

February 19, 2013

## CMS Issues Final Regulations on Federal “Sunshine” Law for Manufacturers and GPOs

### IMPORTANT DATES

*August 1, 2013: Data Collection Begins*

*March 31, 2014: First Report Due*

*September 30, 2014: CMS Publishes Reports*

On February 1, 2013, the Centers for Medicare & Medicaid Services (“CMS”) issued long-awaited final regulations with a lengthy preamble (collectively referred to herein as “Final Regulations”) relevant to Section 6002 of the Patient Protection and Affordable Care Act, also known as the “Physician Payment Sunshine Act.”<sup>1</sup> **The Final Regulations are available at <https://www.federalregister.gov/articles/2013/02/08/2013-02572/transparency-reports-and-reporting-of-physician-ownership-or-investment-interests-medicare-medicaid>.**

Generally, the Physician Payment Sunshine Act requires “applicable manufacturers” of a “covered drug, device, biological, or medical supply” to report annually certain information to CMS regarding “payments and other transfers of value” provided to “covered recipients.” The Physician Payment Sunshine Act also requires applicable manufacturers and “applicable group purchasing organizations (‘GPOs’)” to report annually certain information to CMS regarding “ownership or investment interests” held by physicians and their immediate family members. For an overview of the Physician Payment Sunshine Act generally, see the Epstein Becker Green health reform alert titled “Federal Transparency Is Now a Reality: Challenges and Opportunities for Pharma, Devices and PBMs,” available at <http://www.ebglaw.com/showclientalert.aspx?Show=12676>. Additionally, see the Epstein Becker Green health reform alert titled “CMS Issues Proposed Rules on Federal Sunshine Law for Manufacturers and GPOs,” available at <http://www.ebglaw.com/showclientalert.aspx?Show=15292>, for an overview of the CMS proposed regulations issued December 14, 2011 (“Proposed Regulations”).

CMS is providing an approximately 180-day preparation period to applicable manufacturers and GPOs to implement the Final Regulations and begin collecting data. **Applicable manufacturers and GPOs must begin data collection on August 1, 2013, and the first report is due to CMS by March 31, 2014.** CMS will release the data on a public website by September 30, 2014.

This health reform alert provides an overview of the Final Regulations relevant to applicable manufacturers and GPOs that had significant changes or clarifications from the Physician Payment

<sup>1</sup> By way of background, the Physician Payment Sunshine Act was created as part of the Patient Protection and Affordable Care Act enacted in March 2010. See, Patient Protection Affordable Care Act of 2010, Pub. L. No. 111-148, § 6002, 124 Stat. 395.

Sunshine Act and/or Proposed Regulations. The alert then discusses some key considerations for applicable manufacturers and GPOs to consider as they prepare to implement the regulations.

## **FINAL REGULATIONS REGARDING PAYMENTS AND TRANSFERS OF VALUE**

### ***Definition of “Applicable Manufacturer”***

Based on comments to the Proposed Regulations, CMS limited the definition of “applicable manufacturer” to an entity that “operates” in the United States, which means having a physical location or otherwise conducting activities within the United States, and is “engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply . . . .” The Final Regulations made it clear that entities based outside the United States with operations inside the United States are subject to the reporting requirements. Also, the Final Regulations clarified that entities that manufacture a covered product are applicable manufacturers, even if they do not hold the FDA approval, licensure, or clearance for the covered product.<sup>2</sup>

The Final Regulations specifically excluded certain entities from the definition of “applicable manufacturer,” including, but not limited to, an entity in which the drug, device, biological, or medical supply is used solely within the entity or for the entity’s own patients, as well as distributors, wholesalers, repackagers, relabelers, and kit assemblers that do not hold title to any covered drug, device, biological, or medical supply.

Further, the Final Regulations clarified that a manufacturer that previously did not have any other covered products becomes an “applicable manufacturer” 180 days after its product becomes available for payment under Medicare, Medicaid, or the Children’s Health Insurance Program (“CHIP”).

### ***Definition of “Common Ownership”***

An entity that is under “common ownership” with an applicable manufacturer and “provides assistance or support” to such entity also qualifies as an applicable manufacturer subject to reporting. Common ownership means an entity “where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities.” “Assistance and support” is defined as “providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution” of a covered product.

The Final Regulations clarify that entities satisfying both of those criteria only need to report transfers of value that are related to covered products. CMS further clarified that applicable manufacturers and entities under common ownership may, but are not required to, file consolidated reports.

Additionally, the Final Regulations provide that payments or transfers of value received by a covered recipient in accordance with a joint venture or promotion must be reported in the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of the co-promotion or joint venture agreement state otherwise, so long as the transfers of value or payments are reported by one of the applicable manufacturers.

