

CHAPTER

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**Payments from drug and  
device manufacturers to  
physicians and teaching  
hospitals in 2015**

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# Payments from drug and device manufacturers to physicians and teaching hospitals in 2015

## Chapter summary

Under the Open Payments program, drug and device manufacturers and group purchasing organizations (GPOs) report information to CMS about payments to physicians and teaching hospitals. Payments to each type of provider are reported separately. This program has shed significant light on industry ties to these providers that were previously obscured.

The Open Payments database contains information on financial interactions worth about \$7.3 billion in 2015. Payments for research accounted for just over half of the total; general payments (e.g., royalties and speaking fees) accounted for 35 percent; and physician ownership or investment interests accounted for 11 percent. The data include payments from 1,455 companies to about 618,000 physicians and 1,111 teaching hospitals. Physicians accounted for just over 80 percent of the payments and other transfers of value (about \$6.0 billion); teaching hospitals accounted for almost 20 percent (about \$1.3 billion). The category of physicians included about 502,000 medical doctors and osteopaths and almost 116,000 dentists, optometrists, podiatrists, and chiropractors.

The distribution of general payments to physicians was highly skewed. The top 5 percent of physicians accounted for 86 percent of the dollars; each of these physicians received about \$56,000 in payments, on average. Likewise, the distribution of general payments to teaching hospitals was highly concentrated: 51 percent of the value of these payments (\$307 million)

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went to a single hospital (City of Hope National Medical Center), and almost all of the payments to this hospital were royalty or license payments from a single manufacturer.

Royalty or license payments to physicians (payments for the right to use patents, copyrights, and other intellectual property) totaled \$527 million—the highest share of general payments to physicians in 2015 (26 percent). Royalty or license payments also had the highest average amount per physician: about \$233,000 (median of \$32,363). A comparatively small number of physicians—about 2,300—received one of these payments. Compensation for services other than consulting (e.g., promotional speaking fees) amounted to \$509 million (25 percent of general payments to physicians) and went to about 31,000 physicians. The data reveal the prevalence of industry-provided meals to physicians (about 589,000 physicians received food and beverage), even though food and beverage accounted for only 12 percent of the total value of general payments to physicians.

The physician specialty with the highest amount of general payments was internal medicine, which accounted for \$420 million (21 percent of the value of general payments received by physicians). Orthopedic surgery accounted for \$410 million, or 21 percent of the value of general payments to physicians. The average payment received by orthopedic surgeons was relatively high: \$19,257, with a median of \$418. The large difference between the mean and median values indicates that the distribution is skewed toward physicians who received high payments. Royalty or license payments accounted for 71 percent of payments to orthopedic surgeons (\$293 million), which indicates the close collaboration between orthopedic surgeons and manufacturers in product development.

We also examined the distribution of payments by the type of company that made the payment. Device manufacturers accounted for 48 percent of general payments to physicians, and drug manufacturers accounted for 46 percent. Device manufacturers accounted for the majority (84 percent) of the value of physician ownership or investment interests, while drug manufacturers accounted for only 8 percent.

Although the Open Payments program has increased the transparency of financial interactions between manufacturers and physicians and teaching hospitals, it should be expanded to include additional providers and organizations that have relationships with manufacturers, consistent with the Commission's prior recommendation. In 2009, the Commission recommended that financial ties between manufacturers and a broad range of providers and other entities (e.g., physicians and other prescribers, pharmacy benefit managers, hospitals, medical schools, organizations that sponsor continuing medical education, patient

organizations, and professional organizations) should be publicly reported. We are especially concerned that manufacturers have financial relationships with many advanced practice registered nurses, physician assistants, and patient organizations, but these relationships are not reported. In addition, the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans. Finally, CMS should require companies to report whether they are a GPO or manufacturer, what type of products they make, whether they are a physician-owned distributor, and the portion of a research payment that is related to physician compensation. ■



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## Introduction

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Many physicians have financial relationships with drug and device manufacturers, including research contracts, consulting arrangements, investment interests, meals, and travel. Many of these financial ties have led to technological innovations and improved patient care. Physicians play an important role in the development of new drugs and devices by overseeing clinical trials, inventing new products, and providing expert advice to manufacturers (Campbell 2007). However, some of these relationships may also create conflicts between physicians' obligations to act in the best interest of their patients and the commercial interests of manufacturers.

Studies have shown that physicians' financial interactions with drug makers are associated with greater willingness to prescribe newer, more expensive drugs (Watkins et al. 2003, Wazana 2000). A recent article found that physicians in Massachusetts who received industry payments prescribed brand-name statins to Medicare beneficiaries at a higher rate than physicians who did not receive payments (Yeh et al. 2016). Another study found that physicians who received meals related to the promotion of specific brand-name medications had a higher rate of prescribing those medications to Medicare beneficiaries (DeJong et al. 2016). This study used data from the Open Payments program on industry-sponsored meals (described below).

Organizations that represent drug and device manufacturers, physicians, and academic medical centers have developed voluntary codes of conduct to manage interactions between manufacturers and physicians, but compliance is not systematically monitored or enforced by these organizations (see text box, pp. 184–187). In addition, many individual health systems and academic medical centers have adopted stringent rules for interactions with the drug and device industry.

Creating more transparency around physician–industry financial ties should help payers, researchers, and the general public better understand the scope and nature of these relationships and how they affect practice patterns and health care spending. Although disclosure alone does not eliminate conflicts of interest, public reporting can help the media, researchers, and regulatory agencies identify potential conflicts. For example, academic medical centers could check whether physicians who oversee research grants have financial interests in a manufacturer that could be affected by the research

findings. Disclosure could also motivate physicians to avoid conflicts of interest (Sah and Loewenstein 2014).

In 2009, the Commission and the Institute of Medicine recommended that the Congress require drug and device manufacturers to publicly report their financial relationships with a variety of health care providers and organizations (see text box, p. 188, for Commission recommendations) (Institute of Medicine 2009, Medicare Payment Advisory Commission 2009). The Congress created a public reporting system in Section 6002 of the Patient Protection and Affordable Care Act of 2010. This system—later known as Open Payments—requires manufacturers and group purchasing organizations (GPOs) to submit information to CMS about certain payments and other financial relationships with physicians and teaching hospitals (Centers for Medicare & Medicaid Services 2016a). The database includes information on fees for promotional speeches, royalties, consulting fees, research grants, and other interactions and can be searched or downloaded from a public website. CMS has collected and released data from the last five months of 2013, all of 2014, and all of 2015. For this chapter, we analyzed data from 2015. We previously described data from 2014 in online Appendix 4-A to the March 2016 report to the Congress, available at <http://www.medpac.gov> (Medicare Payment Advisory Commission 2016). In addition, several journal articles have analyzed payments from the last five months of 2013 or from 2014 (Agrawal and Brown 2016, Fleischman et al. 2016, Marshall et al. 2016, Tierney et al. 2016).

