



The National Physician Payment Transparency Program (Sunshine Rule): What You Need to Know

Introduction

Starting August 1, 2013, applicable industries began collecting information about covered “transfers of value” made to physicians and teaching hospitals, which are provided to the Centers for Medicare and Medicaid Services (CMS) for publication on a public website.

Doctors Don’t Report - Industry Does: The National Physician Payment Transparency Program (aka Open Payments (OP)) requires *reporting by applicable manufacturers of drugs, devices, biologics, or medical supplies and group purchasing organizations (GPOs-- organizations that join together to receive discount prices from industry and then sell the purchased products to other entities for a profit)* of payments, ownership and investment interests, and other transfers of value from industry to physicians and teaching hospitals (the “covered recipients”). Industry is required to report covered transfers of value for all licensed physicians (except residents); not just those participating in Medicare, Medicaid or SCHIP.

Reporting Doesn’t Make Something Ethical: Continue to Evaluate Relationships: Many collaborations with industry advance patient care, but relationships with industry can also introduce conflicts of interest that influence prescribing, research, education and utilization. The OP program of CMS does not comment on which relationships are appropriate or not; instead, it facilitates disclosure and transparency. Disclosure does not itself make a behavior ethical, nor is the case that something that is not reportable mean it is ethical. For example, residents are not included in the definition of physician under this regulation, so transfers of value to them are not reportable—but ACP ethics guidelines about relationships with industry apply to residents. Open Payments calls for reporting of “entertainment,” but ACP and industry’s own code on interactions with health care professionals prohibit the provision of entertainment by industry.

Know What Is Reportable: Physicians who have investment interests or relationships with industry should know the kinds of information that will be reported about them to avoid surprises. ACP has guidance [here](#). A free CME activity with CMS faculty, “Are You Ready for the National Physician Payment Transparency Program?” is available on Medscape Education at <http://www.medscape.org/viewarticle/780900> (free Medscape registration may be required).

Wear a Hat in the Sun: ACP has long advocated for transparency and openness in physician-industry relations. Disclosure is an ethical responsibility. But under Open Payments, others—applicable manufacturers and group purchasing organizations—do the actual reporting. Doctors with relationships will want to protect their interests and independently track investments, payments and other transfers of value by checking

industry reports for accuracy. So, let the sun shine—and wear a hat.

In general: *If transfers of value can be identified as having gone to individual physicians, the manufacturer or GPO is required to report (with some exceptions). So in addition to considering the ethics of any given situation, pause before accepting a gift, or registering for a program, or participating/swiping an ID card at a meeting activity—Determine if there is a transfer of value, who is behind it, and if it will entail reporting.*

For the Who, What and When of Reporting:

See the ACP summary of the Rule at

https://www.acponline.org/acp_policy/policies/brief_summary_of_the_national_physician_payment_transparency_act_final_rule_2013.pdf

What Is and Is Not Reportable:

What's Not Reportable:

- Transfers of value of less than \$10, unless total aggregate > \$100
 - Transfers of value under \$10 provided at large scale conferences and similar large scale events are not reportable and are also excluded from aggregate tracking
- Product samples
- Educational materials that directly benefit patients
- Loan of a covered device, not to exceed 90 days
- Items or services provided under contractual warranty
- Discounts (including rebates)
- In-kind items used for charity care
- Dividends or other profit distributions from, or ownership or investment interests in, a publicly traded security or mutual fund
- Payments for employees in self-insured plan
- Transfers of value to non-physicians

Continuing Medical Education

CME activities (e.g. speaker payments, tuition fees) subsidized by industry are not reportable so long as the commercial supporter “does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment to a covered recipient.” Thus, CME activities indirectly supported by an unrestricted grant would not be reportable.

- Food and Beverages
 - The value of food and beverages is reportable based on the per person cost for

physicians who participated with the exception of “buffet meals, snacks, soft drinks or coffee made generally available to all participants of a large-scale conference or similar large-scale events.

Small Gifts

- Payments or other transfers of value less than \$10 are not reportable, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds \$100—so manufacturers will be tracking even small gifts. Incidental items (e.g. pens or notepads) that are under \$10 that are provided at large scale conferences and similar large scale events are excluded from aggregate tracking and reporting. ACP policy discourages the acceptance of gifts, even small gifts, because they can affect clinical judgment and heighten the perception and/or reality of a conflict of interest.

Raffle Prizes

- Unless excluded under the small gifts or another exception, prizes would be reportable.