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<sup>2</sup> However, these manufacturers may report transfers of value related to only the covered product if they do not assist in the marketing, sale, or distribution of the covered product and manufacture the product pursuant to a written agreement for another entity.

***Definition of “Covered Drug, Device, Biological, or Medical Supply”***

CMS clarified that a covered drug, device, biological, or medical supply is a product (i) for which payment is available under Medicare, Medicaid, or CHIP, either individually or as part of a fee schedule or “bundled payment”;<sup>3</sup> and (ii) that 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 device or medical supply that is a device).

***Definition of “Research”***

CMS defined “research” in accordance with the broad definition in the Public Health Service regulations for human research subject protections<sup>4</sup> and expressed its view that this definition encompasses “pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations.”

***Definition of “Payment of Transfer of Value”***

The Final Regulations clarified the definition of “payment or transfer of value” in several ways. For example:

- Items that may not have a discernible value to the covered recipient, but have an economic value generally, must be reported, even if the covered recipient did not request the item (e.g., providing the physician with a text book that the physician may already own).
- Ancillary costs, such as tax and shipping, should be included in the reported value and requires applicable manufacturers to make a reasonable, good faith effort to determine the value of a payment or other transfer of value.
- Payments provided to a group practice should be attributed to the individual physician covered recipient(s) who requested the payment or on whose behalf the payment was made.
- Payments provided to another person on behalf of a covered recipient must be reported but will include the name of the individual or entity who received the payment.
- Payments provided to one covered recipient, but directed by the applicable manufacturer to another specific covered recipient (e.g., teaching hospital to physician), should be reported in the name of the recipient who ultimately received the payment.

***Reporting the Nature of the Payment***

The Final Regulations generally retained the categories for the nature of payment previously provided but added categories for compensation for serving as a faculty or speaker for an unaccredited and non-certified continuing education program and space rental and facility fees. CMS also removed the “other”

<sup>3</sup> The term “bundled payments” means hospital inpatient prospective payment system (“IPPS”), outpatient prospective payment system (“OPPS”), chronic kidney disease drugs and products reimbursed through the end stage renal disease (“ESRD”) bundled payment system, or other similar payments.

<sup>4</sup> 42 CFR § 50.603 (defining research 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”).

category but emphasized that all non-excluded payments or other transfers of value to a covered recipient must be reported, even if a payment or transfer of value does not fit squarely within an identified category.

The Final Regulations further state that if a payment or other transfer of value falls within more than one category, the applicable manufacturer should select the one that best describes the nature of the transaction. Moreover, if a transaction consists of multiple payments or transfers of value, each payment or transfer must be reported separately.

Furthermore, the Final Regulations provide additional guidance on food and beverage reporting requirements. Specifically, applicable manufacturers must report the *per person* cost of food and beverages provided in a group setting for each covered recipient who partakes in the meal.

Also, the Final Regulations permit a payment to be designated “research” if the payment is made pursuant to either a written agreement or a research protocol. The written agreement requirement may be satisfied by an unbroken chain of agreements, such as agreements with contract research organizations (“CROs”), site management organizations (“SMOs”), and other vendors, which link the applicable manufacturer to the covered recipient that ultimately received the payment. Research-related payments are to be reported on a separate form that has a separate line item for each payment, which must include the identities of the recipients of the payment (e.g., the individual principal investigator, a teaching hospital, a nonteaching hospital, or clinic) and the principal investigator for the research.

Applicable manufacturers must report each research payment once as a single interaction. The payments should include all costs contained in the written agreement or research protocol associated with the research, including “costs associated with patient care, such as diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items.” These payments also might include payments associated with medical writing, publications, and travel and meal expenses, provided that these costs are expressly included in the written agreement or research protocol and paid for through the research contract. Any payments or transfers of value outside the written agreement or research protocol or provided by a different mechanism would be subject to reporting in the nature of category payment most closely related to the payment.

Finally, the Final Regulations clarified that donations to a charity in lieu of a payment for consulting services should be reported as consulting services with the physician identified as a covered recipient and the entity paid as the charity.

### ***Exclusions from Reporting***

The Final Regulations instruct applicable manufacturers to use the “dictionary definition” for the categories of items that may be excluded from reporting that are provided in the Physician Payment Sunshine Act. The Final Regulations also provide the following additional guidance on exclusions:

- Food and Beverages or Items of Value Provided at Large-Scale Conferences or Other Events. Buffet meals, snacks, or coffee at conferences or other similar large-scale settings where it is impractical to identify the participating covered recipients are exempt from the reporting requirement. The Final Regulations extend this exclusion to include small incidental items that are under \$10 (e.g., note pads, pens) provided at similar events.