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## Open Payments program

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Under the Open Payments program, manufacturers of drugs, devices, biologics, and supplies are required to annually report to CMS information about certain payments and other transfers of value to physicians and teaching hospitals. In addition, manufacturers and GPOs are required to report ownership or investment interests that physicians or their immediate family members have in their companies. GPOs must also report payments and transfers of value to physicians who have an ownership or investment interest. GPOs are companies that purchase, arrange for, or negotiate the purchase of medical products—namely drugs, devices, biologics, and supplies—for a group of individuals or entities such as hospitals. The data reporting period for 2013 covered the last five months of the year, but the reporting period for 2014, 2015, and future years is the entire calendar year.

## Industry and provider guidelines to manage financial relationships between manufacturers and providers

Organizations that represent manufacturers (e.g., the Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association) and providers (e.g., the American Medical Association, Association of American Medical Colleges, American College of Physicians, and American Academy of Orthopaedic Surgeons) have developed voluntary guidelines for interactions between manufacturers and providers. These codes of conduct set boundaries in areas such as the provision of meals and gifts to physicians, consulting arrangements, support of medical education, and sales presentations. These guidelines are described in Table 6-1 (p. 185) and Table 6-2 (pp. 186–187). The organizations that produce these codes do not systematically monitor or enforce members' compliance with them. Instead, compliance is voluntary and self-monitored by companies. For example, PhRMA refers reports of potential breaches in conduct to individual companies for investigation. Manufacturers and providers are required to comply with the federal anti-kickback statute, which prohibits companies from making payments to induce or reward the ordering or referral of items or services reimbursed by federal health programs such as Medicare. The Office of Inspector General has issued guidance to help drug manufacturers identify practices that may lead to violations of this statute (Office of Inspector General 2003).

In addition to guidelines issued by provider associations, individual hospitals, health systems, and academic medical centers (AMCs) have adopted their own rules on physician–industry relationships. The American Medical Student Association (AMSA) and the Institute on Medicine as a Profession (IMAP) rank AMCs on the stringency of their conflict of interest policies, which has spurred the development of these guidelines. AMSA grades AMCs on the rigor of their policies, with “A” being the highest grade and “C” being the lowest. According to AMSA, medical schools have been creating

stricter policies in recent years, but the majority of schools still receive a rating of “B” (Carlat et al. 2016). Similarly, IMAP reported that several medical schools adopted more stringent policies regarding potential conflicts of interests between 2008 and 2011, but many remained in the middle (Chimonas et al. 2013). IMAP also found a positive correlation between the amount of funding received by the AMC from the National Institutes of Health and the stringency of the policy (i.e., more funding was associated with more stringent policies).

As an example, Harvard University's School of Medicine developed a policy that received an A rating from AMSA in 2014 (Harvard Medical School 2016). This policy prohibits faculty members from receiving gifts, meals, or travel from manufacturers. In addition, faculty members who participate in research on a specific company's technology may receive no more than \$25,000 annually from that company in consulting fees or other income.

Many hospitals and health systems have also imposed restrictions on physician–industry interactions. For example, Dignity Health's policy allows employees to receive gifts or meals of only minimal value (less than \$300 per year) and limits speaker's fees to less than \$1,000 per year. Dignity Health also prohibits employees from investing in a privately held company with which it conducts business (Dignity Health 2016). Kaiser Permanente has also developed a detailed conflict of interest policy for its employees. As an example, individuals who have the authority to sign contracts for Kaiser Permanente are not allowed to accept anything of value from industry representatives, while employees without this authority can accept gifts or meals only if they are worth less than \$25 each. Employees are also prohibited from accepting speaker's fees for presentations related to work conducted for Kaiser Permanente (Kaiser Permanente 2011). ■

*(continued next pages)*

Under the Open Payments program, CMS defines *physicians* as including medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. However, the statute excludes other health professionals,

such as advanced practice nurses and physician assistants, and institutional organizations other than teaching hospitals. By contrast, the Commission has recommended that the program include manufacturers' financial ties to a

## Industry and provider guidelines to manage financial relationships between manufacturers and providers (cont.)

**TABLE  
6-1**

**PhRMA and AdvaMed codes of conduct for financial relationships with physicians**

	<b>The Pharmaceutical Research and Manufacturers of America (PhRMA)</b>	<b>Advanced Medical Technology Association (AdvaMed)</b>
Consulting	<ul style="list-style-type: none"> <li>• May compensate physicians for “fair market value” and reimburse them for travel</li> <li>• Must have a contract and a legitimate need for a consultant; no trips to resorts</li> </ul>	<ul style="list-style-type: none"> <li>• Compensation must be “fair market value”</li> <li>• May pay for travel/lodging/food</li> <li>• Consulting agreements should be in writing and describe services to be provided</li> </ul>
Speakers	<ul style="list-style-type: none"> <li>• Should not use speaking engagements to reward physicians for prescribing a specific medicine/treatment regimen</li> <li>• Speakers should be trained</li> <li>• Each company should set a cap on compensation</li> </ul>	<ul style="list-style-type: none"> <li>• Same rules as for consulting</li> </ul>
Travel	<ul style="list-style-type: none"> <li>• Permitted in some instances (consulting) but not in others (CME)</li> </ul>	<ul style="list-style-type: none"> <li>• Permitted for consulting and sales meetings, but not for guests or spouses</li> </ul>
Gifts	<ul style="list-style-type: none"> <li>• May not give items “that do not advance disease or treatment education” (no promotional mugs or pens)</li> <li>• No gift cards or cash permitted</li> <li>• Occasional educational items permitted if under \$100 (e.g., anatomical models)</li> </ul>	<ul style="list-style-type: none"> <li>• Acceptable to provide educational items if less than \$100 in value (no dollar limit on models or textbooks)</li> <li>• May not give cash or cash equivalents</li> </ul>
Research	<ul style="list-style-type: none"> <li>• Not addressed in code of conduct for interactions with physicians, but addressed in separate code related to clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>• May provide grants for “independent medical research”</li> <li>• Research cannot be linked to medical technology sales</li> </ul>
CME/third-party educational conferences	<ul style="list-style-type: none"> <li>• Funding must go directly to program sponsor</li> <li>• May not pay for lodging/food</li> </ul>	<ul style="list-style-type: none"> <li>• May provide funding if money goes directly to program sponsor</li> <li>• Sponsor must retain control of programming</li> <li>• May provide refreshments</li> </ul>
Education	<ul style="list-style-type: none"> <li>• Addressed in CME section</li> </ul>	<ul style="list-style-type: none"> <li>• May provide grants/funding for fellowships for charity or medically affiliated groups</li> </ul>
Food	<ul style="list-style-type: none"> <li>• May provide food to doctors during workday meetings as a “business courtesy,” as long as it is “modest as judged by local standards” and occurs in conjunction with an educational session</li> <li>• May provide modest meals to attendees of events with speakers</li> </ul>	<ul style="list-style-type: none"> <li>• May provide “modest meals and refreshments” to accompany educational programs or sales, promotional, and other business meetings</li> </ul>
Entertainment	<ul style="list-style-type: none"> <li>• Prohibited</li> </ul>	<ul style="list-style-type: none"> <li>• Prohibited</li> </ul>
Monitoring/enforcement of code	<ul style="list-style-type: none"> <li>• Companies encouraged to seek external verification of their policies and procedures</li> <li>• Companies that comply with code are listed on PhRMA’s website</li> <li>• Potential breaches in conduct are referred by PhRMA to the company’s chief compliance officer</li> </ul>	<ul style="list-style-type: none"> <li>• Companies encouraged to create a compliance program when adopting the code and submit it to AdvaMed to receive certification</li> <li>• Certified companies are listed on AdvaMed’s website</li> <li>• Companies are responsible for enforcing the code</li> </ul>

