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Client Alert

FDA & Life Sciences Practice Group

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CMS Issues Final Rule to Implement Physician Payments Sunshine Act

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On Friday, February 1, 2013, the Centers for Medicare and Medicaid Services (CMS) released the highly anticipated final rule to implement the federal Physician Payments Sunshine Act (the "Sunshine Act"). The final rule will be officially published in the *Federal Register* on February 8, 2013.

The Sunshine Act was passed in March 2010 as part of the Patient Protection and Affordable Care Act. The law requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS payments or other transfers of value they furnish to physicians and teaching hospitals (deemed "covered recipients"). In addition, the law requires certain manufacturers and group purchasing organizations (GPOs) to report ownership or investment interests in their organizations held by physicians. CMS is required to aggregate the information manufacturers and GPOs submit and make it publicly available through a searchable website. The agency issued a proposed rule to implement the requirements in December 2011; comments were due by February 17, 2012.

The final rule was published in the wake of many key stakeholders' (including Senator Charles Grassley (R-IA), the American Medical Association, the Pew Charitable Trusts, and various industry stakeholders) recent pleas to the White House to release the rule as soon as possible.

The final rule has many important implications for life sciences manufacturers and health care professionals and organizations. All interested stakeholders should carefully study the rule's provisions to understand its impact on their day-to-day activities, as well as how these new requirements may impact the perceptions of customers, patients, media outlets, and enforcement authorities.

Manufacturers' Tracking of Payments or Other Transfers of Value Provided to Covered Recipients Must Begin by August 1, 2013

Manufacturers subject to the Sunshine requirements must begin collecting data regarding payments and other transfers of value provided to covered recipients in accordance with the final rule by August 1, 2013. Manufacturers and GPOs must also begin tracking ownership or investment interests held by physicians by August 1, 2013. First disclosure reports providing information about those interactions during the period from August 1, 2013 to December

31, 2013 must be electronically submitted to CMS by March 31, 2014, CMS will publicly post the reported information on its website by September 30, 2014.

"Applicable Manufacturers"

Under the final rule, entities deemed "applicable manufacturers" are required to submit to CMS annual reports of payments or other transfers of value they provide to covered recipients. The final rule defines "applicable manufacturer" as an entity that has a physical location in the United States or that otherwise conducts activities in the United States, whether directly or indirectly through contracted agents, (which the final rule defines as "operating in the United States") and that falls into one of two categories:

1. An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (hereinafter, "covered products"), but not if such covered product is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers that do not hold title to any covered product.

2. An entity under common ownership with an entity in paragraph (1) that provides a service that is necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.

Generally, covered products are those for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, either separately or as part of a bundled payment (irrespective of whether the product is actually reimbursed in any particular situations through one or more of these federal programs). For drugs and biologics, the definition is limited to those that, by law, require a prescription to be dispensed. For medical devices (or medical supplies that are medical devices), the definition is limited to those that require FDA premarket approval or notification. Under this proposed regulatory framework, entities that manufacture exclusively over-the-counter drugs and/or certain Class I or Class II medical devices (those that do not require premarket approval or notification under the 510(k) process, as determined by FDA) would not be subject to the reporting requirements and, therefore, their interactions with covered recipients would not be publicly disclosed.

Regarding wholesalers and distributors, notably, CMS states in the preamble to the final rule that it believes wholesalers and distributors "that hold the title to a [covered product] meet the definition of an applicable manufacturer for the purpose of this rule" and that a manufacturer that "has product(s) with titles held by distributors does not need to report payments or other transfers of value made by the distributor[s] or wholesaler[s] to covered recipients, since these will be reported by the distributor or wholesaler."

Importantly, as a general matter, if an entity is deemed an applicable manufacturer, it must report "all payments or transfers of value to covered recipients rather than only payments related to [covered products] . . . ." The final rule, however, provides for more limited reporting by certain applicable manufacturers that have limited activities that relate to covered products. For instance, among other situations, applicable manufacturers with gross revenues from covered products that constitute less than 10% of total gross revenue for a fiscal year preceding a reporting year are only required to report payments or other transfers of value that relate to covered products. In addition, if an applicable manufacturer has a division that does not manufacture any covered products (*e.g.*, an animal health division), the

applicable manufacturer is only required to report payments or other transfers of value incurred by that division that relate to covered products.

