Arnall Golden Gregory LLP

Client Alert

Contact Attorneys Regarding This Matter:

Lanchi Nguyen Bombalier
404.873.8520 - direct
lanchi.bombalier@agg.com

Jennifer Downs Burgar
404.873.8194 - direct
jennifer.burgar@agg.com

Arnall Golden Gregory LLP
Attorneys at Law

171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031

Two South Biscayne Boulevard
One Biscayne Tower 2690
Miami, FL 33131

1775 Pennsylvania Avenue NW
Suite 1000
Washington DC 20006

www.agg.com

CMS Publishes Final Rule Implementing the "Sunshine Act" Regulations on Physician Ownership and Investment Interests

On February 8, 2013, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule announcing the "National Physician Payment Transparency Program: Open Payments," which is designed to implement the Affordable Care Act's directive to increase public awareness of financial relationships between manufacturers of drugs, medical devices, biologicals and medical supplies and specified health care providers. 78 FED. REG. 9,458 (Feb. 8, 2013).

The Final Rule, which becomes effective on April 9, 2013, contains essentially two overlapping reporting obligations. The first requires drug and medical device manufacturers meeting the definition of an "Applicable Manufacturer" to submit annual reports beginning March 31, 2014 on certain payments or other transfers of value made to physicians and teaching hospitals. The second requirement provides that the Applicable Manufacturers and group purchasing organizations ("GPOs") must disclose on an annual basis any ownership or investment interests held in such entities by physicians (or their immediate family members), in addition to reporting information on payments or other transfers of value made to such owners or investors.

Under the Final Rule, data collection efforts by the regulated industry must begin on August 1, 2013. The first annual reports will be due to CMS by March 31, 2014 and should include the data collected between August 1, 2013 and December of 2013. CMS is currently developing an electronic system to assist with the reporting process and anticipates that release of the data on a public website will occur by September 30, 2014. CMS also notes that the agency will be submitting annual reports to Congress and each State summarizing the aggregated information from each manufacturer and GPO during the preceding calendar year, as well as information on any enforcement actions taken and any penalties paid. The reports to Congress are due on April 1 of each year, beginning on April 1, 2014.

The following summary of the Final Rule, which is 71 pages in length, is not intended to be a comprehensive overview of all the provisions in the Final Rule, but highlights only those provisions which we believe will be of most interest to the regulated industry.

I. General Reporting and Publication Requirements

The general reporting and publication requirements are as follows:

- **Applicable Manufacturers will submit reports to CMS of payments or other transfers of value made to physicians and teaching hospitals. Both Applicable Manufacturers and GPOs will report information about ownership or investment interests held by physician owners or investors (or their immediate family members).** To the extent an individual is both a "Covered Recipient" and a physician owner or investor, a specific payment or other transfer of value need only be reported once.
- Prior to the posting of the collected data to a public website, **CMS will provide a 45-day period for Applicable Manufacturers, GPOs, Covered Recipients and physician owners and investors to review and correct any reported information.** An additional 15 days will be given to correct any data to resolve any disputes, after which the Applicable Manufacturer or GPO may submit and attest to the updated data to CMS to finalize the data submission. If a dispute cannot be resolved within the timeframe provided, CMS will move forward with publishing the most recent attested data (subject to the dispute) while the parties continue to work on a resolution, but will mark the data as disputed. No further account of the information will be published.[1]
- **Reports should include the name, business address, specialty, State professional license number, and National Provider Identifier ("NPI"), if possible, for the physician.** CMS notes that a good faith effort to obtain the NPI must be made, including, but not limited to, asking the physician, checking the National Plan & Provider Enumeration System ("NPPES") database[2], and requesting assistance from the NPPES help desk. Notably, the physician's NPI is required for data collection purposes, but CMS has noted that the NPIs will not be disclosed on the public website.

