Care Act. The Act requires certain manufacturers of medical drugs, biologicals, and devices and certain group purchasing organizations (defined in the Rule as "applicable manufacturers" and "applicable GPOs") to report to CMS payments or other transfers of value made to certain physicians and teaching hospitals (defined in the Rule as "covered recipients") and certain physician owners or investors. CMS will make these reports available for public review. The Act is part of CMS' efforts to create greater transparency between medical manufacturing companies and providers, whose relationships have historically drawn scrutiny from CMS and other governmental agencies. The Rule requires applicable manufacturers and applicable GPOs to gather reportable data beginning on August 1, 2013 and submit their first reports on March 31, 2014. CMS will release the data publicly by September 30, 2014.

The Rule finalizes a number of key definitions and other provisions, including who must submit the required reports to CMS, what data must be submitted in the reports, what the process is for submission and review, how affected parties can dispute submissions, how the public

can access the reports, and what the penalties are for failing to submit the reports.

Interpretation and Clarification of Key Definitions

a. Applicable Manufacturers

The Rule retains the definition of the term "applicable manufacturer" as set forth in the Act; however, the Rule more clearly defines the entities required to make reports under the Act. Under the Rule, an "applicable manufacturer" is an entity operating in the United States that is either: (1) engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply; or (2) under common ownership with an applicable manufacturer that provides assistance or support to the applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.

CMS interprets the phrase "operating in the United States" to mean an entity that (1) has a *physical location* within the United States or a territory, possession, or commonwealth of the United States or (2) otherwise *conducts activities* within the United States or a territory, possession, or commonwealth of the United States. Through this interpretation, the Rule narrows the Act's applicability to foreign manufacturers by making clear that foreign entities that may contribute to the manufacturing process of a covered drug, device, biological, or medical supply, but have no business presence in the United States, are not included as applicable manufacturers. CMS cautions, however, that entities that have operations in the United States are not permitted to circumvent their reporting requirements by making payments to covered recipients indirectly through a foreign entity that has no operations in the United States.

The Rule further clarifies that entities holding Food and Drug Administration ("FDA") licensure, or clearance for a covered drug, device, biological, or medical supply are applicable manufacturers, even if they contract the actual physical manufacturing of the product to another entity. Moreover, the Rule reiterates CMS' "one product sufficient" interpretation, which states that, generally, once an entity is determined to be an applicable manufacturer, payments or other transfers of value to covered recipients must be reported to CMS, even if the payments or transfers of value relate to an item that is not itself a covered drug, device, biological, or medical supply.

i) Limitations to Definition of Applicable Manufacturer

The Rule clarifies certain entities that are excluded from the definition of applicable manufacturer and, therefore, not subject to the reporting requirements. The excluded entities include hospitals, pharmacies, and laboratories that produce or manufacturer materials and products solely for their own use or use by their patients as well as distributors and wholesalers (including repackagers, relabelers and kit assemblers) that do not hold the title of a covered product, *unless* the distributors or wholesalers are under common ownership with an applicable manufacturer and provide assistance and support with respect to a covered drug, device, biological, or medical supply.

CMS acknowledges in the Rule that there are applicable manufacturers whose primary business model is not the production of covered drugs, devices, biological, or medical supplies and, therefore, reduces the reporting requirements on these particular entities. If the applicable manufacturer does not manufacture a covered drug, device, biological, or medical supply, except pursuant to a written agreement to manufacture the covered product for another entity, does not hold the FDA approval, licensure, or clearance for the product, *and* is not involved in the sale, marketing, or distribution of the product, then the manufacturer is *only* required to report payments or other transfers of value related to the covered product. Additionally, CMS clarifies that an applicable manufacturer that receives less than ten percent of its total (gross) revenue from covered drugs, devices, biological, or medical supplies during the previous fiscal year is *only* required to report payments or other transfers of value specifically related to covered drugs, devices, biologicals, or medical supplies.