Finally, the rule provides that applicable manufacturers who are under common ownership with one another may, but are not required to, file consolidated disclosure reports. Where manufacturers opt to use consolidated reporting, the applicable manufacturer that files the consolidated report must identify which manufacturer was responsible for each payment and also is liable for civil money penalties that might be imposed on each of the applicable manufacturers included within the consolidated report.

"Covered Recipients"

Applicable manufacturers must submit to CMS annual reports of direct and indirect payments or other transfers of value they provide to "covered recipients," or to entities or individuals at the request of, or designated on behalf of, "covered recipients." "Covered recipients" include "physicians" and "teaching hospitals."

The final rule defines "physician" in accordance with the definition of "physician" provided in the Social Security Act, which includes licensed doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors.

The final rule excludes as covered recipients those physicians who are employees of the applicable manufacturer that would report the payment (*e.g.*, an employed medical director). In addition, CMS notes in the preamble to the final rule that "residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry, and chiropractic) will not be required to be reported." The term "covered recipients" does not include advanced practice nurses, registered nurses, physician assistants, or pharmacists.

The final rule defines "teaching hospitals" as institutions that receive direct or indirect graduate medical education (GME or IME) payments from CMS during the last calendar year for which the information is available. CMS notes that it will annually publish a list of teaching hospitals "at least 90 days in advance before the beginning of the reporting year, or for the first reporting year, at least 90 days prior to the start of data collection."

Direct and Indirect "Payments or Other Transfers of Value"

The final rule requires applicable manufacturers to report direct and indirect "payments or other transfers of value" they furnish to covered recipients or to entities or individuals at the request of, or designated on behalf of, covered recipients. The rule defines "payments or other transfers of value" as "a transfer of anything of value." In the preamble, CMS notes that it interprets "value" as "discernable economic value on the open market in the United States" and believes that "applicable manufacturers should be allowed flexibility to determine value."

In addition, the final rule provides an express definition for "indirect payments or other transfers of value," which are payments or other transfers of value made to a covered recipient through a third party, where the applicable manufacturer "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. The final rule provides, however, that an indirect payment is not reportable if provided to a covered recipient and the applicable manufacturer "does not know . . . the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year." CMS

defines "know" broadly as having "actual knowledge of the information," acting "in deliberate ignorance of the truth or falsity of the information," or acting "in reckless disregard of the truth or falsity of the information." Notably, in the preamble, the agency clarifies that it will "not consider an applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity in situations when the reason for a payment or other transfer of value is being made through a third party is that the identity of the covered recipient remains anonymous," such as payments for double-blinded market research.

Exclusions from Disclosure

The final rule expressly excludes many types of payments, items, and other benefits from the reporting requirements, including, among others: (1) educational materials that directly benefit patients or are intended for patient use (which CMS believes includes things like "anatomical models" and "wall charts", but not "medical textbooks" or "journal reprints"); (2) product samples (including coupons and vouchers) that are not intended to be sold and are intended for patient use; (3) indirect payments or other transfers of value where the applicable manufacturer does not "know" the identity of the covered recipient (as discussed above); (4) in-kind items used in the provision of charity care; (5) discounts and rebates; and (6) payments or other transfers of value made solely in the context of personal, non-business-related relationships. There is also a broad exclusion for transfers of value that are under $10, where the total value of all payments or transfers of value made to a single covered recipient do not exceed $100 during the reporting year. These $10 and $100 thresholds will be updated annually in accordance with any update to the consumer price index for urban consumers.

Support for Continuing Education Programs

The final rule provides that compensation provided to physicians for speaking at a continuing medical education program is not required to be reported, as long as: (1) the program meets the accreditation requirements and standards for continuing education of one of several listed groups, including the Accreditation Council for Continuing Medical Education and the American Medical Association; (2) the manufacturer is not involved in the selection of the speaker; and (3) the manufacturer does not pay the speaker directly.

Regarding attendees of continuing medical education programs, the preamble notes that "applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events," but that "payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported as required."

Food Provided to Covered Recipients

The final rule provides express instructions for how applicable manufacturers must allocate the cost of food and beverages provided to covered recipients in group settings where individual costs are not separately identifiable. Specifically, the rule requires applicable manufacturers to calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). Applicable manufacturers must only report on those covered recipients who actually partook in the food and beverages, and "does not require the reporting of meals eaten by office staff."

In addition, the final rule provides that applicable manufacturers are not required to report or track "buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event." It also notes that "small incidental items that are under $10 (such as pens and note pads)" provided to covered recipients during similar large-scale events are also excluded from reporting.

