



# National Physician Payment Transparency Program: Open Payment

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## Summary

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### Background

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) released the [final regulation](#) titled “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests.” More commonly referred to as the “Sunshine Act” and now rebranded as the “National Physician Payment Transparency Program: Open Payments,” this final regulation implements Section 6002 of the *Affordable Care Act* which is designed to make information publicly available about payments or other transfers of value from certain manufacturers of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP), defined as applicable manufacturers, to physicians and teaching hospitals, which are defined as covered recipients.

The law specifies that applicable manufacturers must annually report all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) from applicable manufacturers to covered recipients. In addition to reporting on payments, applicable manufacturers also must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities.

### AAFP’s Previous Advocacy Efforts

The [proposed](#) version of this regulation was released on December 14, 2011 and the AAFP reacted in a [letter](#) sent to CMS on February 8, 2012. In this response, the AAFP urged CMS to:

- Exclude all certified and accredited continuing medical education (CME) activities from reporting;
- Specify that only direct transfers of value to physicians are reportable events;
- Establish a uniform, national, and mandatory data verification and arbitration process and work with physician organizations to strengthen the review process;
- Cite that reporting requirements only apply to physicians that personally decide to accept transfers of value from applicable entities; and
- Exclude approved clinical research that was subject to “human subjects IRB review” from these reporting requirements since most clinical research already requires that financial ties to manufacturers be disclosed.

The AAFP also participated with 49 other national physician organizations as well as 43 state medical societies in a [coalition letter](#) coordinated by the AMA. The AAFP also signed onto a separate [coalition letter](#) coordinated by the Council of Medical Specialty Societies with 33 other organizations that focuses on the proposed rule’s impact on Continuing Medical Education.

### Timing

In the final rule, CMS essentially provides applicable manufacturers with 6 months to prepare. Applicable manufacturers must begin collecting data on August 1, 2013 and then submit the data gathered through the end of 2013 to CMS no later than March 31, 2014. CMS is developing an electronic system to facilitate the reporting process. The law requires CMS to provide applicable manufacturers and physicians at least 45 days to review, dispute, and correct reported information before posting on a publicly available website. CMS will notify the covered recipients when the reported information is ready for review. CMS will then release the data on a public website by Sept. 30, 2014 and on June 30 every year thereafter.

## **Covered recipients**

The law requires applicable manufacturers to disclose certain payments or other transfers of value made to covered recipients, or to entities or individuals at the request of, or designated on behalf of, a covered recipient. "Physician" is defined as a doctor of medicine or osteopathy, dentist, podiatrist, optometrist, or chiropractor, who is legally authorized to practice by the state in which he or she practices.

Some commenters suggested that CMS expand the covered recipients to include other entities with prescribing privileges or asked whether residents would be considered physicians. Other commenters requested that the definition exclude physicians who are not actively engaged in the practice of medicine, which might include medical researchers.

In the final rule, CMS did not expand the definition to include other provider types. The agency recognized that, as a result, CMS will not be able to fully capture financial relationships between the industry and all prescribers, specifically non-physician prescribers such as nurse practitioners. However, CMS points out that to the extent that applicable manufacturers make payments or other transfers of value to non-physician prescribers to be passed through to a physician, they would be indirect payments to the physician and would have to be reported under the name of the physician.

Payments or other transfers of value to residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic) will not be required to be reported.

## **Reported information**

Applicable manufacturers must report information on the covered recipient's name, business address, National Provider Identifier (NPI), specialty (as identified by the National Plan & Provider Enumeration System), date of payment, context, and name of the covered drug, device, biological, or medical supply associated with that payment.

The "form of payment" categories are cash or a cash equivalent, in-kind items or services, stock options, any other ownership interest, dividend, profit, or other return on investment, any other form of payment or other transfer of value.

The "nature of payment" categories in the final rule are consulting fees, compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program, honoraria, gift, entertainment, food and beverage, travel and lodging (including the specified destinations), education, research (defined based on the Public Health Service Act 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."), charitable contribution, royalty or license, current or prospective ownership or investment interest, compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program, compensation for serving as faculty or as a speaker for an accredited or certified continuing education program, grant and space rental or facility fees.