The Final Rule provides that indirect payments or transfers of value are subject to the reporting requirements. The Final Rule defines "indirect payments or other transfers of value" as those transfers made by the Manufacturer or GPO to a Covered Recipient through a third party (i.e., medical professional society or non-physician prescriber), where the Manufacturer or GPO requires, instructs, directs or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a Covered Recipient.[3] If a Manufacturer or GPO is not "aware" of or does not "know" the identity of the Covered Recipient (meaning, there is no actual knowledge, as well as no act in deliberate ignorance or reckless disregard of such identity), the indirect payment can be excluded from the reporting requirements. CMS acknowledges that there may

1 Notably, CMS plans to monitor the rate, volume, and terms of disputes and resolutions and provide additional guidance about situations requiring parties to weigh the cost and benefits of resolving a dispute. CMS will also monitor whether an Applicable Manufacturer or GPO has an abnormally high number of disputes or unresolved disputes.

2 The NPPES database is available at https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do.

3 For example, if a manufacturer makes an unrestricted donation to a third-party organization to use at the organization's discretion, the donation would not be considered an indirect payment, even if the organization chose to use the donation to make grants to physicians. However, if a manufacturer donates money earmarked for the purpose of funding grants to physicians to a third-party organization, the grants would be considered indirect payments to Covered Recipients and would be subject to the reporting requirements.

be situations where the involvement of the third party in the payment or transfer is intended to ensure that the identity of the Covered Recipient remains anonymous, but the Manufacturer would not be considered to be acting in deliberate ignorance or reckless disregard of a Covered Recipient's identity.[4]

II. Key Definitions

The Final Rule provides additional clarification on which entities will have a reporting obligation based on the statutory definitions.

A. Applicable Manufacturer

In the Final Rule, CMS provides guidance on the statutory definition of an "Applicable Manufacturer" (subsequently referred to in this Bulletin as "Manufacturer") and finalizes the agency's general position that **reporting is required by any entity that holds Food and Drug Administration approval, licensure, or clearance for a covered product, as well as any entity that actually manufactures at least one covered product, regardless if that entity holds the FDA approval, licensure, or clearance for such product.**[5] CMS notes that the following entities are not considered Manufacturers:

- Entities that only manufacture raw materials or components, which are not themselves covered products, unless there is common ownership with a Manufacturer; [6]
- Distributors or wholesalers (i.e., repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological, or medical supply, unless there is common ownership with a Manufacturer;
- Hospitals, hospital-based pharmacies, and laboratories that produce or manufacture a covered product solely for their own use or use by their own patients; and
- Pharmacies, including compounding pharmacies that meet all the following: (1) maintain establishments that comply with applicable local laws regulating the practice of pharmacy; (2) regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners in the course of their professional practice; and (3) do not produce, prepare, propagate,

4 For example, a manufacturer may hire a third party to conduct a double-blinded market research study, which involves paying physicians for their participation. Even though the manufacturer is aware that payment will be given to physicians, the third party is engaged specifically to maintain the anonymity of the physicians and the sponsor and, thus, the payments are not considered to be reportable indirect payments. In contrast, if a manufacturer instructs a third party to make payments to a certain group of physicians (i.e., top billing cardiologists or the chiefs of staff for certain classes of hospitals), these indirect payments must be reported even if the manufacturer does not have actual knowledge of the individual physicians' identities.

5 "Applicable Manufacturer" is defined as an entity engaged in the production, preparation, propagation, compounding or conversion of covered drug, device, biological, or medical supply for sale or distribution in the United States, its territories, possession or commonwealth, or an entity under common ownership with such an entity, which provides assistance or support that is necessary or integral with respect to such functions.

6 In the Final Rule, CMS finalizes that "common ownership" refers to when the same individual(s) or entity(ies), have five percent (5%) or more direct or indirect ownership in two or more entities. To provide more flexibility and decrease the burden of reporting on multiple entities, CMS provides the option for entities under common ownership to participate in consolidated reporting.

compound, or convert drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients.

CMS notes that entities based outside of the United States that have operations (i.e., sell products) in the United States are subject to the reporting requirements, regardless of where the product is physically manufactured. Furthermore, such entities cannot circumvent the reporting requirements by making payments to Covered Recipients indirectly through a foreign entity that has no operations in the United States, if the entity operating in the United States is aware of the identity of the Covered Recipients.