ii) Definition Includes Entities under Common Ownership

The Rule affirms that an entity under "common ownership" with an applicable manufacturer that "provides assistance or support" to such entity qualifies as an "applicable manufacturer" and must meet the reporting requirements under the Act. CMS defines "common ownership" as an entity where the same individual, individuals, entity, or entities directly or indirectly own five percent or more total ownership of two entities (including, but not limited to, parent companies, subsidiaries and brother/sister corporations). The Rule clarifies the "assistance and support" factor to mean necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. For example, an entity that manufactures an active ingredient for a covered drug is providing "assistance and support;" however, the provision of human resources or other administrative duties may not be considered providing "assistance and support" as the drug can be produced without those activities. The Rule also outlines a process by which applicable manufacturers may report separately or on a consolidated basis depending on the structure of their common ownership.

b. Applicable GPOs

The Rule defines "applicable GPOs" as entities that operate in the United States that purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities, but not solely for the use by the entity itself. The Rule modifies the proposed definition to incorporate the defined term "operating in the United States" as discussed in the "applicable manufacturer" definition above. CMS declines to expand the scope of applicable GPOs to covered devices or covered medical supplies that, by law, require premarket approval from, or premarket notification to, the FDA.

c. Covered Drug, Device, Biological or Medical Supply

In the Rule, CMS reaffirms its proposed definition of "covered drug, device, biological, or medical supply." CMS further clarifies the definition by replacing "composite payment rate" with "bundled payment." Accordingly, under the Rule, a "covered drug, device, biological or medical supply" is defined as a drug, device, biological, or medical supply for which payment is

available under Medicare, Medicaid or Children's Health Insurance Programs ("CHIP"), either separately (through a fee schedule or formulary) or as a part of a bundled payment (through the inpatient prospective payment system, outpatient prospective payment system and other prospective payment systems), *and* which requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a medical device or supply that is a device). The Rule requires that a product must meet both parts of the definition in order to be considered covered.

d. Covered Recipients

A "covered recipient" is defined in the Rule as (1) any physician, except a physician who is a bona fide employee of an applicable manufacturer, and (2) teaching hospitals (those institutions that receive Medicare graduate medical education ("GME") payments during the last calendar year).

CMS clarifies that physicians includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors, who are legally authorized to practice (i.e., have a current license to practice) in their respective states. Further, physicians are considered covered recipients regardless of whether they are enrolled in Medicare. CMS states that residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry, and chiropractic) will not be required to be reported for purposes of the Rule. Concerning teaching hospitals, CMS has stated that it will publish annually a list of those entities it deems to be teaching hospitals to assist applicable manufacturers in determining which teaching hospitals are covered recipients.

e. Payment or Other Transfers of Value

The Rule clarifies the definition of "payment or other transfer of value" through examples that CMS states are to be used as guidelines to assist applicable manufacturers when making a reasonable, good faith effort to determine value. The following are examples of payments or other transfers of value:

- Payments or other transfers of value that do not have "discernible" economic value for the covered recipient specifically, but nevertheless have general economic value (i.e., applicable manufacturer provides a physician with a textbook the physician already owns);
- Any payments or other transfers of value even if the covered recipient does not formally request such payments or transfers of value;
- All tax and shipping related to such payments or other transfers of value;
- Payments to individual physician covered recipient(s) who request such payments when the payments are made to a group practice; and,
- Payments provided to one covered recipient, but directed by the applicable manufacturer to another specific covered recipient (e.g., teaching hospital to physician).

f. Ownership or Investment Interest

The Rule attempts to reduce the broad scope of the definition of "ownership or investment interest" by only requiring applicable manufacturers to report those ownership or investment interests that they know to be

owned by a physician or an immediate family member of a physician.

Also, the Rule does not limit ownership or investment interest provisions to covered recipients; rather, these provisions apply to all "physicians." CMS states in the Rule that this means any ownership and investment interest must be reported for all physicians even if the physician is an employee of the applicable manufacturer or GPO. Further, the requirement to report payments and other transfers of interests apply to these physicians as well.