Contents of Disclosure Reports and Assumptions Documents

For each direct or indirect payment or other transfer of value not excluded from reporting that an applicable manufacturer furnishes to a covered recipient, the applicable manufacturer must report to CMS certain information, including: (1) the name of the covered recipient; (2) the "primary" business address of the covered recipient; (3) if the covered recipient is a physician, the National Provider Identifier, state license number, and specialty; (4) the amount of the payment or other transfer of value; (5) the date of each payment or other transfer of value; (6) the form of the payment or other transfer of value, choosing one of four options (*e.g.*, cash, in-kind item, stock, dividend); (7) the nature of the payment or other transfer of value, choosing one of 17 options (*e.g.*, consulting fee, food and beverage, education, research, royalty or license, etc.); (8) the name(s) of the covered product(s) to which the payment or other transfer of value relates, if any; (9) an indication as to whether the payment or other transfer of value is subject to delayed publication (which is available for certain types of research payments, as discussed below); (10) if the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other entity or individual; (11) an indication as to whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest in the applicable manufacturer; and (12) if desired, a statement that provides additional context for the payment or other transfer of value.

The final rule permits, but does not expressly require, applicable manufacturers to submit an assumptions document that describes the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, including rationales for why particular "nature" descriptors were used to describe certain types of payments or other transfers of value. Notably, CMS states in the preamble that it does "not intend to use the assumptions document for prosecution, but acknowledge[s] that the reporting based on the assumptions [whether produced to CMS or not] would be open to prosecution."

Special Rules for Research Payments (Including Delayed Publication of Certain Research Payments)

The final rule provides special requirements governing the information that must be reported for "research" payments subject to a written agreement or research protocol, or both. The final rule defines "research" as "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research."

Such research payments must be reported to CMS separately from other payments or other transfers of value, and include the following information: (1) the name of the institution, individual or entity receiving the payment or other transfer of value; (2) total amount of the research payment, including all research related costs for activities outlined in a written agreement, research protocol, or both; (3) name of the research study; (4) names of any related covered products, if any; (5) the name, NPI, state license number, specialty, and primary business address for each physician principal investigator; (6) if desired, contextual information for the research; and (7) if desired, the clinicaltrials.gov identifier.

Regarding what should be included in reported research payments, CMS notes in the preamble that the amount reported "should include the aggregated amount of any payments for services included in the written agreement/research protocol", including "the costs associated with patient care, including 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."

In addition, the Sunshine Act requires CMS to delay publication of certain research payments or other transfers of value made under a product research or development agreement. Specifically, under the final rule, publication of such research payments may be delayed if they relate to: (1) research on or development of a new (or a new application of an existing) drug, device, biological, or medical supply; or (2) clinical investigations regarding a new drug, device, biological, or medical supply. For such publication to be delayed, the reporting applicable manufacturer must designate the research payments in question as being subject to the delay provisions. Publication of such payments or other transfers of value is delayed until the first annual publication date after the earlier of: (1) the date of the approval, licensure, or clearance of the product by FDA; or (2) four calendar years after the date of the payment or other transfer of value.

Physician Ownership and Investment Interests

The final rule also requires each applicable manufacturer and applicable GPO[1] to report certain information regarding any "ownership or investment interest" (other than an interest in a publicly traded security or mutual fund) held by a physician (or his/her immediate family member, as defined in the final rule) in the reporting manufacturer or GPO. Under the final rule, such interests held on or after August 1, 2013 must be annually reported CMS.

The final rule defines "ownership or investment interest" as including, but not limited to, any direct or indirect: (1) stock or stock options (but not including those received as compensation, until they are exercised); (2) partnership shares; (3) limited liability company memberships; and (4) loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue. It would not, however, include an interest that arises from a retirement plan through a physician's employment with an applicable manufacturer or applicable GPO, an unsecured loan subordinated to a credit facility, or an ownership or investment interest about which an applicable manufacturer or applicable GPO did not "know" (which, as described above, is defined broadly to include actual knowledge of, or acting in deliberate ignorance or reckless disregard of, the information).