Note: CME (continuing medical education). The PhRMA code was published in 2008 but took effect in January 2009.

Source: Advanced Medical Technology Association 2009, Pharmaceutical Research and Manufacturers of America 2008.

## Industry and provider guidelines to manage financial relationships between manufacturers and providers (cont.)

**TABLE  
6-2**

**Codes of conduct for financial relationships with industry, developed by physician associations and Association of American Medical Colleges (cont. next page)**

	<b>American Medical Association</b>	<b>American College of Physicians</b>	<b>American Academy of Orthopaedic Surgeons</b>	<b>Association of American Medical Colleges</b>
Travel	<ul style="list-style-type: none"> <li>• Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>• Discourages acceptance of hospitality or trips from the health care industry that might diminish the objectivity of professional judgment</li> </ul>	<ul style="list-style-type: none"> <li>• Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>• Funding for travel should be prohibited except for legitimate reimbursement or contractual services</li> </ul>
Gifts	<ul style="list-style-type: none"> <li>• Prohibits acceptance of cash gifts from a group that has a direct interest in physicians' treatment recommendations or in which reciprocity is expected</li> <li>• Accepted gifts must be of minimal value and directly benefit patients</li> </ul>	<ul style="list-style-type: none"> <li>• Discourages acceptance of gifts from the industry that might diminish the objectivity of professional judgment</li> </ul>	<ul style="list-style-type: none"> <li>• Recommends disclosure to patient if surgeon receives anything of value</li> </ul>	<ul style="list-style-type: none"> <li>• Academic medical centers should establish their own policies, which should prohibit accepting gifts</li> </ul>
Royalties	<ul style="list-style-type: none"> <li>• Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>• Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>• Surgeons should disclose royalties to patients</li> </ul>	<ul style="list-style-type: none"> <li>• Not addressed</li> </ul>
Research	<ul style="list-style-type: none"> <li>• Physicians should not receive compensation for more than the value of their time</li> <li>• Physicians should disclose financial ties to journals</li> </ul>	<ul style="list-style-type: none"> <li>• Financial interests and funding sources should be disclosed in writing to publishers and potential research collaborators</li> <li>• Researchers must have contributed to research in order to have their names on it</li> <li>• Physicians should not participate in research if negative results will not be published</li> </ul>	<ul style="list-style-type: none"> <li>• Surgeons are allowed to receive fair market reimbursement for reasonable administrative costs related to a clinical trial</li> <li>• Must disclose financial interests when reporting on clinical research on a particular product or procedure</li> <li>• Ghostwriting is not acceptable</li> </ul>	<ul style="list-style-type: none"> <li>• Researchers should report related financial interests to the institution, including dollar amount</li> <li>• Ghostwriting should be prohibited</li> </ul>
CME	<ul style="list-style-type: none"> <li>• Physicians should participate in CME events but should not accept subsidies from outside groups to do so</li> <li>• Physicians who participate in CME events should disclose financial support from the industry</li> </ul>	<ul style="list-style-type: none"> <li>• Organizations hosting CME events may accept industry funding if they are in charge of the event; industry cannot influence programming</li> </ul>	<ul style="list-style-type: none"> <li>• Should participate in CME events</li> </ul>	<ul style="list-style-type: none"> <li>• AMCs should establish a central CME office and adhere to guidelines from the Accreditation Council for Continuing Medical Education</li> <li>• Physicians should not accept gifts or payments from industry for attending a CME event</li> </ul>

Note: CME (continuing medical education), AMC (academic medical center).

Source: American Academy of Orthopaedic Surgeons 2011, American College of Physicians 2016, American Medical Association 2016b, American Medical Association 2016c, Association of American Medical Colleges 2010, Association of American Medical Colleges 2008.

## Industry and provider guidelines to manage financial relationships between manufacturers and providers (cont.)

**TABLE  
6-2**

**Codes of conduct for financial relationships with industry, developed by physician associations and Association of American Medical Colleges (cont.)**