Payment and Other Transfer of Value Report Content Reports

a. High Level Outline of Report Content

The Rule indicates the content required in the required reports. For each payment or transfer of value, applicable manufacturers are required to include the following in their reports:

- Applicable manufacturer name;
- Covered recipient identification information:
  - Name as listed in NPPES (Note: CMS requires the first, middle initial and last, as appropriate);
  - Primary business street address (i.e., teaching hospital location or physician's primary practice location);
  - Physician specialty (Note: The specialty name and code as identified in the provider taxonomy list on the NPPES should be used);
  - NPI; and
  - State professional license number(s).
- Amount of payment or other transfer of value, including the date of payment;
- Name of related covered drug, device, biological or medical supply:
  - Include for drugs and biological the National Drug Code ("NDC"); and,
  - Include for devices and medical supplies the name under which it is marketed or the therapeutic area or product category.
  - Additionally, if the payment or transfer of value is not reasonably associated with any product, then the applicable manufacturer should report "none," and if it is reasonably related to a non-covered product, then the applicable manufacturer should report "non-covered."
- Form of payment, nature of payment and the name of the entity paid (if not provided to the covered recipient directly). Form of payment includes: cash or cash equivalent; in-kind items or services; stock, stock option or any other ownership interest; and dividends, profit or other return on investment (Note: In the Rule, CMS breaks the form of payment category of "stock, stock option, or any other ownership investment interest, dividend, profit, or other return on investment" into two separate categories);

- Eligibility for delayed publication;
- Payments to third parties; and
- Contextual information for each payment or other transfer of value (Note: This is an optional reporting obligation).

b. Reportable Categories

The Rule lists the following mandatory reportable categories under the Act: (1) charitable contributions; (2) food and beverage; (3) compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program; (4) compensation for serving as faculty or as a speaker for an accredited or certified continuing education event; (5) consulting fees; (6) compensation for services other than consulting; (7) honoraria; (8) gift; (9) entertainment; (10) travel and lodging; (11) education; (12) royalty or license; (13) current or prospective ownership or investment interests; (14) grant; (15) research; and (16) space rental or facility fees. Of note, the Rule adds the final category, "space rental or facility fees," and deletes the previously proposed "other" category which would have served as a catch-all category.

CMS declined to provide precise definitions for each reportable payment category opting instead to use descriptive categories that reflect the nature of the payments or transfers of value. However, the Rule emphasizes all non-excluded payments and transfers of value to covered recipients must be reported under whatever category most closely describes the payment or transfer of value. If more than one category applies, the applicable manufacturer or applicable GPO should reasonably determine the nature of the payment or transfer of value and choose the appropriate category for the report.

i) Charitable Contributions

Despite using descriptive reportable categories, the Rule provides some guidance on certain of these categories. For example, a charitable contribution is described as "any payment or transfer of value made to an organization with tax-exempt status under the internal revenue code," and contributions to, at the request of, or on behalf of covered recipients by applicable manufacturers must be reported. However, this category should not include a payment that is made in exchange for a service or benefit. Accordingly, if a physician provides consulting services to an applicable manufacturer and the physician requests payment be made for his or her services to a charity, this is more appropriately categorized as a consulting fee and not a charitable contribution. Alternatively, payments made to a covered recipient tax-exempt teaching hospital should be reported as a charitable contribution, provided there is no exchange for any service or benefit.

ii) Food and Beverage

Unlike the proposed rule, which would have required manufacturers to report the cost of food and beverage *per covered recipient* present in a group setting (regardless of whether they consume any food or beverage), the Rule requires manufacturers to report the cost *per person* in the group setting who actually eats or drinks food and/or beverage provided the amount of the consumed items exceeds $10. This also includes meals dropped off at offices or situations where the attendees consuming food or beverages in an unorganized or uncontrolled setting. However, applicable manufacturers

do not need to report buffet-style meals or other food and drink offered in large-scale settings where the identities of recipients would be difficult to ascertain, such as conferences.