CMS provides some leeway in limiting the reporting obligations under certain circumstances for some Manufacturers whose business models may not necessarily focus on covered products. However, CMS notes that, in most circumstances, Manufacturers of at least one covered product and any non-covered products will be required to report all payments or transfers of value to Covered Recipients, **including those related to the non-covered products.**

B. Covered Recipient

A "Covered Recipient" refers to any physician (i.e., doctors of medicine or osteopathy, dentists, podiatrists, optometrists, and chiropractors) or any teaching hospital.[7] Physicians who are bona fide employees of the Applicable Manufacturer that is reporting payment are excluded from the definition of a Covered Recipient. CMS notes that all physicians with a current license to practice are considered to be Covered Recipients, regardless of whether the physician is enrolled in Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP"). Because State licensure laws vary regarding whether residents must be licensed to practice, CMS clarifies that reporting on payments or transfers of value to residents will not be required under the Final Rule.

C. Covered Product

A "covered drug, device, biological, or medical supply" (generally, a "covered product") is one for which payment is available under Medicare, Medicaid, or CHIP, whether the product is reimbursed separately or as part of a bundled payment under any of the prospective payment systems. U**nder the Final Rule, CMS also finalized two exceptions to limit the definition to drugs and biologicals that, by law, require a prescription (i.e., no over-the-counter products) and to devices and medical supplies that require premarket approval or notification to FDA (i.e., excluding many Class I and certain Class II devices).** Additionally, CMS has noted that, when a product becomes "covered," a Manufacturer will have a grace period of 180 days following the date of the product becoming "covered" to begin complying with the data collection and reporting requirements.

7 CMS intends to publish a list of those teaching hospitals considered to be Covered Recipients once annually, to be available publicly and for download at least 90 days prior to the start of data collection in the first reporting year and, thereafter, at the beginning of the reporting year.

D. Research and Research-Related Payments

In the Final Rule, CMS adopts the Public Health Service Act definition of "research" at 42 C.F.R. § 50.603, which is interpreted to include pre-clinical research, FDA Phase I-IV research, and investigator-initiated investigations.[8] CMS also issued several clarifications related to payments falling within the research category:

- CMS indicates that a research-related payment only needs to be subject to a written agreement or contract or a research protocol, which includes an unbroken chain of agreements linking the Manufacturer to the Covered Recipient.
- All research-related payments will be included on the public website, even if a product has never received FDA approval, licensure or clearance. Manufacturers may indicate on reports whether or not a payment or other transfer of value should be granted a delay from publication (or should remained delayed, if applicable). If a publication delay is granted, publication will occur on the first annual publication date after the date of FDA approval, licensure or clearance of the covered product or four calendar years after the date the payment or other transfer of value was made, whichever date is earlier.
- Recognizing that research-related payments are unique, CMS provides that **Manufacturers will report research-related payments separately, using a different template.** Manufacturers will not have to indicate whether a research payment was direct or indirect and should report each research payment once as a single interaction. The name of the entity paid and the name(s) of the principal investigator(s) must be provided, as part of the report.
- Generally, Manufacturers will be required to report the study name, the name of the covered product, and the National Drug Code ("NDC") (if any). However, CMS has allowed for slight modifications for reporting related to pre-clinical research, noting that the associated product or study name need not be included.
- The total research payment amount should include the "aggregated amount of any payments for services included in the written agreement/research protocol," including costs associated with patient care (i.e., diagnostics, exams, lab expenses, health care professional time), the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items.

III. Additional CMS Guidance on Reporting and/or Publication Requirements

In the Final Rule, CMS provides additional clarification on the reporting and publication requirements in specific circumstances. The following table is not a comprehensive list of all such guidance, but highlights certain items of potential interest for the regulated industry.

8 "Research" is 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."