	<b>American Medical Association</b>	<b>American College of Physicians</b>	<b>American Academy of Orthopaedic Surgeons</b>	<b>Association of American Medical Colleges</b>
Funding for medical education	<ul style="list-style-type: none"> <li>Institutions/fellowship programs may accept funding if:                             <ol style="list-style-type: none"> <li>funding is based on institution-specific criteria and</li> <li>funding is not attributed to specific sponsors</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Scholarships/educational funds must go directly to the administration of the AMC</li> <li>Funders cannot be involved in the selection of funding recipients</li> </ul>
Food	<ul style="list-style-type: none"> <li>Not specifically addressed; gifts of “minimal value” are acceptable</li> </ul>	<ul style="list-style-type: none"> <li>Discourages acceptance of hospitality from the industry that might diminish the objectivity of professional judgment</li> </ul>	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Institutions should prohibit food/meals at AMCs and off site</li> </ul>
Speaking	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Physicians should disclose their interests in writing when speaking</li> </ul>	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Physicians should disclose to their AMC when speaking at industry-sponsored events</li> <li>Participation in speakers’ bureaus should be discouraged</li> </ul>
Drug samples	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Physicians cannot sell free samples</li> </ul>	<ul style="list-style-type: none"> <li>Not addressed</li> </ul>	<ul style="list-style-type: none"> <li>Free samples should be handled by a central manager</li> </ul>
Ownership of company or facility	<ul style="list-style-type: none"> <li>Physicians should not refer patients to facilities that they own/invest in if they do not also provide care there</li> </ul>	<ul style="list-style-type: none"> <li>May invest in facilities, but should not refer patients to facilities at which they do not provide care</li> </ul>	<ul style="list-style-type: none"> <li>Patient should be notified if surgeon has an interest in product/company</li> </ul>	<ul style="list-style-type: none"> <li>Faculty and staff should disclose financial interests</li> <li>Individuals with financial interests should not be involved in purchasing decisions related to their interests</li> </ul>

Note: CME (continuing medical education), AMC (academic medical center).

Source: American Academy of Orthopaedic Surgeons 2011, American College of Physicians 2016, American Medical Association 2016b, American Medical Association 2016c, Association of American Medical Colleges 2010, Association of American Medical Colleges 2008.

broader set of providers and organizations, including other prescribers (e.g., advanced practice nurses and physician assistants), pharmacists, health plans, pharmacy benefit managers, hospitals, medical schools, organizations that sponsor continuing medical education, patient

organizations, and professional organizations (see text box, p. 188) (Medicare Payment Advisory Commission 2009).

Manufacturers are required to report the name, state license number, national provider identifier (NPI), specialty, and address of physicians who receive payments

## Prior Commission recommendations on public reporting by drug and device manufacturers of financial relationships

### Recommendation 5-1 from the March 2009 report to the Congress

The Congress should require all manufacturers and distributors of drugs, biologicals, medical devices, and medical supplies (and their subsidiaries) to report to the Secretary their financial relationships with:

- physicians, physician groups, and other prescribers;
- pharmacies and pharmacists;
- health plans, pharmacy benefit managers, and their employees;
- hospitals and medical schools;
- organizations that sponsor continuing medical education;
- patient organizations; and
- professional organizations.

### Recommendation 5-2 from the March 2009 report to the Congress

The Congress should direct the Secretary to post the information submitted by manufacturers on a public website in a format that is searchable by:

- manufacturer;
- recipient's name, location, and specialty (if applicable);
- type of payment;
- name of related drug or device (if applicable); and
- year.

### Recommendation 5-3 from the March 2009 report to the Congress

The Congress should require manufacturers and distributors of drugs to report to the Secretary the following information about drug samples:

- each recipient's name and business address;
- the name, dosage, and number of units of each sample; and
- the date of distribution.

The Secretary should make this information available through data use agreements. ■

or other transfers of value. They must also report the name and address of teaching hospitals that receive payments. In addition, manufacturers must report the type of payment (e.g., research or consulting); the amount; the payment date; and the name of the drug or device related to the payment (if a specific drug or device is related to the payment). Manufacturers and GPOs may voluntarily report brief contextual information about payments but are not required to do so. All of these data except physician NPIs are available on a public website (the statute prohibits CMS from including NPIs on the website). The data include direct payments or transfers of value to physicians or teaching hospitals as well as indirect payments and third-party payments. Indirect payments occur when the manufacturer makes a payment to an intermediary (such as a specialty society) and

requires, instructs, or directs the intermediary to provide the payment to a physician or teaching hospital. Third-party payments are payments that are designated by a physician or teaching hospital for a third-party such as a charity.

Several types of payments and transfers of value are excluded from reporting, such as samples, educational materials that are for patient use, and discounts on products purchased by physicians or teaching hospitals (such as drug rebates). In 2015, payments or transfers worth less than \$10.21 are also excluded unless the aggregate amount transferred by a manufacturer to a recipient during the year exceeds \$102.07.<sup>1</sup> Until 2016, if a manufacturer sponsored an accredited continuing medical education (CME) program, payments made

by that program to physician speakers were excluded from reporting if the manufacturer did not influence the choice of speakers. Specifically, the manufacturer was not allowed to (1) select the speaker of the program or provide a list of individuals to be selected as the speaker or (2) directly pay the speaker. Beginning in 2016, manufacturers are required to report these payments if they are indirect payments and if they know or can determine the identity of the physicians who attended or spoke at the CME event during the reporting year or by the end of the second quarter of the following reporting year (Centers for Medicare & Medicaid Services 2017c).

CMS divides the payments and transfers of value into three broad categories: research payments, ownership or investment interests, and general payments. Research payments include payments to teaching hospitals and physicians for basic research, applied research, and product development. Manufacturers must report all payments for services included in the written agreement or research protocol. Research payments to physicians include payments for which the physician is the primary recipient as well as payments to research institutions for which a physician is a principal investigator on a project. These payments may cover costs associated with patient care, the time spent managing the study, the drugs or devices that are studied, and other items provided by the manufacturer. The payment information does not distinguish between costs associated with the study and the physician's compensation for managing the study.

Manufacturers may request that CMS delay publication of research payments related to research or development of a new drug, device, biologic, or medical supply, or a new application of an existing product. Publication of these payments may be delayed for four years or until the date of approval, licensure, or clearance of the product by the Food and Drug Administration, whichever date comes first. The goal of this statutory provision is to balance manufacturers' desire to protect proprietary information about new products with the goal of public transparency.

Ownership or investment interests include ownership interests by physicians in manufacturers or GPOs, including stocks, stock options, partnership shares, and limited liability company memberships. They also include loans, bonds, and other financial instruments that are secured with an entity's property or revenue. General payments include all other reported payments and transfers of value to physicians and teaching hospitals, such as promotional speaking fees, royalty and license

payments, consulting fees, food and beverage, travel and lodging expenses, and education.