iii) Research

Payments for "research" (as defined at 42 C.F.R. § 50.603) must be reported under the Act. CMS agrees with comments that requiring both a written agreement or contract and a research protocol would limit the scope of the research category too much, as not all research has a research protocol. Instead, if a payment falls within the nature of payment category for research it only needs to be subject to a written agreement or contract, *or* a research protocol. This may include an unbroken chain of events that links the manufacturer with the covered recipient.

c. Exceptions to Reporting Obligations

The Rule excludes various categories of payments and transfers of value from its reporting requirements, including: (1) existing personal relationships; (2) payments or transfers of value less than $10; (3) educational materials that directly benefit patients or are intended for patient use; (4) discounts and rebates; (5) in-kind items for the provision of charity care; (6) product samples; (7) short-term loans; (8) contractual warranties; (9) covered recipients acting as patients; (10) the provision of healthcare; (11) nonmedical professionals; (12) civil or criminal actions or civil proceedings; (13) indirect payments or other transfers of value through a third party; and (14) indirect payments made to speakers. The Rule discusses the following exceptions in greater detail than the others.

i) Payments of Less Than $10

The Act provides that for CY 2013, applicable manufacturers and applicable GPOs do not need to report payments of less than $10 unless payments to a covered recipient exceed $100 annually. These thresholds will increase beginning in CY 2014 consistent with increases to the consumer price index. Applicable manufacturers have the option of reporting small payments individually or bundled together with similar nature of payment categories so long as the reporting mechanism is consistent and clear.

Items dispersed at conferences need not be reported or tracked for aggregation purposes, unless the items individually exceed $10 (however, every item over $10 must be tracked and reported regardless of the size of the event).

ii) Discounts, Rebates, and Samples

In the Rule, CMS confirms applicable manufacturers do not need to report discounts and rebates they provide to covered recipients (for covered drugs, devices, biologicals, and medical supplies). Similarly, product samples, coupons, and vouchers intended for patient use are not a required disclosure category. Written agreements that confirm samples are provided to patients are sufficient to qualify applicable manufacturers and GPOs for this exception.

iii) Transfers of Value through a Third Party

The Rule clarifies the reporting obligations under the Act do not extend to an applicable manufacturer that indirectly pays or transfers value to a covered recipient through a third party but is unaware of the covered

recipient's identity, given there is no affirmative duty to ascertain the identity of a covered recipient. CMS has adopted a knowledge standard consistent with that of the False Claims Act, such that an applicable manufacturer or applicable GPO that does not have actual knowledge of a covered recipient's identity need not report indirect payments to the recipient. However, an applicable manufacturer or applicable GPO cannot deliberately ignore, or recklessly disregard, the identity of a covered recipient to be exempt from the reporting requirements.

Reports of Physician Ownership and Investments

The Rule requires applicable manufacturers and applicable GPOs to submit two reports: one report for all payments and other transfers of value and one report for all physician ownership or investment interests. To minimize overlap between each report, applicable manufacturers and applicable GPOs should disclose payments or other transfers of value provided to physician owners or investors in the report for payments or other transfers of value. This report should note that the covered recipient is a physician owner or investor. The Rule directs applicable GPOs reporting such payments to comply with the data elements required for payments or other transfers of value.

Additionally, when reporting the ownership and investment interests held by physicians' immediate family members, the Rule indicates applicable manufacturers and applicable GPOs need not report the specific name and relationship of immediate family members. Further, applicable manufacturers and applicable GPOs can aggregate reported interests across multiple immediate family members. The Rule also clarifies reportable ownership or investment interests, whether direct or indirect, do not include stock options that have not been exercised. Finally, the Rule indicates a list of information applicable manufacturers and GPOs must submit to comply with this requirement, including the name, address, NPI, specialty of physician owner/investor, as well as a dollar amount, value, and terms of ownership or investment.