Specific Reportable Activities	CMS Guidance
Payments or transfers of value to board members, medical directors, prospective employees, and retirees as "employees" of the Manufacturer or GPO	CMS will employ a case-specific analysis to determine whether payments would be excluded from reporting.
Payments or other transfers of value to a specific entity or individual "at the request" of the Covered Recipient (i.e., Covered Recipient does not receive the payment or transfer personally)	The Manufacturer must report the payment or other transfer of value under the name of the Covered Recipient and include the name of the entity. If the payment was provided to an individual, the Manufacturer should report "individual" rather than providing the individual's name. Note that if the Covered Recipient declines to accept the payment or other transfer of value and does not request that it be directed to another entity or individual, the payment or other transfer of value offered by the Manufacturer does not need to be reported at all.
Payments or other transfers of value provided to a group or practice (i.e., multiple Covered Recipients)	The payment or other transfer of value should not necessarily be reported for all members the group. The payments or other transfers of value may need to be divided evenly in some cases and in a different manner in other cases in order to fairly represent the situation.
Compensation to a Covered Recipient for speaking at Continuing Education Program	If all the following are met, no reporting is required: (1) Speaking event meets accreditation or certification requirements and standards for continuing education of the certain accrediting/ certifying bodies (ACCME, AAFP, ADA CERP, AMA, or AOA); (2) Manufacturer does not pay the speaker directly; and (3) Manufacturer does not select speaker or provide the third party (i.e., continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

Per person value of meals for Covered Recipients (when more than the minimum threshold of $10 in value per person)	No reporting is required if a Covered Recipient did not partake in the food or beverage. However, the calculation of per person costs should include both Covered Recipients and non-Covered Recipients (such as support staff). Buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a conference or similar event, where it is difficult to identify the identity of those participating, does not need to be reported.
Payments or other transfers of value at conferences or similar events, including events open to the public	Small incidental items that are under $10 in value provided at large-scale conferences and similar large-scale events do not need to be reported. In addition, no tracking is required for aggregation purposes.
Material transfers (i.e., provision of a protein) to a researcher for discovery collaboration	The material transfer does not need to be reported when it is not part of a commercial or marketing plan and precedes the development of a new product. (Due to the early stage of the research process, the transferred material does not have independent value.)
Product samples, short-term loans (of a covered device), and discounts and rebates for covered products	No reporting is required. Product samples are interpreted broadly to include traditional drug samples, as well as single use or disposable devices, demonstration devices, and evaluation equipment that are provided to a Covered Recipient and intended for patient use.
Provision of "in-kind items for the provision of charity care" provided to a Covered Recipient for one or more patients who cannot pay	As long as the Covered Recipient neither receives, nor expects to receive, payment from the patient and the items are not provided for the care of all of the Covered Recipient's patients (i.e., including those who can pay), the transfer of value does not have to be reported. The Manufacturer and Covered Recipient should agree in writing that the Covered Recipient will use the in-kind items only for charity care.

Provision of "educational materials that directly benefit patients" or that are "intended for patient use" to Covered Recipient	CMS indicated that medical textbooks and journal reprints are not typically provided for patient use and, therefore, may need to be reported as a payment or other transfer of value. However, CMS notes that wall models and anatomical models which are ultimately intended to be used with a patient are excluded for reporting purposes. Similarly, if educational materials are provided to a physician on a flash drive to be distributed to patients, the flash drive would be excluded. Overhead expenses, such and printing and time, are included in the exclusion if they are directly related to the development of the excluded materials.
Reporting of Specific Data Elements	**CMS Guidance**
If a payment or other transfer for value is related to marketing, education, or research specific to a covered product	Manufacturer reports the name of the covered product.
If a payment or other transfer for value is not related to any specific product	Manufacturer should report "none."
If a payment or other transfer for value is related to a specific product, which is not a covered product	Manufacturer should report "non-covered product."
If the payment or other transfer of value is related to at least one covered product and at least one non-covered product	Manufacturer reports any covered products by the name and non-covered products may be provided in one of the fields for reporting associated product. Up to five related covered products may be reported for each interaction and, if more than five products are involved, those products most closely related to the payment or other transfer of value should be reported. Drugs and biological should be identified by the market name and NDC number, if available. If a market name is not yet available, the name registered on clinicaltrials.gov should be used. For devices and medical supplies, the market name or therapeutic area or product category should be reported.

