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Getting ready for transparency of industry payments to physicians and teaching hospitals

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Part 1 in this series on the Sunshine Act focuses on reporting requirements and what physicians should do to prepare.

Collaboration among physicians, teaching hospitals, and biopharmaceutical and medical device manufacturers contributes to the development and delivery of life-saving products, including treatments that have led to declining death rates over the last few decades for heart disease, stroke, cancer and HIV/AIDS. However, for many years, some government officials and other stakeholders have expressed concern that industry activities involving physicians and teaching hospitals, such as consulting, sponsorships, and industry-supported research, training and education, may result in potential conflicts of interest that may influence physician decision-making and raise health care spending.

In response to these concerns, over the years the American Medical Association, the Pharmaceutical Research and Manufacturers of America and other trade groups developed voluntary guidelines to manage interactions between manufacturers and physicians. In addition, a growing number of academic medical centers, professional medical associations, medical journals and clinical guideline-writing committees have adopted stringent rules for interactions with the industry, and several states have enacted transparency laws. Notwithstanding these developments, Congress and government officials continued to express concern that industry guidelines were voluntary, and states were criticized for having payment data on websites that were unsearchable or difficult to access.

Given these concerns, coupled with the growing amount and scope of industry involvement in medical research, education and clinical practice, the Medicare Payment Advisory Commission and the Institute of Medicine recommended in 2009 that Congress enact a new regulatory program to address transparency in physician-industry relationships. Sen. Charles Grassley, R-Iowa, and former Sen. Herb Kohl, D-Wisc., proposed the bipartisan Physician Payment Sunshine Act (Sunshine Act), which was eventually enacted as Section 6002 of the Affordable Care Act.

The Sunshine Act — which is now referred to by the Centers for Medicare and Medicaid Services as "Open Payments" — requires "applicable manufacturers" of drugs, devices, biologicals or medical supplies covered under Medicare, Medicaid or CHIP to report annually to CMS, in an electronic format, certain payments or other transfers of value to "covered recipients" — physicians and teaching hospitals. These include payments for meals, travel, research, consulting, honoraria, training or education, grants, textbooks, journal reprints and other related items. Payments to prospective employee physicians (eg, recruiting costs), including travel, lodging and meals, are also reportable. For each separate payment (eg, meal, travel, grant), manufacturers are required to report a separate line item.

Certain payments related to industry support for accredited continuing medical education are excluded from reporting, as well as product samples intended for patients; 90-day medical device loans; discounts and rebates; certain indirect payments; and educational materials, such as anatomical or wall models, to be used with patients.

Data collection and reporting began on Aug. 1, 2013, and applicable manufacturers have already begun reporting to CMS payment data from this date through Dec. 31, 2013. CMS expects to publish the data for this period in a searchable format on Open Payments, CMS's official public website, by Sept. 30.

Who is a physician?
The final rule defines "physician" as doctors of medicine and osteopathy, dentists, dental surgeons, podiatrists, optometrists and licensed chiropractors. It includes all physicians who have an active or current state license, regardless of whether they are enrolled with CMS, living in the U.S. or currently seeing patients. Payments or transfers of value made to physician fellows are also reportable. Medical residents, however, are excluded from reporting, as are bona fide physician employees of applicable manufacturers.

Unless a physician plans to terminate all financial relationships with industry, there is no creative way to evade having data reported. For example, physicians cannot establish a third-party entity to contract with manufacturers and have the manufacturer report the name of the third party, rather than the physician. Additionally, physicians cannot avoid having payments or other transfers of value attributed to them or publicly reported by having such payments donated to charities or other entities. Such payments are deemed "indirect payments" attributable to the physician making the request. For example, if a physician provides consulting services to a manufacturer but requests that his payment for the services be made to a charity, this would not be a charitable contribution for the manufacturer, but rather a "directed consulting fee." The manufacturer must report the payment to the physician for the consulting services and list the charity as the "entity paid."

What information will be reported?
While the law requires specific categories of payment information to be reported, and CMS has issued draft templates of what manufacturers must submit, it is still unclear exactly what the Open Payments website will look like. Nevertheless, we anticipate that, at a minimum, the following information will be made public:

- The name of the manufacturer that provided the payment or transfer of value;
- The name and business address of the physician or teaching hospital;
- Specialty and potentially state professional license number of the physician;
- The date, amount and form of payment (eg, cash, stock);
- The nature of payment (eg, meals, travel, education, honoraria);
- The name of a drug or device if the payment was related to education, research or marketing; and
- Brief contextual information (optional for the manufacturer)

Manufacturers also must report a physician's national provider identifier number, but this information will not be made public. The database, by law, must be searchable; therefore, patients and other interested individuals, such as other physicians, family members, the IRS, the OIG or the FBI, as well as the media, will be able to see payments attributed to physicians from multiple manufacturers.

What should physicians do to prepare?
First, because manufacturers will be using physician information from the National Plan and Provider Enumeration System, physicians should update this information to ensure that their name, address and specialty are correct. This can be done at https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do.

Second, CMS recommends that when the registration portal is available, physicians should register with Open Payments to keep informed about the program. CMS has not yet formally announced that registration is available for physicians or teaching hospitals, but registration is expected to be available shortly. CMS also has provided a number of resources dedicated to physicians, as well as a number of frequently asked questions for stakeholders. The AMA has also provided resources for physicians about the Sunshine Act.

Once CMS launches the physician and teaching hospital registration, the agency will electronically notify registered physicians and teaching hospitals when a manufacturer has attributed a payment to them. Through this notification, a physician or teaching hospital may initiate a "dispute" as to the amount or nature of payment or other potential mistakes or discrepancies. However, physicians have only 45 days to initiate the dispute after receiving notification, and any dispute must be resolved no later than 60 days after the physician receives notification.

Third, physicians employed or affiliated with a hospital, academic medical center or other institution should check with their appropriate department chair or administrator regarding internal policies and procedures for engaging in relationships with industry before entering into any such agreement. Many teaching hospitals already have internal policies and procedures in place governing physician-industry relationships, and these policies may limit the types of interactions physicians may have with manufacturers. Physicians also should check with any medical societies, professional medical associations, government panels, clinical guidelines committees, and pharmacy and therapeutics committees with which they are affiliated for similar policies.

Fourth, physicians should ensure that any relationship with a manufacturer, such as a consulting agreement, clinical trial investigator agreement or participation on an advisory board, does not risk violating federal or state fraud and abuse laws. Ideally, any such agreement would meet the personal services safe harbor of the federal Anti-Kickback Statute, which includes the following seven criteria: there is a signed, written agreement; the agreement covers all of the services to be performed; the services to be performed are itemized in a performance schedule; the agreement contains at least a 1-year term; the aggregate compensation to be paid for the services is set in advance, is not based on volume or value of business or referrals, and is "consistent with fair market value;" the services to be performed do not involve counseling or promotion of an unlawful activity; and the services do not exceed those reasonably necessary to accomplish the reasonable business purposes of the service.

Finally, physicians should begin thinking about how to discuss such relationships with patients, as well as communication plans for any local media outlets.

As physicians and industry move into a new era of transparency, physicians and teaching hospitals should continue to collaborate with manufacturers to develop new therapies and lifesaving products, as well as educate patients and their peers. While transparency of these relationships may raise concerns for some, physicians should clarify and emphasize to their patients and other stakeholders the important role these relationships have in advancing medicine and the potential benefits for patient care.

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