Ownership or Investment Interests of Physicians and their Immediate Family Members

- Ownership and investment interests and payments or transfers of value such as stocks, stock options, or any other ownership interest, dividend, profit, or other return on investment held by physicians and their immediate family members (spouse; parent, child, sibling (including step); in-laws; grandparents and grandchildren and their spouses) must be reported except for dividends or other profit distributions from, or ownership or investment interest in, a publicly traded security or mutual fund. The family member’s name will not be reported.

Charitable Contributions

- Charitable contributions are reported when an applicable manufacturer makes a payment or other transfer of value to a charity on behalf of a physician and not in exchange for any service or benefit. If a physician provides consulting services to an applicable manufacturer and requests that payment for the services be made to a charity, this would be reported as a directed consulting fee.

Research

- Research will be reported separately (in a different template) and will include information about each physician principal investigator whether payment is received directly from the manufacturer or not. The individual or entity receiving the payment will be reported as well, even if not a covered recipient.
- Research is defined 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.”

- The regulation allows for delays in publication of payments/transfers of value for designated research related to the development of a new product or application to protect confidential proprietary activities.
- A payments falls within a research payment category if it is subject to either: 1) a written agreement; 2) a contract; or 3) a research protocol. Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment.

Educational Materials

- The education material exclusion applies only to materials and items directly benefiting patients or intended for patient use such as anatomical models. Medical textbooks or journal reprints are not excluded and are therefore reportable. The value of a journal reprint “should reflect the cost that an applicable manufacturer or applicable group purchasing organization paid to acquire the reprint from the publisher or other distributor.”

Indirect Payments and Payments to Third Parties

- Reporting is required of both direct and indirect payments and other transfers of value provided by an applicable manufacturer or applicable group purchasing organization to a covered recipient.
- An indirect payment is a payment or transfer of value made by an applicable manufacturer, or an applicable group purchasing organization, to a covered recipient, or a physician owner or investor, through a third party, where the applicable manufacturer, or applicable group purchasing organization, 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. Information on the covered recipient is reportable; the third party is not.
- Funds to a medical professional society earmarked for awards or grants for physicians would be indirect payments subject to reporting. An unrestricted donation for the society to use at its discretion would not be an indirect payment.
- If a covered recipient requests a payment be made to a third party, both the covered recipient and the third party are reportable.

Date of Payment

The date of payment is when the transfer of value is made.

State Laws and Other Reporting

The federal law preempts state laws requiring disclosures of the same information, but states may continue to require submission of information if they seek different

information. States with regulations are California, Colorado, Connecticut, Maine, Massachusetts, Minnesota, Nevada, Vermont, West Virginia plus the District of Columbia. A number of pharmaceutical companies must publish payments to physicians on their websites under Corporate Integrity Agreements (requirements imposed by a civil legal settlement) and some others report voluntarily.

Open Payment Reporting and Publication Schedule

- Data Collection (Calendar Year)
- Registration (1st Quarter following year)
- Data Submitted by Manufacturers and GPOs (by March 31)
- Data Review and Dispute Period (April- June)
- Correction Period (April- June)
- Publication of Information on CMS Website (June 30)

What Should Physicians Do Now?

Manufacturers and group purchasing organizations will be doing reporting, not physicians. Physicians with relationships with industry will want to protect their interests and know the extent of their relationships by doing their own independent tracking of investments, payments and other transfers of value to then check against company reports for accuracy. Having records would also be useful in case of a dispute.

Physicians will receive a general notification when the reported information is ready for review if they have registered with CMS at <http://go.cms.gov/openpayments>. The College strongly recommends that its members register and review the data reported to CMS by industry. Registration is voluntary and should be open in early 2014; more info is to come from CMS. Additionally, CMS will post online and provide notifications through its listserve.

For more information:

ACP Sunshine Rule Materials

<https://www.acponline.org/practice-resources/regulatory-resources/regulatory-compliance/physician-payment-sunshine-rule>

ACP Ethics Policy on Physician-Industry Relations

<https://www.acponline.org/clinical-information/ethics-and-professionalism/ethics-issues-and-position-papers/physician-industry-relations>

Free CME offering from Medscape with CMS faculty: Are You Ready for the National Physician Payment Transparency Program?

<http://www.medscape.org/viewarticle/780900>

Open Payments Program Website
<http://go.cms.gov/openpayments>

The information provided herein is educational; it does not constitute legal advice.