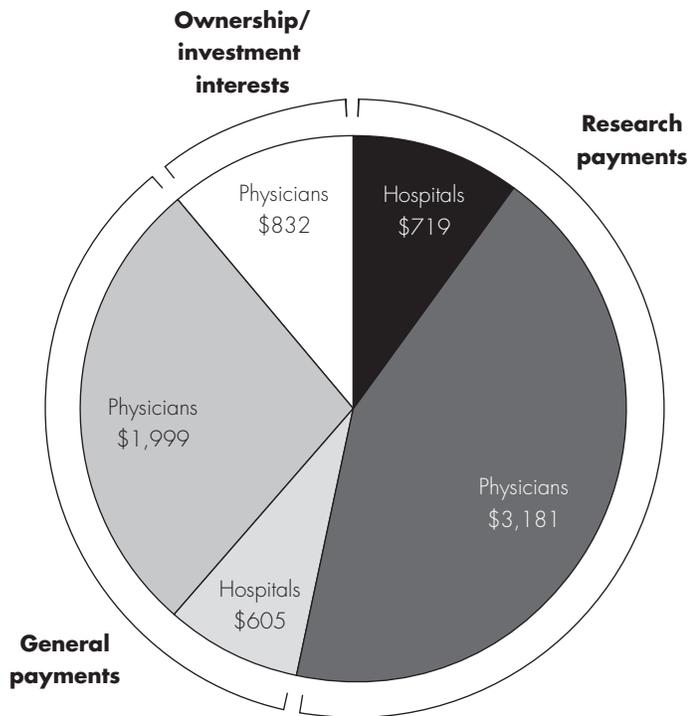
CMS encourages physicians and teaching hospitals to review data reported by manufacturers and GPOs before the records are published on the website. If these recipients register with the Open Payments system, they may dispute information reported about them that may be inaccurate. Recipients have 45 days to review and dispute records before they are posted to the website, but they may continue to dispute records after they are published. Manufacturers and GPOs are able to review disputed information and correct it if necessary.

About 28,000 physicians and 450 teaching hospitals registered in the Open Payments system to review payments made in 2013 or 2014 (Centers for Medicare & Medicaid Services 2016a). These numbers represent about 4 percent of all physicians who received a payment in either year and about 40 percent of all teaching hospitals that received a payment in either year. These recipients disputed about 25,000 payment records from 2013 or 2014 (less than 1 percent of the total). Most of these disputes (about 85 percent) were resolved by the end of the review period. About 17,000 payment records from 2015 were disputed by physicians and teaching hospitals, but CMS has not yet released the number of recipients who reviewed payments from 2015 (Centers for Medicare & Medicaid Services 2016b).

The American Medical Association (AMA) asserts that the process for physicians to register with the Open Payments system is confusing and overly burdensome, which they believe deters many physicians from reviewing and verifying payments attributed to them (American Medical Association 2016a). During 2016, CMS used e-mails, Twitter, blogs, conference calls, and presentations to educate physicians and teaching hospitals about the Open Payments program and how to register with the system to review their records (Centers for Medicare & Medicaid Services 2016c). CMS also created a free mobile app for physicians to track the payments they receive in real time, which they can use to verify the accuracy of payments reported by the industry (Centers for Medicare & Medicaid Services 2017b). In addition, the AMA has encouraged physicians to register with the system and review their payments (American Medical Association 2016d). We do not yet have information on whether the number of recipients who reviewed Open Payments data has increased over time.

**FIGURE 6-1**

**Payments and other transfers of value by manufacturers and GPOs to physicians and teaching hospitals, by payment type, 2015 (in millions)**



Note: GPOs (group purchasing organizations). "General payments" includes promotional speaking fees, royalty and license payments, consulting fees, food and beverage, and other items. "Research payments" does not include payments that are subject to delayed publication (manufacturers may request that CMS delay publication of payments related to research or development of a new drug, device, biologic, or medical supply, or a new application of an existing product). Research payments to physicians include payments for which the physician is the primary recipient as well as payments to research institutions for which a physician is a principal investigator on a project. "Physicians" includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors.

Source: MedPAC analysis of Open Payments data for 2015 from CMS (data released in January 2017).

**Analysis of Open Payments data from 2015**

To analyze Open Payments data from 2015, we used three Open Payments data files (general payments, research payments, and ownership or investment interests) for 2015 and a file that contains information on each physician who

received a payment (the physician profile supplement file). We used the specialty code for each physician from the physician profile supplement file.

The Open Payments program has several limitations. First, many research payments are reported to CMS but not publicly released because of a statutory provision that allows manufacturers to delay publication of certain research payments. This provision makes it difficult to assess the full scope of industry support for research. In 2014, \$1.3 billion in research payments were subject to delayed publication (CMS has not yet released the comparable number for 2015) (Centers for Medicare & Medicaid Services 2016a).

Second, the data do not indicate whether a GPO or a manufacturer made the payment or whether a manufacturer that made a payment produces drugs, biologics, devices, or supplies (the database lists the manufacturer's name but not the types of products it makes). To examine the distribution of payments by type of company, we used websites and other sources to identify whether each company was a drug manufacturer, device manufacturer, producer of both drugs and devices, a traditional GPO (not a physician-owned distributor), a physician-owned distributor (POD), or another type of company. PODs are physician-owned entities that derive revenue from selling, or arranging the sale of, implantable medical devices ordered by their physician-owners for procedures performed by the physician-owners at hospitals or other facilities (Office of Inspector General 2013a). (See Chapter 7 of this report.) According to CMS, most PODs are a type of GPO and are therefore subject to the Open Payments reporting requirements (Centers for Medicare & Medicaid Services 2013). However, PODs that purchase devices for resale to a single hospital rather than a group of hospitals do not meet CMS's definition of a GPO and are therefore excluded from reporting.<sup>2</sup> To identify PODs, we used the membership list of the American Association of Surgeon Distributors, a POD association. We also assumed that companies that met the following criteria were likely to be PODs:

- the company focused on spinal implants—because PODs have been most prevalent in the field of spinal surgery (U.S. Senate Committee on Finance 2016),
- the company had a small number of physician owners, and
- the ownership interest of each physician owner was worth a similar amount.

Third, in the absence of additional information, it is difficult for patients and researchers to determine from the data whether a financial relationship served a legitimate purpose or posed a potential conflict of interest. For example, the Open Payments website does not contain information on whether a consulting payment from a manufacturer to a physician was related to a written contract under which the physician performed legitimate work for the company. Fourth, there may be underreporting of information by companies. For example, the Senate Finance Committee found that many PODs do not report their physician ownership interests to CMS (U.S. Senate Committee on Finance 2016).

