

HealthReformGPS

NAVIGATING IMPLEMENTATION

*A project of the George Washington University's Hirsh Health Law
and Policy Program and the Robert Wood Johnson Foundation*



Update: Physician Payment Sunshine Act

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Background

Drug companies and medical device manufacturers commonly collaborate with physicians when developing or modifying drugs or devices.¹ These collaborations may include consulting arrangements through which physicians provide input and guidance related to drug or device development, participation in clinical trials testing the efficacy and effectiveness of the drug or device, or educational programs to train and teach physicians about the benefits of a new drug or in the case of a medical device, how to use the device effectively. In return for their services and expertise, physicians often receive payment or other items of value such as an honorarium and/or travel expenses. These financial relationships between manufacturers and physicians, while largely beneficial, raise concerns about conflicts of interest as physicians' treatment decisions may be improperly influenced by their financial relationship with a manufacturer. There is also concern in the industry that these types of arrangements are used to disguise illegal kickbacks (e.g., providing money or other items of value in return for prescribing a particular drug or using a particular medical device).²

To avoid any real or perceived conflicts or kickbacks from these arrangements and ensure that patients and consumers are aware of these arrangements when making healthcare decisions, Congress included the Physician Payment Sunshine Act in the Affordable Care Act. The Sunshine Act requires "Applicable Manufacturers" to annually report "payments or transfers of value" ("Payments") made to "Covered Recipients" or persons designated by a Covered Recipient.³ Applicable Manufacturers and "Applicable Group Purchasing Organizations" ("GPOs") must annually report information regarding ownership in the applicable entity by physicians or their immediate family members. Reports regarding ownership and investment interests in publically traded securities or mutual funds are exempt from the reporting requirement. The Secretary of Health and Human Services, acting through the Centers for Medicare & Medicaid Services (CMS) must publish reported information on a website after giving Applicable Manufacturers, GPOs, Covered Recipients, and Physicians an opportunity to review the information.

This Update to our July 2012 [Implementation Brief](#) discusses the finalized Physician Payment Sunshine Act regulations.

¹ Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests 76 Fed. Reg. 78742 (Dec. 19, 2011).

² Gardiner Harris, Crackdown on Doctors Who Take Kickbacks (Mar. 3, 2009), <http://www.nytimes.com/2009/03/04/health/policy/04doctors.html>.

³ § 6002; 42 U.S.C. 1320a-7h(a).

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Sunshine Act Final Regulations

CMS finalized regulations for the Sunshine Act on February 8, 2013.⁴ These regulations became effective April 9, 2013 requiring Applicable Manufacturers to begin data collection on August 1, 2013 and report to CMS on March 31, 2014.⁵ CMS will publish data through the “OPEN PAYMENTS” website.⁶ Key aspects of the Final Rule include:

- *Definitions.* *Applicable Manufacturer* refers to an entity that operates within the United States that either (1) produces or prepares a covered drug or device; or (2) provides the producer/preparer of a covered drug or device with assistance and support (e.g. marketing, promotion, distribution) while under common ownership with the producer/preparer. *Applicable Manufacturer* does not refer to entities that produce covered drugs or devices for their sole use or distributors and wholesalers that lack title to the covered drug or device. *Applicable Group Purchasing Organization (GPO)* refers to an entity operating within the United States that “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.” *Covered drugs, devices, biologicals, and medical supplies* refers to items paid for by the Medicare and Medicaid programs and, in the case of drugs and biologicals, require a prescription to be dispensed or, in the case of a device, require the FDA’s premarket approval. *Covered Recipient* refers to physicians and teaching hospitals that receive Medicare graduate medical education payments. *Covered Recipient* does not include physicians employed by the reporting applicable manufacturer. *Indirect Payments or other Transfers of Value* refers to payments or transfers of value to covered physicians that occur, via a third party, at the direction of an Applicable Manufacturer or Applicable GPO.
- *Payment Reporting.*⁷ The Final Rule requires Applicable Manufacturers to report all direct and indirect payments provided to Covered Recipients as well as payments to third parties made at the direction of a Covered Recipient during the preceding calendar year. Reports must contain, among other items, the Covered Recipient’s name and address, the amount and date of the payment or transfer of value, the form⁸ and nature⁹ of payment or transfer of value, and the

⁴ Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458 (Feb. 8, 2013).

⁵ *Id.*

⁶ National Physician Payment Transparency Program: OPEN PAYMENTS, Centers for Medicare & Medicaid Services, <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html> (last visited Apr. 16, 2013).

⁷ 42 C.F.R. § 403.904; 42 C.F.R. § 403.908.

⁸ Applicable Manufacturers must identify every payment or transfer of value as one of the following: (1) cash or cash equivalent; (2) in-kind item or service; (3) stock, stock option, or other ownership interest; or (4) a dividend, profit, or other investment return. 42 C.F.R. § 403.904.

