

“Sunshine” Law

Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Final Rule Summary February 2013

On February 4, 2013, the Centers for Medicare and Medicaid Services (CMS) released its final rule implementing a provision in the Affordable Care Act that requires manufacturers of drugs, devices, biological, or medical supplies covered under Medicare, Medicaid or the Children’s Health Insurance Program (CHIP) to report payments or other transfers of value to physicians and teaching hospitals. The law requires manufacturers and group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Manufacturers are required to report any payment or transfer of value of \$10 or more, with some exceptions. Manufacturers and GPOs must begin collecting required data on August 1, 2013 and report the data to CMS by March 31, 2014. This information will be made available to the public on September 30, 2014.

The following summary is intended to provide details to physicians about what information manufacturers and GPOs will be required to report to CMS, the impact of regulations on physician professional societies and continuing medical education (CME) programs, and the processes for physician review and appeal of reported information.

Definitions

Applicable Manufacturer: An entity that operates in the United States, or in a territory, possession, or commonwealth of the United States and is engaged in the production, preparation, propagation, compounding or conversation of a *covered* drug, device, biological or medical supply.

An applicable manufacturer (referred to hereinafter as manufacturer) is also an entity that is under common ownership with any above described entity and which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.

Covered Drug, Device, Biological, or Medical Supply: A covered drug, device, biological, or medical supply is one for which payment is available under Medicare, Medicaid, or CHIP and which requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the Food and Drug Administration (FDA) (in the case of a device or a medical supply that is a device).

Covered Recipients: The law defines a covered recipient as: 1) a physician, other than a physician who is an employee of a manufacturer; or 2) a teaching hospital. CMS clarifies in the rule that the definition of a physician

hinges on whether a physician is “legally authorized” to practice. All physicians that have a current license to practice will be considered covered recipients.

Residents, including residents in medicine, osteopathy, dentistry, podiatry, optometry, and chiropractic will not be considered covered recipients.

Identification of Covered Recipients

- ❖ The law requires manufacturers report the covered recipient’s name and business address, and for physicians, the physician’s national provider identifier (NPI) and specialty. Additionally, the manufacturer must also report the state(s) and appropriate state professional license number(s) for at least one state where the physician maintains a license.

Payments or Other Transfers of Value

- ❖ The law requires that manufacturers report a “payment or other transfer of value” made to a covered recipient or “to an entity or individual at the request of or designated on behalf of a covered recipient.” CMS clarifies that it interprets the law to include situations in which an entity or individual receives and keeps the payment that was made on behalf of (or at the request of) the covered recipient and the covered recipient does not receive the payment or other transfer of value.

CMS outlines in the rule a few guidelines to help with determining value:

- Payments or other transfers of value that do not have a “discernible” economic value for the covered recipient specifically, but have a discernible economic value generally must be reported.
- Even if a covered recipient does not formally request the payment or other transfer of value, it still must be reported.
- When calculating value, all aspects of a payment or transfer of value, such as tax or shipping, should be included in the reported value.
- All manufacturers must make a reasonable, good faith effort to determine the value of a payment or other transfer of value.
- ❖ Payments provided to a group or practice (or multiple covered recipients generally) should be attributed to the individual physician covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value. This means that the payment or other transfer of value does not necessarily need to be reported in the name of all members of a practice.
- ❖ Payments provided to one covered recipient but directed by the manufacturer to another specific covered recipient should be reported in the name of the covered recipient who ultimately received the payment.
- ❖ All payments or other transfers of value made to an entity at the request of or designated on behalf of a covered recipient should be reported in the name of the covered recipient as well as the name of the entity that received the payment or other transfer of value. If the payment is provided to an individual at the

request of or designated on behalf of the covered recipient, the individual's name will not be reported. The manufacturer will only report "individual" in the field for entity paid.

- Review and correction for entities that receive a payment at the request of or designated on behalf of a covered recipient will be done by the covered recipient.
- If a covered recipient waives a fee from a manufacturer, the covered recipient should make very clear to the manufacturer whether they would like their waived fee paid to another individual or entity.

Payment and Other Transfer of Value Report Content

❖ The law sets forth the categories of information required to be reported for each payment or other value transfer. These categories are as follows:

- ***Name***
- ***Business Address***
- ***Specialty and NPI***
- ***Date of Payment***
- ***Context***
 - Manufacturers can provide brief contextual information for each payment or value transfer, but it is not required.
- ***Related Covered Drug, Device, Biological or Medical Supply***
 - The law requires that if a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, manufacturers must report the name of the covered product.
 - CMS directs manufacturers to fill in associated product fields as follows:
 - If the payment or other transfer for value is not related to at least one covered product, then the manufacturer should report "none."
 - If the payment or value transfer is related to a specific product, which is not a covered product, the manufacturer should report "non-covered product."
 - If the payment or value transfer is related to at least one covered product, as well as at least one non-covered product, the manufacturer must report the covered products by name and may include non-covered products in one of the fields for reporting associated product.