- Educational Materials. This exclusion should be interpreted to apply to written and electronic materials and wall and anatomical models used in patient education. The Final Regulations are clear that materials, such as medical textbooks and journal reprints that are provided to covered recipients for their personal education, are not excluded from reporting.
- Charity Care. This exclusion is limited to *in-kind* items provided to a charitable organization for patients who are unable to pay, or for whom payment would be a significant hardship. The exclusion does not apply if the applicable manufacturer provides either (i) in-kind items to a charitable organization for all of the covered recipient's patients, or (ii) a payment or transfer of value that is not an in-kind item. This exclusion may be satisfied by a written agreement between the applicable manufacturer and charitable organization agreeing that the in-kind items will be used only for charity care.
- Product Samples. The Final Regulations clarified that this exclusion extends to coupons and vouchers.
- Short-Term Loans. The Final Regulations clarified that the provision of up to a 90-day supply of disposable or single-use devices falls within this exception.
- Payments on Behalf of a Covered Recipient. The Final Regulations provide that a payment that is refused by the covered recipient does not need to be reported. Similarly, a payment made to another individual or entity that is not made at the request of a covered recipient does not need to be reported.
- Indirect Payments Through a Third Party. The Final Regulations provide that an applicable manufacturer will not need to report funds if it is unaware of the identity of the covered recipient (e.g. double-blind research or unrestricted funds to a medical society that may ultimately be received by a covered recipient). However, if an applicable manufacturer could easily ascertain the identity of the covered recipient, then it must do so and report. Alternatively, if the applicable manufacturer “requires, instructs or directs” the payment to be provided to a known covered recipient, then it must be reported.
- Indirect CME Speaker Payments. The Final Regulations exclude from reporting payments that meet all of the following requirements:
  - The program satisfies all of the accreditation or certification requirements of certain specified accrediting and certifying organizations;
  - The applicable manufacturer does not select or provide a distinct set of identifiable individuals to be considered; and
  - The applicable manufacturer does not pay the covered recipient directly.

### **Report Content**

The Final Regulations provided clarification regarding certain content required in the report:

- Business Address. Applicable manufacturers may use the physician's primary practice location and are permitted, but not required, to use the address information provided in the National Plan &

Provider Enumeration System (“NPES”). However, an applicable manufacturer is required to use the address of the teaching hospital provided in the list published by CMS.

- Physician’s National Provider Identifier (“NPI”). Applicable manufacturers must include each physician’s NPI. This can be left blank if, after a good faith effort, an applicable manufacturer cannot obtain the physician’s NPI.
- State License Number. Applicable manufacturers must also include an appropriate state professional license number for at least one state, which must be identified in the report.
- The Amount of the Payment or Other Transfer of Value. The Final Regulations permit applicable manufacturers to report payments or transfers of value under \$10 that meet the \$100 threshold either as one total amount for each relevant category or as separate line items.
- The Identity of the Associated Covered Drug, Device, Biological, or Medical Supply. The Final Regulations require that the name of the covered product reasonably associated with the payment or transfer of value be reported. In addition:
  - 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.”
  - The Final Regulations permit applicable manufacturers to report up to five covered products that are reasonably associated with the payment or transfer of value.
  - With respect to covered drugs and biologics, applicable manufacturers must report the name under which the product is marketed and the product’s National Drugs Code (“NDC”) (if the product has an NDC) or, if not yet marketed, report the name registered on [clinicaltrials.gov](http://clinicaltrials.gov).
  - With respect to covered devices, applicable manufacturers must report either the name under which the device is marketed or the therapeutic area or product category of the device.
- Eligibility for Delayed Publication. The applicable manufacturer must indicate each reported item that is eligible for delayed publication.
- Payments to Third Parties. Payments provided at the request of or designated on behalf of a covered recipient to an individual or entity must be reported in the name of that covered recipient. Applicable manufacturers must also note the name of the entity that received the payment or state “individual” if the funds were transferred to an individual, on behalf of the covered recipient.
- Assumptions Document. Applicable manufacturers may file an assumptions document with their reports to explain any assumptions made when collecting and reporting.<sup>5</sup>

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<sup>5</sup> CMS does not intend to use the assumptions document for prosecution but acknowledges that the reporting based on the assumptions would be open to prosecution.

In addition to the required elements, applicable manufacturers are permitted, but not required, to include a brief statement that provides contextual information for each payment or transfer of value. In response to the comments, CMS suggests that physicians who wish to opt out of reporting requirements should just refuse all payments and transfers of value from applicable manufacturers.

