

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:

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- 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

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

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.

develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This term encompasses basic

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

applicable manufacturer or applicable group purchasing organization paid to

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 Informati

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

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