## **Continuing Medical Education**

In the final rule, CMS stated that they "understand the importance of continuing medical education" and that reporting requirements "should not include compensation for accredited or certified continuing education payments." The regulation discussed that, "Accredited and certified continuing education that complies with applicable standards of the accrediting and certifying entities generally includes safeguards designed to reduce industry influence" and that CMS believes that "reportable payments or transfers of value made to support accredited and certified continuing medical education should remain in a distinct category from unaccredited or non-certified continuing education."

The final rule discusses how CMS received numerous comments that urged CMS to exempt from reporting indirect payments or other transfers of value for education. CMS responded and agreed that “industry support for accredited or certified continuing education is a unique relationship” and that “industry standards for commercial support, create important and necessary safeguards prohibiting the involvement of the sponsor in the educational content.”

However, CMS believes that even with this separation, the sponsor could still influence the selection of faculty by offering suggestions to the accredited or certified continuing education provider. Although the continuing education provider may not be required to follow these suggestions, CMS believes that it may often be impossible to distinguish when a suggestion is influential and when it is not. Therefore, CMS finalized policy that an indirect payment made to a speaker at a continuing education program is not an indirect payment or other transfer of value for the purposes of this rule and, therefore, does not need to be reported, when all of the following conditions are met:

- The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:
  - The Accreditation Council for Continuing Medical Education (ACCME)
  - The American Academy of Family Physicians.
  - The American Dental Association’s Continuing Education Recognition Program.
  - The American Medical Association
  - The American Osteopathic Association.
- The applicable manufacturer does not pay the covered recipient speaker directly.
- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

If the payment or transfer of value does not meet all of these requirements, then it must be reported. CMS provided the following related examples.

- If the payment is for an accredited education program, but the manufacturer pays the speaker directly or provides a list of speakers, or both, the payment must be reported in the category “Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.”
- Payments or other transfers of value that do not meet the accreditation requirements and standards for CME should be reported under the nature of payment category “Compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program.”
- Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category “Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program.”

Conversely, when the sponsor does not suggest speakers, they are allowing the continuing education provider full discretion over the CME programming, so the payment or other transfer of value will not be considered an indirect payment for purposes of these reporting requirements.

### **Payments or Other Transfers of Value of Less than \$10**

Small payments or other transfers of value, which the statute defines as payments or other transfers of value less than \$10, do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds \$100. For subsequent calendar years, the dollar amounts specified will be increased by the same percentage as the percentage increase in the consumer price index (CPI).

Regarding reporting of payment or other transfers of value at conferences or similar events, in the final rule CMS discusses that:

*...at events open to the public, it will be extremely difficult for applicable manufacturer to identify physician covered recipients. Therefore, we will finalize that small incidental items that are under \$10 (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events will be exempted from the reporting requirements, including the need to track them for aggregation purposes. While these small payments are excluded by statute, the \$100 aggregate payment requirement generally requires the tracking of small payments in order to determine whether covered recipients received more than \$100 annually. For these covered recipients, we believe it would be difficult for applicable manufacturers to track who receives these small items at conferences or similar events, due to the nature and disparate attendance at large-scale conferences or similar events. Additionally, this method is consistent with our decision to not require reporting of food and beverage at large-scale conferences.*

However CMS still requires that payment or other transfers of value of \$10 or more (for CY 2013) need to be tracked and reported even when provided at large-scale conferences or similar events.

In the final rule, CMS states that the agency:

*...will not provide a standard template for reporting by entities that organize and oversee events and conferences. These event and conference vendors are not applicable manufacturers, so we do not believe we should have any contact with them or impose requirements on them. We recognize that applicable manufacturers and their vendors will need to devise business practices to meet the requirements; however, we believe that many of the interactions at large-scale conferences and similar events will not be reportable, so we do not believe this will be excessively burdensome.*