## Results

In 2015, through the Open Payments program, manufacturers and GPOs reported about \$7.3 billion in payments and other transfers of value to physicians and teaching hospitals. By comparison, the total value of payments in 2014 was \$7.5 billion. The total for both years excludes research payments that were subject to delayed publication (i.e., they were reported to CMS but not published). Compared with reported payments in 2014, payments in 2015 were \$40 million lower for general payments, \$100 million higher for research payments, and about \$230 million lower for ownership or investment interests. In 2015, research payments accounted for just over half of the total amount, general payments accounted for 35 percent, and physician ownership or investment interests accounted for 11 percent (Figure 6-1). The 2015 data include payments from 1,455 companies to about 618,000 physicians and 1,111 teaching hospitals (Centers for Medicare & Medicaid Services 2017a). The category of physicians included about 502,000 medical doctors and osteopaths and almost 116,000 dentists, optometrists, podiatrists, and chiropractors.

Among physicians who received at least one general payment, the average amount per physician was \$3,242 (median of \$157). To calculate the average dollar amount per physician, we aggregated all the transactions for each physician and calculated the mean dollar amount across all physicians. We did not calculate the average amount of research payments per physician because many research payments list multiple physicians as principal investigators and we could not attribute these payments to an individual physician. Teaching hospitals received \$550,791, on average, in general payments (median of \$16,910) and \$1.04 million in research payments, on average (median of \$100,409). We also examined physician ownership or

investment interests in a manufacturer or GPO (companies do not report this information for teaching hospitals). Physicians had an average ownership or investment interest of \$215,045 (median of \$4,667).

Physicians accounted for just over 80 percent of the payments and other transfers of value in 2015 (about \$6.0 billion); teaching hospitals accounted for almost 20 percent (about \$1.3 billion) (Table 6-3, p. 192). About half of total physician payments were research payments, one-third were general payments, and 14 percent were ownership or investment interests. Over half of total payments to teaching hospitals were research payments and just under half were general payments.

### General payments to physicians and teaching hospitals

We examined general payments in greater detail because they include a variety of payment types and most represent direct compensation to physicians.<sup>3</sup> By contrast, research payments may include costs associated with managing a study and patient care in addition to direct physician compensation. We analyzed general payments by type of payment, type of recipient (physician or teaching hospital), and physician specialty.

A small proportion of physicians accounted for a majority of the total dollars received by physicians in the general payments category. In 2015, the top 5 percent of physicians received 86 percent of the dollars; each of these physicians received about \$56,000 in payments, on average. The top 10 percent of physicians received 91 percent of the dollars, with each physician receiving about \$30,000, on average. By contrast, physicians in the bottom 90 percent received only 9 percent of the dollars, with each physician receiving \$311, on average.

We examined the distribution of general payments to physicians in 2015 by type of payment (Table 6-4, p. 193). Royalty or license payments (payments for the right to use patents, copyrights, and other intellectual property) accounted for the highest share of general payments (26 percent) and had the highest average amount per physician: about \$233,000 (median of \$32,363). Only 2,265 physicians received a royalty or license payment. Compensation for services other than consulting accounted for 25 percent of the value of general payments to physicians. According to CMS, this category should include payments to physicians for speaking, training, and educational engagements that are not related to continuing education (e.g., a manufacturer pays a

**TABLE  
6-3**

**Payments and other transfers of value by manufacturers and GPOs to physicians and teaching hospitals, by recipient and payment type, 2015**

	Physicians		Teaching hospitals		Total	
	Dollars (in millions)	Share of total physician payments	Dollars (in millions)	Share of total teaching hospital payments	Dollars (in millions)	Share of total
Research payments	\$3,181	53%	\$719	54%	\$3,900	53%
General payments	1,999	33	605	46	2,604	35
Physician ownership or investment interests	832	14	N/A	N/A	832	11
Total	6,012	100	1,324	100	7,336	100

Note: GPO (group purchasing organization), N/A (not applicable). "General payments" includes promotional speaking fees, royalty payments, consulting fees, food and beverage, and other items. "Research payments" does not include payments that are subject to delayed publication (manufacturers may request that CMS delay publication of payments related to research or development of a new drug, device, biologic, or medical supply, or a new application of an existing product). Research payments to physicians include payments for which the physician is the primary recipient as well as payments to research institutions for which a physician is a principal investigator on a project. "Physicians" includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Open Payments data for 2015 from CMS (data released in January 2017).

physician to talk about a drug to other physicians at a restaurant) (Centers for Medicare & Medicaid Services 2017d). However, we also found several large payments to physicians to acquire physician-owned companies in this category, which suggests that CMS should create a separate category for such payments. About 31,000 physicians (5 percent of physicians who received at least one general payment) received compensation for services other than consulting; the average amount per physician was about \$16,000 (median of \$4,000) (Table 6-4). Consulting fees were received by about 36,000 physicians and accounted for 17 percent of the total value of general payments. Food and beverage accounted for 12 percent of the total but were received by about 589,000 physicians (96 percent of physicians who received at least one general payment), indicating the prevalence of industry-sponsored meals. The average value of food and beverage per physician was \$400 (median of \$138). A study that used Open Payments data from the last five months of 2013 and data on prescriptions from Medicare Part D found that physicians who received meals related to the promotion of specific brand-name medications had a higher rate of prescribing those medications to Medicare beneficiaries (DeJong et al. 2016). About 70,000 physicians received travel and lodging, with

an average value of \$2,669 per physician (median of \$1,030).

The distribution of general payments to teaching hospitals in 2015 was highly concentrated: 51 percent of the value of these payments (\$307 million) went to a single hospital (City of Hope National Medical Center, Duarte, CA), and almost all of the payments to this hospital were royalty or license payments from a single manufacturer. Overall, royalty or license payments accounted for 70 percent of the total value of general payments to teaching hospitals (Table 6-5, p. 194) compared with 26 percent of general payments to physicians (Table 6-4). Grants accounted for 11 percent of the value of general payments to teaching hospitals compared with only 1 percent of the physician total. The gifts category accounted for only 2 percent of the total value of general payments to teaching hospitals but was the most prevalent type of payment, received by 78 percent of hospitals.