⁹ Applicable manufacturers must categorize each payment or transfer of value as one of the following: (1) consulting fee; (2) compensation for services other than consulting (e.g. event speaker); (3) honoraria; (4) gift; (5) entertainment (6) food and beverage; (7) travel and lodging; (8) education; (9) research; (10) charitable contribution; (11) royalty or license; (12) current or prospective ownership interest; (13) compensation for serving as a speaker for an accredited and certified or non-accredited and non-certified CLE; (14) grant; and (15) for teaching hospitals only, space rental or facility fees. 42 C.F.R. § 403.904.

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covered drug to which the payment or transfer relates. Applicable Manufacturers must report research related payments separately from non-research related payments and include information such as the name of the researching institution and the name of the research study. The Final Rule contains special rules for the reporting of payments related to continuing education programs¹⁰ and the provision of food and beverages.¹¹ The Final Rule exempts Applicable Manufacturers from reporting various payments or transfers of value (e.g. in-kind items used for charity care, dividends from ownership in a publically traded security or mutual fund).

- *Ownership and Investment Reporting.*¹² Applicable Manufacturers and GPOs must report physician ownership and investments interests annually to CMS as well as ownership and investment interests held by a physician's immediate family member. Reports must contain specified information including the identity of the physician and, if applicable, family member and the value of the ownership or investment interest.
- *Delayed Publication.*¹³ Payments or transfers of value related to the research and development of new drugs, devices, medicals supplies or biologicals are eligible for delayed publication. Applicable Manufacturers must report such research related payments or transfers of value pursuant to the normal reporting requirements, but may indicate that the payment or transfer is eligible for delayed publication. CMS will delay publication until the earlier of the product obtaining FDA approval or four years after the time of payment. Information submitted for delayed publication is confidential and exempt from the Freedom of Information Act and similar Federal, State, and local laws. The confidentiality will extend until CMS publishes the information.

Key Issues

- *Payments to Residents.*¹⁴ Whether an individual is a *Physician* under the Final Rule and thus subject to the reporting requirements hinges on whether they are "legally authorized" to practice medicine. Some states legally authorize residents to practice medicine, so residents in these states will technically fall within the scope of the Rule. Since not all states permit residents to practice, CMS has chosen to exempt residents from the reporting requirements. Consequently, Applicable Manufacturers may choose to make payments or transfers of value to residents rather than Physicians, as they will not have to report the payment or transfer. CMS should consider including removing the resident exemption if Applicable Manufacturers use it as a means to avoid the reporting requirements.

¹⁰ The Final Rule exempts Applicable Manufacturers from reporting payments to related to continuing education programs if the event is accredited and certified, the applicable manufacturer does not select the speaker, and the applicable manufacturer does not directly pay the speaker. 42 C.F.R. § 403.904.

¹¹ Applicable manufacturers must report food and beverage as a per person value when it is not possible to allocate costs to individuals (e.g. sponsored buffet). Reporting is not necessary, however, for food or drink supplied to all participants at a large-scale conference or event. 42 C.F.R. § 403.904.

¹² 42 C.F.R. § 403.906; 42 C.F.R. § 403.908.

¹³ 42 C.F.R. § 403.910.

¹⁴ 78 Fed. Reg. at 9466-67.

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- *Economic Value.*¹⁵ The Final Rules give Applicable Manufacturers flexibility in calculating the value of payments or transfers to Covered Recipients. CMS only notes that (1) Applicable Manufacturers must still report items that have no “discernable value” to the Covered Recipient as well as items not formally requested by the Covered Recipient; and (2) Applicable Manufacturers must report “all aspects” of the payment or transfer (e.g. tax and shipping). While providing Applicable Manufacturers with flexibility to determine the economic value of payments and transfers may ease their administrative burden, the lack of uniformity may undermine the soundness of the aggregated data.
- *Data Correction and Disputes.*¹⁶ Physicians and Covered Recipients will have 45 days to challenge reported information and resolve disputes before CMS publishes the information on the Internet. Failure to resolve disputes will result in CMS publishing the information submitted by the Applicable Manufacturer or GPO along with a designation of the information as “disputed.” This 45-day period may not provide enough time for parties to resolve disputes.¹⁷ Further, publishing only the information from Applicable GPOs and Manufacturers, in the event of a dispute, may undermine the purpose of the Act by decreasing transparency. A significant number of disputes could additionally cast doubt on the soundness of aggregated data.
- *Cost.*¹⁸ Complying with the Sunshine Act requirements will cost manufacturers, GPOs, and physicians an estimated \$ 269 million during the first year and an estimated \$180 million thereafter. These costs could harm business growth because manufacturers may have to spend more money on compliance at the expense of their innovation and marketing efforts.

¹⁵ *Id.* at 9470.

¹⁶ 42 C.F.R. § 403.908.

¹⁷ Charles Fiegl, *Organized medicine seeks more latitude to challenge industry gift reports*, AMERICAN MEDICAL NEWS (Mar. 12, 2012), <http://www.ama-assn.org/amednews/2012/03/12/gvsa0312.htm>.

¹⁸ 78 Fed. Reg. at 9459.