

February 7, 2012

Marilyn Tavenner
Acting Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-5060-P

Dear Ms. Tavenner:

The Medicare Payment Advisory Commission welcomes the opportunity to comment on the Center for Medicare & Medicaid Services (CMS) proposed rule entitled Medicare, Medicaid, Children's Health Insurance Programs; Transparency reports and reporting of physician ownership or investment interests; notice, published in the *Federal Register*, vol. 76, no. 243, pages 78742 to 78773. We appreciate your staff's efforts to establish a system for manufacturers to publicly report their payments to physicians and teaching hospitals, particularly considering the agency's competing demands.

This proposed rule would implement Section 6002 of the Patient Protection and Affordable Care Act of 2010 (PPACA), which requires manufacturers of drugs, devices, biologicals, or medical supplies to annually report to the Secretary certain payments or transfers of value provided to covered recipients, or to an entity or individual at the request of or designated on behalf of a covered recipient. The statute defines a covered recipient as a physician or teaching hospital. In addition, PPACA requires manufacturers and group purchasing organizations (GPOs) to report on physician ownership or investment interests. The Secretary is directed to publish the information submitted by manufacturers and GPOs on a public website.

The Commission strongly supports the requirement that manufacturers report data on their financial relationships with physicians and other health care entities to the Secretary, who would post this information on a public, searchable website.¹ Manufacturers have extensive financial relationships with physicians, hospitals, professional organizations, and other health care entities.

¹ Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC.

These financial ties have led to many advances in medical research, technology, and patient care. However, they may also create conflicts between the commercial interests of manufacturers and physicians' obligation to do what is best for their patients. The line between appropriate and inappropriate interactions may not always be clear, but there is no doubt that those relationships should be transparent. Our support for greater transparency does not imply that all—or even most—of these financial ties are inappropriate or undermine physician–patient relationships.

Requiring manufacturers to publicly report their financial relationships with physicians and other health care organizations would help Medicare, other payers, and the general public better understand how these ties affect physicians' practice patterns and health care costs. Public reporting could also discourage physicians from accepting gifts or payments that violate professional guidelines. Further, it would help hospitals, patients, and researchers identify potential conflicts of interest. Although several manufacturers have begun to voluntarily disclose certain payments to physicians, such as consulting and speakers' fees, the amount of information disclosed and the accessibility of the data vary by company. Therefore, there is a need for a mandatory public reporting system that applies to all manufacturers, clearly defines the data that companies must report, and allows the general public to easily search and download information.

Our comments on this proposed rule address the following issues:

- expanding the types of recipients included in the reporting requirement,
- reporting indirect payments or other transfers of value,
- defining the form and nature of payments or transfers of value,
- making National Provider Identifiers available to researchers, and
- delaying publication of payments made pursuant to product research or development agreements and clinical investigations.

Expanding the types of recipients included in the reporting requirement

Although the public reporting requirement in PPACA was limited to payments or transfers of value made to physicians and teaching hospitals (as well physician ownership or investment interests in GPOs and manufacturers), the Commission recommended that manufacturers be required to report their financial relationships with a broad range of individuals and entities that may receive industry payments:

- physicians, physician groups, and other practitioners (such as nurse practitioners);
- pharmacies and pharmacists;
- health plans, pharmacy benefit managers, and their employees;
- hospitals and medical schools;
- organizations that provide continuing medical education;
- patient organizations; and
- professional organizations.²

² Medicare Payment Advisory Commission. 2009.

We recognize that CMS does not currently have the statutory authority to include all of the individuals and organizations recommended by the Commission, but we encourage CMS to seek the authority to do so. Expanding the scope of recipients that are subject to public reporting will enhance the public's understanding of manufacturers' financial ties with individuals and entities that deliver health care services, discover and develop new treatments, and educate patients and practitioners.

Reporting indirect payments or other transfers of value

The reporting requirement in the statute includes two types of payments or other transfers of value from manufacturers to covered recipients (physicians and teaching hospitals):

- Direct payments, in which the manufacturer gives the payment or transfer of value directly to a covered recipient; and
- Indirect payments, in which the manufacturer gives the payment or transfer of value to an individual or entity at the request of or designated on behalf of a covered recipient.

An example of an indirect payment would be a payment to a physician group that is designated for an individual physician in the group. In this case, CMS proposes that the manufacturer would report both the name of the individual physician and the physician group. CMS believes that this approach will maximize transparency by allowing users to determine the flow of indirect payments. We support this proposal because it will help the public understand the role of organizations that transfer money from manufacturers to physicians or use money from manufacturers to provide services and activities to physicians (such as companies that provide medical education programs).