**General payments by physician specialty**

Table 6-6 (p. 195) shows general payments for the top 10 physician specialties for 2015. Internal medicine accounted for \$420 million, or 21 percent of the total value of general payments. The internal medicine

**TABLE  
6-4**

**General payments by manufacturers and GPOs to physicians, by payment category, 2015**

	Payments		Physicians			
	Amount (in millions)	Share of total	Number	Share of all physicians who received a general payment*	Mean payment per physician	Median payment per physician
Royalty or license	\$527	26%	2,265	<1%	\$232,693	\$32,363
Compensation for services other than consulting	509	25	31,369	5	16,224	4,000
Consulting fee	349	17	36,319	6	9,603	2,415
Food and beverage	235	12	589,042	96	400	138
Travel and lodging	187	9	70,046	11	2,669	1,030
Ownership or investment interest	51	3	769	<1	66,859	4,000
Honoraria	36	2	6,880	1	5,273	2,210
Education	36	2	120,341	20	297	35
Serving as faculty for medical education program	35	2	4,788	1	7,301	2,740
Grant	19	1	2,472	<1	7,802	1,873
Gift	9	0.5	22,726	4	409	90
Charitable contribution	5	0.2	257	<1	18,665	1,000
Entertainment	0.4	0.02	3,203	1	117	56
<b>Total</b>	<b>1,999</b>	<b>100</b>	<b>616,567</b>		<b>3,242</b>	<b>157</b>

Note: GPO (group purchasing organization). "Physicians" includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. "Royalty or license payments" includes payments for the right to use patents, copyrights, and other intellectual property. "Compensation for services other than consulting" includes promotional speaking fees and payments to acquire physician-owned companies. "Ownership or investment interest" includes interests that manufacturers or GPOs give to physicians but excludes interests that are purchased by physicians. All ownership or investment interests, whether given to physicians or purchased by physicians, appear in a separate file. "Serving as faculty for medical education program" includes compensation for serving as faculty for unaccredited and accredited education programs. The number of physicians does not sum to 616,567 because a single physician could have received payments in multiple categories. Numbers for share of total payments do not sum to 100 percent due to rounding.

\*This column indicates the share of physicians in the general payments file that received a payment in each category. Because a single physician could have received payments in multiple categories, this column does not sum to 100 percent.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released in June 2016).

category includes internal medicine plus related specialties such as endocrinology, gastroenterology, medical oncology, and rheumatology. Each physician in the internal medicine category received \$3,522 on average, with a median of \$260. The large difference between the mean and median values indicates that a small number of physicians received high payment amounts, while most physicians received relatively small amounts. Compensation for services other than consulting (e.g., promotional speaking fees, payments to acquire physician-owned companies) accounted for the highest share of payments received by internal medicine physicians (42 percent) (data not shown).

Orthopedic surgery accounted for \$410 million, or 21 percent of the total value of general payments. The average amount received by orthopedic surgeons was relatively high: \$19,257, with a median of \$418. Royalty or license payments accounted for 71 percent of payments to orthopedic surgeons (\$293 million), which indicates the close collaboration between orthopedic surgeons and manufacturers in product development (data not shown). This specialty accounted for 56 percent of all royalty payments across all physicians.

Neurological surgeons also had relatively high average payment amounts (\$21,906). Dentists and family medicine physicians had relatively low average payments (\$873 and \$819, respectively).

**TABLE  
6-5**

**General payments by manufacturers to teaching hospitals, by payment category, 2015**

	Payments		Hospitals			
	Amount (in millions)	Share of total	Number	Share of all hospitals that received a general payment*	Mean payment per hospital	Median payment per hospital
Royalty or license	\$423	70%	88	8%	\$4,803,321	\$30,690
Grant	68	11	693	63	97,704	4,463
Consulting fee	30	5	238	22	124,221	3,063
Space rental/facility fees	21	3	669	61	30,997	6,007
Charitable contribution	18	3	257	23	18,665	1,000
Compensation for services other than consulting	18	3	585	53	30,483	2,800
Education	14	2	733	67	19,761	2,221
Gift	12	2	854	78	13,768	3,578
Other categories	2	0.3	698	64	2,558	401
<b>Total</b>	<b>605</b>	<b>100</b>	<b>1,098</b>		<b>550,791</b>	<b>16,910</b>

Note: "Royalty or license payments" are payments for the right to use patents, copyrights, and other intellectual property. "Other categories" include compensation for serving as faculty for medical education programs, travel and lodging, food and beverage, honoraria, ownership or investment interest, and entertainment. Numbers in the first column ("Amount") do not sum to total due to rounding. Numbers for share of total do not sum to 100 percent due to rounding. The number of hospitals does not sum to 1,098 because a single hospital could have received payments in multiple categories.  
\*This column indicates the share of hospitals in the general payments file that received a payment in each category. Because a single hospital could have received payments in multiple categories, this column does not sum to 100 percent.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released in June 2016).

### Distribution of payments to physicians by type of company making the payment

We examined the distribution of payments to physicians by the type of company that made the payment: device manufacturer, drug manufacturer, manufacturer of both drugs and devices, traditional GPO (not a POD), POD, or "other" company (e.g., cryotherapy facilities and blood banks). Device manufacturers accounted for 48 percent of general payments to physicians, and drug manufacturers accounted for 46 percent (Table 6-7). Device manufacturers accounted for the majority (84 percent) of the value of physician ownership or investment interests, while drug manufacturers accounted for only 8 percent (Table 6-8, p. 196).

We identified only 8 PODs in the general payments file and 16 PODs in the physician ownership or investment interests file. A Senate Finance Committee report found evidence that many PODs do not report their physician ownership interests to Open Payments, and some PODs have changed how they compensate physicians

to circumvent the reporting requirements (U.S. Senate Committee on Finance 2016) (see the section on requiring companies to report their company type, p. 198).

### Expanding and improving the Open Payments program

Although the Open Payments program has shed significant light on financial interactions between manufacturers and physicians and teaching hospitals, it should be expanded to include additional providers and organizations that have relationships with manufacturers. In addition, the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans. Finally, CMS should require companies to report whether they are a GPO or manufacturer, the type of products they make, whether they are a POD, and the portion of a research payment that is related to physician compensation.

**TABLE  
6-6****General payments by manufacturers and GPOs to physicians, top 10 specialties, 2015**

Specialty	Payments (in millions)	Share of total	Number of physicians	Mean payment per physician	Median payment per physician
Internal medicine	\$420	21%	119,224	\$3,522	\$260
Orthopedic surgery	410	21	21,310	19,257	418
Cardiology	168	8	21,660	7,749	829
Psychiatry and neurology	144	7	32,282	4,455	222
Neurological surgery	98	5	4,486	21,906	461
Other surgery	76	4	23,644	3,220	249
Radiology	66	3	14,315	4,620	116
Dentist	64	3	73,310	873	63
Ophthalmology	60	3	13,725	4,346	195
Family medicine	54	3	65,549	819	178

Note: GPO (group purchasing organization). "Internal medicine" includes internal medicine, endocrinology, gastroenterology, hematology, medical oncology, pulmonary disease, rheumatology, and some other specialties. "Other surgery" includes hand surgery, pediatric surgery, plastic surgery, trauma surgery, vascular surgery, surgical oncology, and surgical critical care.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released in June 2016).