Payments for meals and travel costs related to research	Manufacturers should report these payments separately under the food/travel payment categories, unless the costs were included in the written agreement or research protocol and paid for through the large research contract.
Delayed Publication of Product Research or Development Agreements and Clinical Investigations	**CMS Guidance**
Payments or other transfers of value related to new generic products	New generic products, including drugs receiving approval under an Abbreviated New Drug Application and devices under the premarket notification (510(k)) process, will be considered to be "new products" for the purposes of delayed publication (see discussion of delayed publication under Section II.D above).
Payments or other transfers of value related to research for new applications of existing products	Manufacturer may be granted a delay for publication purposes only if the research does not meet the definition of "clinical investigation."
Payments for "business development activities" or any related payments or other transfers of value that would not be reported as part of the "research" payment category	Manufacturer will not be granted a delay for publication purposes.

In order to facilitate CMS' ability to provide further guidance to the regulated industry on classifying and reporting payments or other transfers of value, **CMS has provided for the voluntary submission of an "assumptions" document, to include information on the assumptions and methodologies used by a Manufacturer or GPO in classifying the nature of payment categories, as well as any other assumptions, such as those used in determining whether an interaction constituted a payment or other transfer of value.** Any assumptions documents submitted will not be made public, but will be subject to the predisclosure notification procedures if a Freedom of Information Act request is submitted. However, the document could be accessed by various enforcement agencies, as part of an audit or investigation of the Manufacturer or GPO.

IV. Record Retention Requirements and Related Penalties

Manufacturers and GPOs must maintain all books, contracts, records, documents and other evidence that relates to reports for at least five years from the date of publication of the payment, other transfer or value, or ownership or investment interest on the public website. Under certain

circumstances, this requirement will result in such records being retained for up to nine years, as certain payments or other transfers of value may be eligible for delayed publication. The Department of Health and Human Services ("HHS"), CMS and the Office of Inspector General ("OIG") or their designees have the authority to perform audits, inspection, investigations, or evaluations of such records to ensure compliance with the reporting requirements.

CMS and OIG may impose civil monetary penalties for failure to report information in a timely, accurate or complete manner. P**enalties imposed for failures to report and knowing failures to report will be aggregated separately and subject to separate aggregate totals, with a maximum combined annual total of $1,150,000** in accordance with procedures outlined in federal regulations at 42 C.F.R. § 402, subparts A and B. In addition, compliance with the reporting requirements outlined in the Final Rule will not exempt any parties from any potential liability associated with payments, other transfers of value, ownership interest or investment interests (e.g., the federal Anti-Kickback statute or the False Claims Act).

V. Next Steps for CMS

Despite the level of detail provided by CMS in the 71 pages of the Final Rule, there will no doubt be additional questions and clarifications from industry manufacturers and GPOs, as well as the health care providers involved in the reporting process. Due to the difficulty in anticipating all potential manufacturing arrangements and payment situations, there will be gaps or flaws in the guidance that will be more apparent after data collection efforts by the regulated industry begin and when CMS rolls out its electronic reporting system. At this time, CMS anticipates providing more guidance on the implementation of the Final Rule in the form of a Frequently Asked Questions document. Thus, stakeholders should have an opportunity to request additional informal guidance on the Final Rule from the agency in the coming months.

The Final Rule also notes that the federal reporting requirements do not preclude State and/or local entities from requiring reporting of other categories of information for payments or other transfers of value that are not captured under the Federal law, including those categories that are specifically excluded from reporting under the Final Rule. Therefore, industry manufacturers and GPOs should continue to keep updated on any applicable State and local disclosure requirements to ensure that all reporting obligations are met -- on the federal, State, and local levels. **For example, both Massachusetts and Vermont have indicated an intent to continue to require reporting of transfers of value to persons and entities that fall outside of the definition of Covered Recipient (for example, nurse practitioners).**