- For drugs and biological, manufacturers must report the market name of the product and must include the National Drug Code if any. If a market name is not available, manufacturers should use the name registered on clinicaltrials.gov. For devices and medical supplies, reporting is allowed of either the name under which the device or medical supply is marketed, or the therapeutic area or product category.

- **Form of Payment and Nature of Payment**

- Form of Payment Categories:
 - Cash or cash equivalent
 - In-kind items or services
 - Stock, a stock option, or any other ownership interest
 - Dividend, profit, or other return on investment
- Nature of Payment Categories: All payments or other transfers of value must be reported, unless excluded, even if they do not explicitly fit into one of the categories below. Manufacturers must select the category that best describes the payment or other value transfer.
 - Consulting fee
 - Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
 - Honoraria
 - Gift
 - Entertainment
 - Food and Beverage
 - Food and beverage provided at conferences in settings where it would be difficult to establish the identities of people partaking in the food do not need to be reported (e.g. buffet meals, snacks or coffee at booths at conferences).
 - However, if meals are provided to select individual attendees at a conference where the manufacturer can establish the identity of attendees, then it is reportable.
 - For meals in a group setting (other than buffet meals at conferences or other large-scale settings), CMS will require manufacturers to report the per person cost (not the per covered recipient cost) of the food/beverage for each covered recipient that partakes in the meals.
 - Travel and Lodging (including the specified destinations)
 - Education
 - With this category, CMS does not intend to capture the *attendees* at accredited or certified continuing education events whose fees have been subsidized through the CME organization by a manufacturer.
 - Any travel or meals provided by a manufacturer to specified covered recipients associated with these events must be reported under the appropriate nature of payment categories.

- Research
 - Defined as “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.”
 - If a payment falls within this category, it only needs to be subject to a written agreement or contract or a research protocol.
 - CMS will require reporting of research payments to primary investigators (PIs) who meet the definition of physician, even if they do not regularly treat patients.
 - Material transfers (e.g. provision of a protein) to a researcher for discovery collaboration does not need to be reported when not part of a commercial or marketing plan and precedes the development of a new product.
 - Manufacturers must report the name of the individual or entity (regardless of whether it is a covered recipient) that received the payment for the research services, as well as the PI(s) who meet the definition of a covered recipient.
- Charitable Contribution
 - To be used when a manufacturer makes a payment or value transfer to a charity on behalf of a covered recipient and not in exchange for any service or benefit.
- Royalty or License
- Current or prospective ownership or investment interest
- Compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education event
- Grant
- Space Rental or Facility Fees

Reporting Exclusions

- ❖ The law excludes specific types of payments or other transfers of value from reporting requirements.
 - ***Existing Personal Relationships***
 - e.g., a spouse, who works for an applicable manufacturer, gives a present to the other spouse who is a covered recipient.
 - ***Payments or Other Transfers of Value of Less Than \$10***
 - Payments or other value transfers of less than \$10 do not need to be reported except when the total annual value to a covered recipient exceeds \$100.
 - For subsequent calendar years, the dollar amounts will be increased based on the consumer price index for all urban consumers.
 - These guidelines will apply to conferences and similar events, as well as events open to the public. Meaning, if the payment or transfer is \$10 or more it needs to be tracked and reported even when provided at large-scale conferences or similar events.

- Small incidental items that are under \$10 (pens, note pads) provided at conferences or large-scale events will be exempted from the reporting requirements, including the need to track them for aggregation purposes.
- ***Educational Materials that Directly Benefit Patients or are Intended for Patient Use***
 - Examples include: wall models, anatomical models for patient education, educational materials (including overhead expenses, such as printing and time, to develop the materials).
 - Medical textbooks and journal reprints provided to covered recipients could not be excluded from reporting.
- ***Discounts and Rebates for Covered Drugs, Devices, Biologicals, and Medical Supplies***
- ***In-Kind Items for the Provision of Charity Care***
 - Exclusion applies to products intended for patient use, e.g. product samples, coupons/vouchers to defray the cost of a covered drug, device, biological, medical supply.
- ***Short-Term Loan***
 - Exclusion includes “the loan of a covered device for a short-term period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.”
 - Exclusion includes covered devices and those under development.
 - Exclusion includes a supply of disposable or single use devices intended to last no more than 90 days.
- ***Contractual Warranty***
 - The law excludes from reporting, “items and services provided under contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase of lease agreement for the covered device.”
 - CMS will also exclude items and services provided under a contractual service or maintenance agreement.
- ***Covered Recipient Acting as a Patient***
- ***Nonmedical Professional***
 - The law excludes “in the case of a covered recipient who is a licensed nonmedical professional, a transfer of anything of value to the covered recipient if the transfer is solely for the non-medical professional services of such licensed nonmedical professional.”
- ***Civil or Criminal Action or Administrative Proceeding***
 - The law excludes “in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of a covered recipient with respect to a civil or criminal action or administrative proceeding.”