The statute does not require manufacturers to report indirect payments or other transfers of value when the manufacturer is unaware of the identity of the covered recipient who ultimately receives the payment. CMS proposes that a manufacturer is considered to be aware of the identity of a covered recipient if the manufacturer has knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient. For example, if a manufacturer provides a payment through a third party to physicians who are department chairs at a hospital, this payment would need to be reported if the identities of the department chairs are publicly available. We support this approach because it will increase the transparency of payments.

However, even if manufacturers are aware of the identities of covered recipients who receive indirect payments, they may not have information on how much money each covered recipient receives from the third party. For example, if a manufacturer provides a grant to a company to run a medical education program, the manufacturer may not be aware of the compensation paid to each physician who speaks at the program. CMS should clarify how manufacturers should report specific payment amounts for covered recipients in these cases. One option would be to create a separate category for indirect payments in which manufacturers are aware of the identities of the covered recipients but unaware of the specific amounts received by each covered recipient.

Defining the form and nature of payments or transfers of value

CMS proposes rules for defining the form and nature of payments or transfers of value to physicians and teaching hospitals. The form of a payment indicates whether it is cash, in-kind items or services, or stock. The nature of a payment indicates its purpose. The statute lists the following categories for the nature of a payment:

- consulting fees
- compensation for services other than consulting
- honoraria
- gifts
- entertainment
- food
- travel
- education
- research
- charitable contribution
- royalty or license
- current or prospective ownership or investment interest
- direct compensation for serving as faculty or as a speaker for a medical education program
- grant
- any other payment or transfer of value (as defined by the Secretary).

We agree with CMS's proposal that the categories for the form of payment and nature of payment should be defined as distinct from one another; overlap among categories would make the information less useful. If a physician receives meals and travel (e.g., transportation and lodging) in connection with a consulting fee, CMS proposes that each item be reported separately in its appropriate category (i.e., the manufacturer would report three separate line items for the meals, travel, and consulting fee). We agree with this proposal because it should encourage consistent reporting by manufacturers and make it easier for users of the information to distinguish among payments for different purposes.

With regards to research payments, CMS proposes that manufacturers should classify research payments to physicians based on whether the payment went indirectly or directly to the physician. CMS proposes to define an indirect research payment as a payment that is made to a clinic, hospital, or other institution conducting the research, when that organization pays a physician serving as the principal investigator. By contrast, CMS proposes to define a direct research payment as a payment that is made directly to a physician rather than through an intermediary. CMS proposes that indirect research payments be reported under the name of the physician who serves as the principal investigator. The rationale for separating indirect from direct research payments is that an indirect research payment probably covers multiple items and activities besides the physician's time and services, whereas a direct research payment is directly

related to the physician's time and services. For this reason, we agree with the proposal to require separate reporting of indirect and direct research payments.

CMS proposes to limit the research category to bona fide research activities that include both a written agreement between the manufacturer and researcher and a research protocol. CMS recognizes that this definition may exclude other research-related activities, such as post-marketing studies that have neither a written agreement nor a protocol, and asks for comment on whether to (a) expand the research category to include these additional activities or (b) create a new category. We believe it is very important to collect data on all research-related payments, whether or not the research activities have a written agreement and protocol, because some industry-sponsored research appears to serve promotional, rather than scientific, purposes. For example, the Office of Inspector General (OIG) alleged that a device company paid several physicians \$5,000 each to test five patients with a new spinal cord stimulation product.³ According to the OIG, this research activity did not provide clinical or scientific value but was instead used as a marketing tool to increase sales. We do not have a view as to whether CMS should expand the research category to include these activities or create a new category for such activities.

Another important payment category is direct compensation for serving as faculty or as a speaker for a medical education program. CMS proposes to broaden this category to include all payments to physicians to serve as speakers, whether or not the forum is a medical education program. We agree with this proposal because physicians who serve on speakers' bureaus may give talks at events that are not considered medical education programs. According to a survey of physicians, about 9 percent of physicians received payments for speaking from drug and device manufacturers in 2009.⁴ If CMS expands this category, it could consider eliminating the category of payments for honoraria, which is currently an independent category. If CMS does not eliminate the honoraria category, it should clarify how honoraria differ from other types of industry payments.

The Commission supports allowing manufacturers to report additional clarifying details about the context for a payment (e.g., to explain that a payment was related to training other physicians in the proper use of an implantable device).⁵ Therefore, CMS should allow manufacturers to voluntarily submit such information along with the mandated data on payments, and CMS should post this information on the public website. These additional details may help the public further understand the purpose of specific payments.