Report Submission Process

The Rule solidifies the process for submitting required reports. The initial reporting period will be from August 1, 2013 to December 31, 2013, after which applicable manufacturers must submit the required reports by March 31, 2014 and on the ninetieth day following the end of each calendar year thereafter. CMS had considered requiring applicable manufacturers and applicable GPOs to disclose to covered recipients and physician owners or investors the information they intended to report prior to making the reports to CMS, but decided against imposing such a requirement. Instead, CMS encourages applicable manufacturers and GPOs to provide such advance information even though it is not required.

Each applicable manufacturer and applicable GPO that is required to submit reports must register with CMS ninety days prior to the end of the calendar year after which a report is due whether or not they make the submissions individually or on a consolidated basis. CMS will open the registration process before the reporting deadline each year. CMS will prescribe a template for reporting that includes all the data requirements. Reporting will be completed electronically and will occur once each year. Applicable manufacturers and applicable GPOs will not be allowed to aggregate

payments made to a covered recipient, but must report each payment individually. Applicable manufacturers under common ownership may submit reports to CMS on a consolidated basis provided each applicable manufacturer is individually registered with CMS as explained above and identified in the consolidated report. CMS further indicates in the Rule it will likely use a portal for the submission process, the details of which will be forthcoming.

As part of the submission process, an officer of the reporting applicable manufacturer or applicable GPO must attest that the report is timely, accurate, and complete to the best of his or her knowledge. The Rule adds flexibility to this requirement by allowing non-traditional officers (officers other than chief executive officer, chief financial officer and chief operating officer) to satisfy the attestation requirement. If applicable manufacturers report on a consolidated basis only one attestation is required, but the attesting applicable manufacturer will bear liability for the all applicable manufacturers that are part of the report.

Review and Corrections Process

The Rule finalizes the review, corrections, and dispute process for reports submitted by applicable manufacturers and applicable GPOs. CMS indicates in the Rule it will notify applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors when reportable information is ready for review. It will notify applicable manufacturers and applicable GPOs though the methods specified by such parties as part of the reporting process. After considering various methods of notification, CMS settled on indirectly providing notifications to affected covered recipients and physician owners or investors that reports have been made through email listservs, CMS' website, and the Federal Register. CMS will directly provide notifications to affected covered recipients and physician owners and investors that register with CMS beforehand through email. CMS will only issue such notifications to initiate the review and corrections process once a year, rather than on an ongoing basis.

Covered recipients and physician owners or investors will have forty-five days from the date specified in the notifications to review reports submitted by applicable manufacturers and applicable GPOs. During this time period, covered recipients and physician owners or investors may review reported data from the current and two previous years. To do this, they will need to log on to a secure website to review reported information that only applies to them. Once they review the reported information, they may (but are not required to) electronically certify the information is correct or they can initiate a dispute with the applicable manufacturer or applicable GPO. CMS clarifies in the preamble to the Rule that it will not act as a mediator – it is the responsibility of the involved parties to resolve any disputes.

After resolving any disputes, applicable manufacturers and applicable GPOs must submit and re-attest to the corrected data no later than fifteen days after the forty-five day review and corrections period for CMS to publish the corrected data. Otherwise, CMS will publish the originally submitted data, but indicate it has been disputed. This will not prevent parties from continuing to resolve disputes after the review and corrections period is past, but the corrected data will not be published until the next publication date. CMS comments in the preamble to the Rule that while it will only publish the reported data once a year, it will publish an update at least one more time during the year.

CMS will allow for delayed publication of payments or other transfers of value made by applicable manufacturers under a product research or development agreement. Delayed publication will be limited to (1) research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply and (2) clinical investigations regarding a new drug, device, biological, or medical supply. The product research or development agreement must include a written agreement, a research protocol or both between the applicable manufacturer and covered recipient. The publication of this information will be delayed until the earlier of (1) the date of approval, licensure or clearance of the covered drug, device, biological, or medical supply or (2) four calendar years from the date the payment or other transfer of value was made. CMS clarifies in the preamble to the Rule that while it will delay publication of this information, applicable manufacturers are still be required to report the required data, which will be kept confidential by CMS.