Indirect Payments or Other Transfers of Value through a Third Party

- ❖ The law excludes the reporting of payments or other transfers of value that an applicable manufacturer makes indirectly to a covered recipient through a third party where the applicable manufacturer is unaware of the identity of the covered recipient.
- ❖ CMS defines an indirect payment or other transfer of value as one that an applicable manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the covered recipient.
- ❖ CMS defines that a manufacturer is “unaware” if it does not know the identity of a covered recipient, and that “know” means that the manufacturer has actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity.
- ❖ CMS provides the following example. If a manufacturer provided an unrestricted donation to a physician professional organization to use at the organization’s discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute “indirect payments” because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians. In this situation, the manufacturer would not be required to report the donation even if a portion of the payment was ultimately provided to a covered recipient as a grant. However, if the money from the manufacturer was given to a professional medical society earmarked for funding awards or grants for physicians, this would be subject to reporting requirements.
- ❖ CMS does not believe it is necessary or appropriate to provide any requirements on the information third parties should or should not report. For example, CMS believes that physician professional societies generally keep track of the physicians to whom they provide industry-funded grants and may not need to put new accounting systems in place in order for manufacturers to be able to comply with the reporting requirements.
- ❖ Payments or other transfers of value made to a speaker at a continuing education program is not an indirect payment or transfer of value and does not need to be reported when the following conditions are met: 1) the program meets the accreditation certification requirements and standards of the ACCME, AOA, AMA, AAFP, or ADA CERP; 2) the manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers; and 3) the manufacturer does not directly pay the covered recipient speaker.
- ❖ Manufacturers will not be responsible for reporting payments to CME vendors that are used to subsidize attendee’s tuition fees for continuing education events.
- ❖ For unaccredited and non-certified education, payments or transfers of value should be reported as required for any other payment or transfer of value.

Reports on Physician Ownership and Investment Interests

- ❖ The law requires applicable manufacturers and applicable GPOs to report information concerning ownership and investment interests held by physicians or their immediate family members in such manufacturers or GPOs.

Report Submission and Review

- ❖ Manufacturers and GPOs are required by law to submit their reports for the preceding calendar year electronically to CMS on March 31, 2013, and on the 90th day of each calendar year thereafter. CMS is not requiring manufacturers to provide reports to covered recipients for pre-submission review.
- ❖ The law requires that manufactures, GPOs, covered recipients, and physician owners or investors have the opportunity to review the data submitted to CMS for a period of at least 45 days prior to the data being made publically available. If covered recipient, physician owner or physician investor initiates a dispute of data, manufacturers or GPOs may begin resolving the dispute and correcting the data as soon as the dispute is initiated. Following the end of the 45-day review period, manufacturers and GPOs will have an additional 15 days to correct data. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period will be captured in the initial publication of the current reporting year of data on the public website.
- ❖ Notification to physicians and teaching hospitals will be provided annually to announce the review and correction period and will include specific instructions for performing this review. Covered recipients will have the opportunity to register with CMS to ensure they receive communications about the process for review. CMS is strongly recommending that all covered recipients and physician owners or investors register prior to the review and correction period so they can review the data attributed to them.
- ❖ Covered recipients and physician owners and investors will only be granted access to data regarding payments or other transfers of value and/or ownership or investment interests submitted on their behalf.
- ❖ No more than two years of data will be available for review and correction. CMS will update the current and previous year's data at least once annually beyond the initial data publication following the submission of the data.
- ❖ If a covered recipient or physician owner or investor decides to initiate a dispute, he/she will be directed to fill out electronic fields detailing the dispute, including the proposed corrections. The system will automatically flag that the transaction was disputed and the system will notify the appropriate manufacturer or GPO of the dispute. If a dispute cannot be resolved by the end of the 15-day resolution period, the parties should continue to work to reach resolution and update the data. However, CMS will move forward with publishing the original and attested data, but it will be marked as disputed.

Public Availability

- ❖ The first data publication will be September 30, 2014 for 2013 data.

- ❖ CMS notes in the final rule that the public website will clearly state that disclosure of a payment or other transfer of value does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing.
- ❖ A physician's NPI will not be published on the public website.

Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations

- ❖ The law provides for delayed publication of payments or other transfers of value from manufacturers to covered recipients made pursuant to certain kinds of product research or development agreements and in connection with clinical investigations.

Relation to State Laws

- ❖ Federal reporting requirements pre-empt any State or local laws requiring reporting of the same type of information covering payments or other transfers of value made by manufacturers to covered recipients. CMS has interpreted "type of information" to refer to the categories of information for each payment or transfer of value required to be reported. Thus, states/localities can require reporting of non-required categories of information, including payment categories excluded by the federal law, with the exception of those that do not meet the federal minimum dollar threshold. .