³ Demske, G. E., Office of Counsel to the Inspector General. 2008. Examining the relationship between the medical device industry and physicians. Oral testimony before the Special Committee on Aging, U.S. Senate. 110th Cong., 2nd sess. February 27.

⁴ Campbell, E.G., S.R. Rao, C.M. DesRoches, et al. 2010. Physician professionalism and changes in physician-industry relationships from 2004 to 2009. *Archives of Internal Medicine* 170, no. 20 (November 8): 1820–1826.

⁵ Medicare Payment Advisory Commission. 2009.

Making National Provider Identifiers available to researchers

The statute requires manufacturers to report the National Provider Identifier (NPI) of physicians who receive payments, but prohibits CMS from including physicians' NPIs on the public website that will contain other information submitted by manufacturers and GPOs. It is important to collect NPIs, which function as Medicare billing numbers, because it would permit researchers to link Medicare claims data to information on physicians' financial relationships with drug and device companies. Researchers could use a linked database to examine whether gifts, meals, consulting fees, and other payments influence the type and amount of drugs physicians prescribe and the type and volume of surgical procedures they perform. Therefore, CMS should provide NPIs to researchers through a data use agreement process. If CMS does not allow researchers to access the NPIs of physicians who receive industry payments, it will be very difficult for them to match Medicare claims to data on industry payments. We note that the statute does not prohibit CMS from sharing the NPIs with researchers who sign a data use agreement.

Delaying publication of payments made pursuant to product research or development agreements and clinical investigations

The statute provides for delayed publication of payments or other transfers of value that are related to product research or development agreements or clinical investigations. The purpose of delaying publication is to maintain the confidentiality of information related to the development of new drugs, devices, biologicals, and medical supplies. The term "product research or development agreement" is not defined in the statute. Therefore, CMS proposes to define such an agreement as one that includes a written statement or a contract between the manufacturer and recipient and a written research protocol. This definition is fairly broad and could include research to identify new potential targets for therapies and preclinical drug testing. By contrast, the statute specifically defines a "clinical investigation" as an experiment involving one or more human subjects in which a drug or device is administered. The statute requires that information subject to delayed publication be posted on the public website after the earlier of (1) the approval by the Food and Drug Administration (FDA) of the product or (2) four calendar years after the date of payment. For example, if a manufacturer provides a research grant to a teaching hospital for a clinical trial of a new drug in December 2012, this payment would be reported to CMS in 2013 but would not be published on the public website until after FDA approval or in 2017, whichever comes first (2017 is at least four years after the payment was made).

CMS proposes to allow delayed publication of payments pursuant to research or development agreements or clinical investigations that are related to a new product. However, based on its interpretation of the statutory language, CMS proposes to treat research or development agreements differently than clinical investigations with regards to research on new applications of an *existing product*. CMS would allow delayed publication of payments pursuant to *research or development agreements* that are related to a new application of an existing product, but would not allow delayed publication of payments for *clinical investigations* that are related to a new application of an existing product.

The Commission recommended that manufacturers be allowed to delay the public reporting of payments related to the development of *new products* (such as a payment for a clinical trial related to a new drug), but did not recommend extending delayed publication to payments related to research on new applications of *existing products*.⁶ Allowing delayed publication of payments for research on new applications of existing products could enable manufacturers to shield a significant number of payments from public view for up to four years. Therefore, we support CMS's proposal to not allow delayed publication of payments for clinical investigations that are related to a new application of an existing product, and we urge CMS to apply the same rule to payments related to research or development agreements.

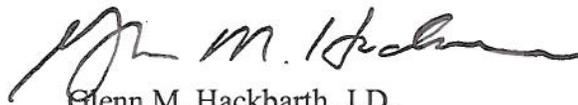
Although the statute provides for the confidentiality of specific information on payments that are subject to delayed reporting, CMS should examine whether the statute would allow it to publish the aggregate amount of these payments across all recipients and manufacturers. If so, we encourage CMS to annually publish the aggregate amount of payments that are subject to delayed public reporting to inform the public about the scope of manufacturers' payments to physicians and teaching hospitals for research and development on new products. This information could also help policymakers assess whether the rules for delayed publication should be adjusted (e.g., whether the timeframe for delayed publication should be reduced from four years to two years). CMS could publish the aggregate amount in the annual report that it is required by statute to submit to the Congress.

Conclusion

The Commission appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. We also value the ongoing cooperation and collaboration between CMS and Commission staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, the Commission's Executive Director.

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

GMH/aw/w

⁶ Medicare Payment Advisory Commission. 2009.