Public Availability

The Act requires CMS to publish the reported data on a publicly available website that CMS intends to develop in the near future. In response to the comments received to the proposed rule, CMS will engage stakeholders to develop the website, agreeing that it must be user-friendly and provide accurate and understandable data to the public. In the preamble to the Rule, CMS outlines a number of guiding principles it will use in the development of the website. For example, the website will:

- Accurately and completely describe nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions;
- Provide information to stakeholders about data submission, review, dispute, dispute resolution and other processes; and,
- Emphasize that disclosure does not mean payments or transfers of value are not legitimate or a conflict of interest exists.

Once CMS establishes the format and function for the website, at a minimum, the following data will be available to the public:

- Applicable manufacturer's name;
- Covered recipients:
  - Name;
  - Specialty (physician only); and
  - Primary business street address (practice location).
- Amount of payment or other transfer of value in U.S. dollars;
- Date of payment or other transfer of value;
- Form of payment or other transfer of value;
- Nature of payment or other transfer of value;
- Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable;
- NDCs of related covered drugs and biologicals, if any;

- Name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly; and
- Statement providing additional context for the payment or other transfer of value (optional).

For research payments or other transfers of value, at a minimum the following research related information will be available on the website:

- Name of research institution/entity receiving payment;
- Total amount of research payment;
- Name of study;
- Name(s) of the related covered drugs, devices, biologicals or medical supplies;
- NDCs of related covered drugs and biologicals, if any;
- Principal investigator(s) (including name, specialty and primary business address);
- Context of research; and
- ClinicalTrials.gov identifier (optional).

For physician ownership and investment interests, at a minimum the followinginformation would be included on the website in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's or applicable GPO's name;
- Physician owner or investor's:
  - Name;
  - Specialty; and
  - Primary business street address.
- Whether the ownership or investment interest is held by a physician or an immediate family member of the physician;
- Dollar amount invested;
- Value and terms of each ownership or investment interest;
- Any payment or other transfer of value provided to the physician owner or investor, including:
  - Amount of payment or other transfer of value in U.S. dollars;
  - Date of payment or other transfer of value;
  - Form of payment or other transfer of value;
  - Nature of payment or other transfer of value;
  - Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable;
  - NDCs of related covered drugs and biologicals, if any;
  - Name of the entity that received the payment or other transfer of value, if not provided to the physician directly; and

- Statement providing additional context for the payment or other transfer of value (optional).

CMS also intends to provide FAQs regarding the website to help users understand reported information and the context for reporting. Further, and as required by the Act, data will be aggregated, searchable across multiple fields and downloadable from the website. CMS also notes it will establish mechanisms to make available to researchers information that is not published on the website or publicly available to support its transparency initiative.

Record Retention and Audits

The Rule requires applicable manufacturers and applicable GPOs to maintain books, records, documents and other materials sufficient to enable an audit, evaluation, or inspection of compliance with the Act for a period of at least five years from the date of payment, transfer of value, or ownership or investment interest is published publicly on the website. This could mean a retention period of up to nine years for applicable manufacturers that are eligible to delay publication of reports related to certain research and clinical investigations as explained above.

Penalties

Applicable manufacturers and applicable GPOs that fail to make the required reports under the Act are subject to the imposition of civil monetary penalties ("CMPs"). If an applicable manufacturer or applicable GPO *fails to submit* required information, they are subject to CMPs of at least $1,000, but no more than $10,000, for each unreported payment or other transfer of value, or investment or ownership interest, with the maximum fine capped at $150,000 for each annual submission. For a *knowing failure to submit* the required information in a timely manner, applicable manufacturers and GPOs are subject to CMPs of at least $10,000, but no more than $100,000, for each unreported payment or transfer of value, ownership or investment interest, capped at $1,000,000 for each annual submission. As previously indicated, the Rule also finalizes CMS' proposal that the "knowingly" element be the same standard as in the False Claims Act. CMS indicates the factors it will consider in determining the amount of CMPs to impose on a party, which are as follows:

- Length of time of failure to report, including length of time an applicable manufacturer or GPO knows of a payment or transfer of value, or ownership or investment interest;
- Amount of payment, transfer of value, ownership or investment interest;
- Level of culpability;
- Nature and amount of information reported in error; and
- Degree of diligence exercised in correcting information reported in error.