### ***Consolidated Reporting***

The Final Regulations provide significant flexibility with respect to consolidated reporting. Applicable manufacturers are not only permitted to consolidate reports with entities that solely qualify as applicable manufacturers because they provide assistance or support to an applicable manufacturer with which they are under common control, they are also permitted, but not required, to submit consolidated reports with other applicable manufacturers with which they are under common control. With respect to consolidated reporting, the report must identify the manufacturer that made each payment or transfer of value.

### ***Delayed Reporting of Research Payments***

The Physician Payment Sunshine Act provides for a delay in the publication by CMS of payments related to certain bona fide research activities,<sup>6</sup> when made in the following instances: (i) research on or development of a new product, or a new application of an existing product; and (ii) clinical investigations regarding a new product. The Final Regulations maintain the application of the delayed publication but provide that payments in connection with research related to new applications of existing products will not be subject to delayed publication unless the research activities that resulted in the payment were not within the scope of a “clinical investigation,” as defined in the statute.<sup>7</sup> Pursuant to the Final Regulations, new generic products, including drugs subject to an Abbreviated New Drug Application (“ANDA”) and devices subject to 510(k) clearance, will be deemed “new products” subject to the delayed publication provisions.

Payments subject to delayed reporting will not be published publicly by CMS until the first publication date after the earlier of the following: (i) the date of approval, licensure, or clearance of the covered drug, device, biological, or medical supply by FDA; or (ii) four calendar years after the date the payment or other transfer of value was made. CMS clarified that “Congress clearly intended that all payments should be included on the public website, even if a product never received FDA approval, licensure or clearance.”

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<sup>6</sup> Consistent with CMS’s approach for categorizing the nature of payment as research, to be considered bona fide research for which delayed publication may be available, research must be conducted pursuant to a written agreement or research protocol, including: (i) research in connection with a potential new medical technology or a new application of an existing medical technology; (ii) the development of new drug, device, biological, or medical supply; and (iii) in connection with a clinical investigation of a new drug, device, biological, or medical supply.

<sup>7</sup> The Physician Payment Sunshine Act defines “clinical investigation” for the purposes of the delayed reporting provisions to include “any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.”

**FINAL REGULATIONS REGARDING PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS*****"Applicable GPO"***

The Final Regulations clarify that entities that engage in rare and circumstantial resale of products are not likely to fall within the scope of an applicable GPO.<sup>8</sup> Further, CMS specifically declined 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.

***"Ownership or Investment Interest"***

Although the definition of "ownership or investment interest" is quite broad, the Final Regulations attempt to limit the scope 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<sup>9</sup> of a physician.

***Definition of "Physician"***

The ownership or investment interest provisions apply to all "physicians" and not just "covered recipients." CMS has interpreted this to mean that ownership and investment interest must be reported for all physicians regardless of whether a physician is an employee of the applicable manufacturer or GPO. Additionally, the requirement to report payments and other transfers of interests apply to such physicians.

***Reporting of Ownership and Investment***

Understanding that ownership and investment interest reporting requirements are significantly different than the payment or transfer-of-interest reporting requirements, the Final Regulations require this information to be reported separately.<sup>10</sup>

If ownership or investment interests are owned by multiple family members, the reports can be aggregated across all family members who hold interests that are subject to the same terms. If an applicable manufacturer or GPO seeks to aggregate interest across family members, the value of the interest must be aggregated as well.

In addition to reporting the ownership or investment interests, the Final Regulations require applicable manufacturers or GPOs to report all payments or other transfers of interest made to physicians, or to third

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<sup>8</sup> The term "applicable group purchasing organization" means an entity that operates in the United States and purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities but not solely for use by the entity itself.

<sup>9</sup> CMS finalized the proposed definition of "immediate family member" to include the following: spouse; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother, or stepsister; father, mother, daughter, son, brother, or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.

<sup>10</sup> The following information must be included in the report: (i) identification of the physician owner, including the physician's name as listed in NPDES, specialty, primary business address, NPI, and state professional license number for at least one state; and (ii) information regarding the holder of the interest. The report must state whether the ownership or investment interest is held by the physician or an immediate family member. If the interest is held by a family member, the report does not need to include the name or the relationship of the family member, amount of investment, and value and terms of each ownership or investment interest.

parties on behalf of physicians, holding ownership or investment interests. Applicable manufacturers with physician owners should include such transfers in the same report used to capture payments and other transfers to covered recipients. An applicable manufacturer will need to indicate on the report that the recipient was a physician owner or investor.