Under the final rule, applicable manufacturers and applicable GPOs must report to CMS the following information for all ownership or investment interests that were held by a physician (or his/her immediate family member) during the preceding year: (1) the name of the physician, and whether the interest is held by an immediate family member; (2) the primary business address of the physician; (3) the physician's National Provider Identifier, state license number, and specialty (even if the interest is held by the physician's immediate family member); (4) the dollar amount invested by

[1] Notably, the final rule broadly defines "applicable group purchasing organization" as an entity that has a physical location in the United States or that otherwise conducts activities in the United States, which "purchases, arranges for or negotiates the purchase of [a covered product] for a group of individuals or entities, but not solely for use by the entity itself." CMS explains that this broad definition is expressly intended to include, among others, as many forms of physician owned distributor organizations as would be potentially captured by the statutory language of the Sunshine Act.

the physician (or his/her immediate family member); (5) the value and terms of the interest; and (6) required information regarding any payment or other transfer of value provided to the physician holding the interest (in accordance with applicable requirements for reporting such payments or other transfers of value). Similar to the other disclosure reports, the first report is due to CMS by March 31, 2014, covering interests held on or after August 1, 2013 to December 31, 2013.

45-Day Review and Correction Period

The Sunshine Act requires CMS to provide applicable manufacturers, applicable GPOs, and covered recipients an opportunity to review and submit corrections to information submitted by applicable manufacturers and applicable GPOs for a period of not less than 45 days before CMS publicly posts the information.

To facilitate this review, CMS will provide a secure website where each individual and entity may log-in and review information specific to it. The agency will similarly notify applicable manufacturers and applicable GPOs that the information is ready for review through the points of contact identified for purposes of report filings. The agency states that it will notify physicians and teaching hospitals using "online posting and notifications on CMS's listserves," and that covered recipients may also register with CMS to receive such a notification. In fact, the agency "strongly recommend[s] that all covered recipients and physician owners or investors register" and notes that "[a]lthough registration is not mandatory for [covered recipients], in order for covered recipients to be able to review the data attributed to them, they will be required to register so we can appropriately match them to their data."

Upon review of the data, if a covered recipient agrees with the information, he/she/it may electronically certify that the information is accurate. In the event a physician or teaching hospital disagrees with the information, a dispute can be initiated directly with the applicable manufacturer or applicable GPO to resolve the issue. If the dispute is not resolved within 15 days after the 45-day review period closes (in other words, 60 days after the 45-day review period begins), CMS will post the applicable manufacturer's or applicable GPO's version of the payment or other transfer of value, and mark it as disputed. Once any dispute is resolved, CMS will update the public website the next time the website is refreshed, as will be done from time-to-time to make corrections of reporting errors. In addition to the 45-day review period, applicable manufacturers and applicable GPOs are required to provide notice to CMS of any erroneous reporting or omissions that are identified through any means.

Public Availability of Reported Information

The provisions of the final rule do not provide much detail about CMS's plans to make reported information publicly available. In the preamble, CMS provides that "we plan to engage stakeholders regarding the content of the website, since we recognize that stakeholders and the public must be a part of the development process."

Interestingly, the preamble also states:

> *We plan to ensure that the public website accurately and completely describes the nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions. In addition, we plan to provide information to stakeholders regarding the data submission, review, dispute, dispute resolution and other*

applicable operational processes. As proposed, the website will clearly state that disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. We appreciate the support of this language and plan to emphasize it on the website. We also plan to provide Frequently Asked Questions (FAQs) and other methods to help users find and understand this important contextual information.

CMS also notes that agency plans to "establish mechanisms for researchers who may want information that is not publicly available [to download the data]."

Penalties, Audits, and Document Retention Requirements

Penalties for failing to timely, accurately, or completely report information as required by the final rule can be as high as $1,150,000 per applicable manufacturer or applicable GPO, per each annual submission. Furthermore, in the event an applicable manufacturer or applicable GPO discovers an error or omission in its annual report, the final rule requires it to submit corrected information to CMS "immediately upon confirmation of the error or omission." Notably, in the preamble to the final rule, CMS states that it does "not intend that errors corrected during the review and correction, and dispute resolution periods will be subject to penalties for failure to report in instances when the original submission was made in good faith," but that "outside this period, any errors or omissions will be considered failures to report timely, accurately, or completely, and will be subject to penalties."

In addition, the final rule requires applicable manufacturers and applicable GPOs to maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection by CMS or the Office of Inspector General (or their designees) of the applicable manufacturer's or applicable GPO's compliance with the disclosure requirements, for a period of at least five years from the date the payment or other transfer of value is published on CMS's website.

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