CMS also clarifies in the preamble to the Rule that "failure to report" means failing to report timely and accurately an entire transaction, as well as certain fields related to the transaction. CMS also states that CMPs for failures and knowing failures to report are subject to separate caps and may be aggregated to equal amounts up to $1,150,000 per year. Further, the Rule indicates the provisions of 42 C.F.R. § 402 subpart A and subpart B apply to the imposition, appeal and collection of CMPs.

Finally, CMS explains in the preamble to the Rule that corrections submitted after the review and corrections period, including the additional fifteen day dispute period, will not subject the applicable entity to CMPs but original submissions should be made in good faith. For consolidated reports, CMPs will be imposed on the attesting entity for each individual other entity whose information is part of the report and the caps will apply on an individual basis. Given this, the attesting entity could face penalties above and beyond the individual cap on CMPs.

Preemption

The Rule finalizes the requirement that the Act preempts similar state laws such that states cannot require entities to report the same information as required under the Act, unless it is being collected by a federal, state or local governmental agency for public health, surveillance, investigation or other public health purposes or health oversight. CMS' comments in the preamble to the Rule indicate these preemption provisions will not take effect until the requirements of the Act take effect, which is August 1, 2013. CMS further clarifies that state and local entities may still require reporting of non-required categories of information for payments or other transfers of value reported to CMS. Such categories may include those excluded from the Act with the exception of those that do not meet the minimum dollar threshold or disclosures from non-covered recipients or by non-applicable manufacturers. CMS acknowledges in the preamble to the Rule the potential broad interpretations of the preemption exceptions above but does not provide specific clarifications on how it will narrow such interpretations. Nevertheless, CMS defines "public health agencies" to include agencies charged with preventing or controlling disease, injury or disability and/or conducting oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions or other activities necessary for oversight of the health care system. These exceptions still appear to be broad and are likely to evolve as CMS makes determinations of preemptions on a case by case basis.

Practical Effects

a. Applicable Manufacturers and GPOs

The reporting requirements under the Act, as clarified by the Rule, will impose significant costs and administrative burdens on applicable manufacturers and applicable GPOs. Drug, device, biological and medical supply companies that make payments or other transfers of value to covered recipients or physician owners or investors should evaluate whether they will be covered by the Act, including analyzing all available exceptions. If so, they should first become familiar with the information they are required to report and second begin developing strategies and procedures to collect and store reportable data beginning August 1, 2013 through December 31, 2013 to report to CMS. Applicable manufacturers and applicable GPOs should also make sure to register with CMS prior to when they must make the required reports and understand that a failure to meet their reporting requirements may result in significant CMPs.

b. Covered Recipients and Physician Owners or Investors

While covered recipients and physician owners or investors may have no reporting obligations under the Act, such entities and individuals should take steps to register with CMS prior to the reporting deadline so they are directly notified if an applicable manufacturer or applicable GPO makes a report that includes their

information. Covered recipients and physician owners or investors should then closely review any reported data that affects them and be ready to dispute such reported data, if necessary. To do this, covered recipients and physician owners or investors may consider implementing mechanisms to track any payments or other transfers of value they receive during an applicable reporting period so they are ready to initiate and resolve any disputes within the short review and corrections period. Covered recipients and physician owners or investors may also consider including in any written agreements with applicable manufacturers and applicable GPOs specific provisions that such organizations will disclose any data they intend to report to CMS to the covered recipient, physician owner or investor in advance of submitting it to CMS. This will help eliminate any "surprises" and will give covered recipients and physician owners or investors additional time to consider and initiate a dispute, if necessary.

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