## **REGULATIONS REGARDING ANNUAL REPORTING**

### ***Reporting Process***

Applicable manufacturers and GPOs that have payments or transfers of value to report are required to register with CMS and electronically submit their reports, with an applicable officer attestation, by March 31, 2014, or the 90th day of each year thereafter. Applicable manufacturers that will be part of a consolidated report must register individually. Any applicable manufacturer filing a consolidated report must identify all the manufacturers included in such report.

### ***Report Correction Process***

CMS will notify covered recipients and physician owners and investors of reported payments and allow for a 45-day review and correction period prior to publication. Applicable manufacturers and GPOs will have an additional 15 days to resolve any disputes and submit updated data. Any disputed data will be finalized at the end of the 45-day review and correction period and will be published as is with a notation—“disputed.” Any amounts disputed and updated outside of the 45-day review and correction period will be corrected in next annual update.

### ***Penalties***

The Final Regulations clarified penalties for consolidated reports, stating that the applicable manufacturer submitting the consolidated report will be subject to the maximum penalties for *each* individual applicable manufacturer included in the consolidated report; therefore, the submitter may be subject to penalties for all subsidiaries’ submissions, even though the penalties together may exceed the maximum penalty allowed. CMS finalized that a civil monetary penalty may be imposed for failure to report information in a timely, accurate, or complete manner, including failure to report certain aspects of a transaction or a whole transaction. Also, CMS clarified that penalties imposed for failure to report and knowing failures to report will be aggregated separately and are subject to separate aggregate totals, with a maximum combined annual total of \$1,150,000.

### ***Preemption***

The Final Regulations preempt any statute or regulations of a state that requires an applicable manufacturer to disclose or report the “same type of information” reported under the federal statute, except information requested for public health reporting purposes. CMS clarified that the “same type of information,” for purposes of preemption, refers to the categories of information for each payment or other transfer of value required to be reported. Therefore, states may require reporting for items not required under the federal statute, including exclusions. CMS also clarified that public health and oversight activities may not be used to avoid preemption. Therefore, if collecting such information is for transparency purposes, and not for public health reporting purposes, the information will be preempted under the federal statute.

**KEY CONSIDERATIONS FOR MANUFACTURERS AND GPOS**

- Applicable manufacturers and GPOs should carefully review and evaluate the definitions provided in the Final Regulations to determine the applicability of the provisions to their activities, contracts, and business infrastructure. Understanding the definitions is critical to determining whether the Physician Payment Sunshine Act applies and in what circumstances manufacturers must report payments, and enables manufacturers to strategically structure certain activities for ease of reporting.
- Current state marketing laws are preempted only in part by the Physician Payment Sunshine Act. Applicable manufacturers need to evaluate carefully all current state marketing laws to determine the extent of reporting that will still be required. Current policies, processes, and systems will need to be reevaluated and updated. Applicable manufacturers should take this opportunity to develop a robust infrastructure for tracking and reporting all payments and other transfers of value at the federal and state levels.
- Applicable manufacturers may consider educating their customers and other physicians of the impact of the Physician Payment Sunshine Act and how it may affect the contractual relationships and interactions between manufacturers and physicians and/or teaching hospitals.
- Applicable manufacturers should carefully evaluate whether to submit an assumption document with their reports. Although the U.S. Department of Justice and the Office of Inspector General of the Department of Health and Human Services will have access to these documents, the existence of written, well-thought-out, reasonable assumptions may go a long way in showing that any omission or any improperly reported data was not the result of deliberate ignorance or reckless disregard—the knowledge standard established by the Final Regulations.
- Due to the importance of reporting physician NPIs and the professional license number for at least one state for each physician, applicable manufacturers should require that this information be reported accurately by the physician as part of the contracting process.
- Although the Final Regulations now allow more flexibility regarding consolidated reporting, applicable manufacturers should evaluate whether the added convenience is worth the additional potential liability to which the reporting manufacturer will be subject.
- Applicable manufacturers should review the manner in which costs associated with bona fide research activities, such as travel and meal expenses related to investigator meetings and other research-related meetings, are currently paid and consider whether payment mechanisms for these costs and associated agreement templates may need to be modified in accordance with the Final Regulations' reporting requirements for research-related payments.
- Applicable manufacturers and GPOs must determine efficient reliable processes for collection, reporting, and data retention in order to defend the processes in place, if audited.
- Applicable manufacturers will need to consider the resources required to implement a cost effective and efficient pre-review process, which can handle challenges from covered recipients in a timely manner in order to comply with the 45-day review and correction requirement.

For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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