### Include additional providers and organizations in the Open Payments program

The statute that created the Open Payments program requires manufacturers and GPOs to report financial interactions with physicians and teaching hospitals but not with other health professionals or organizations. Consistent with our recommendation from 2009, we urge the Congress to expand this reporting requirement so

that it also applies to financial ties with other clinicians (e.g., advanced practice registered nurses (APRNs) and physician assistants (PAs)), pharmacists, health plans, pharmacy benefit managers, other hospitals, medical schools, organizations that sponsor continuing medical education, patient organizations, and professional organizations (see text box, p. 188) (Medicare Payment Advisory Commission 2009). We are especially concerned that payments and other transfers of value from

**TABLE  
6-7****General payments to physicians, by type of company, 2015**

Company type	Payments			
	Amount (in millions)	Share of total	Number of unique companies	Share of total number of companies
Device manufacturer	\$962	48%	816	67%
Drug manufacturer	910	46	242	20
Drug and device manufacturer	99	5	56	5
Other	15	1	69	6
GPO	10	<1	33	3
POD	3	<1	8	<1
Total	1,999	100	1,224	100

Note: GPO (group purchasing organization), POD (physician-owned distributor). "Other" includes blood banks, cryotherapy facilities, and companies whose company type could not be identified. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released June 2016).

**TABLE  
6-8**

**Value of physician ownership or investment interests, by type of company, 2015**

Company type	Ownership or investment interests			
	Value (in millions)	Share of total	Number of unique companies	Share of total number of companies
Device manufacturer	\$699	84%	150	71%
Drug manufacturer	68	8	6	3
Drug and device manufacturer	33	4	4	2
Other	26	3	34	16
POD	6	1	16	8
GPO	0.1	<1	1	<1
Total	832	100	211	100

Note: POD (physician-owned distributor), GPO (group purchasing organization). "Other" includes blood banks, cryotherapy facilities, and companies whose company type could not be identified.

Source: MedPAC analysis of Open Payments data from the physician ownership file for 2015 from CMS (data released in January 2017).

manufacturers to APRNs, PAs, and patient organizations are not reported to Open Payments, even though the industry has financial relationships with many of these providers and organizations.

### **Growth in the number of APRNs and PAs and their interactions with drug manufacturers**

The number of APRNs and PAs has increased in recent years, and they play an increasingly important role in the health care system, such as coordinating care and managing medications. From 2013 through 2015, the number of APRNs and PAs billing Medicare grew from 3.2 per 1,000 beneficiaries to 3.6 per 1,000 beneficiaries, an increase of 13.4 percent (Medicare Payment Advisory Commission 2017). According to a ProPublica analysis, these clinicians wrote about 10 percent of all Medicare Part D prescriptions in 2013 and 15 percent of prescriptions across all payers in the first five months of 2013 (Ornstein 2015). A national survey of nurse practitioners (NPs), a type of APRN, found that nearly all of them (96 percent) had regular contact with sales representatives from drug companies (Ladd et al. 2010). Almost half of the NPs reported regular attendance (one to five times during the prior six months) at industry-sponsored lunch events, and 64 percent reported regular attendance at sponsored dinner events. Almost half stated that they were more likely to prescribe a drug highlighted at an industry-sponsored event after attending the

event. The exclusion of APRNs and PAs from the Open Payments system creates an incentive for manufacturers to shift payments from physicians to these clinicians to avoid the reporting requirements.

### **Most patient organizations receive industry funding, but many do not routinely disclose funding sources**

Patient organizations engage in policy and advocacy activities, educate patients, and fund and conduct important research (Rose et al. 2017). Most of these organizations receive industry funding, which may influence their agendas and activities, but many of them do not routinely disclose all of their funding sources. A survey of these entities conducted in 2013 and 2014 found that about two-thirds received industry funding, with 12 percent receiving more than half of their funding from industry (Rose et al. 2017). The largest share of industry funding came from pharmaceutical, device, and biotechnology companies (the median share of funding from these sectors was 45 percent). A recent study of the 104 largest patient advocacy organizations found that at least 83 percent received financial support from drug, device, and biotechnology companies (McCoy et al. 2017). Although 57 percent of these organizations disclosed the donations they received, the amounts were typically disclosed as broad ranges rather than precise figures. In most cases, this practice made it impossible to calculate the precise amount of industry support for an organization.

Media coverage has also highlighted extensive financial ties between drug manufacturers and several large patient organizations (Fauber 2012, Mullins 2017, Ornstein and Weber 2011, Thomas 2016).

Industry funding can create conflicts between the missions of patient organizations and their funders' financial interests. For example, a large advocacy group for patients with pain, which received almost 90 percent of its funding from drug and device manufacturers, produced guides for patients, journalists, and policymakers that downplayed the risks associated with opioids and exaggerated their benefits (Ornstein and Weber 2011). Requiring drug and device companies to publicly report their financial support for patient organizations through Open Payments would enable the public and policymakers to assess potential conflicts of interest.

### **Require the Secretary to make data on drug samples available to oversight agencies, researchers, payers, and health plans**

In 2012, the pharmaceutical industry provided free drug samples worth \$5.7 billion to practitioners and other providers (Pew Charitable Trusts 2013). According to a national survey of physicians conducted in 2009, 64 percent of physicians received drug samples in the prior year (Campbell et al. 2010). A national survey of NPs conducted in 2007 and 2008 found that 66 percent of NPs dispensed drug samples for treatment. Although samples clearly offer benefits for many patients, they may also lead clinicians and patients to rely on more expensive drugs when cheaper products may be equally effective. Comprehensive information about the distribution of samples would enable CMS, the Office of Inspector General (OIG), congressional oversight agencies, and researchers to study their impact on prescribing patterns, overall drug spending, and patients' adherence to treatment regimens. Such data could also help payers and health plans improve their counter-detailing programs (also known as academic detailing), which provide information on drugs to physicians through educational visits by clinicians (Kaiser Family Foundation 2005). These programs are designed to reduce excessive use of expensive drugs by offering evidence-based information on the safety, efficacy, and costs of alternative medications. For example, a program may share evidence with physicians that a brand-name drug is no more effective than a cheaper, older alternative. Manufacturers and distributors of pharmaceuticals currently report information about drug samples to the Food and Drug

Administration (FDA). Consistent with the Commission's recommendation from 2009 on samples, the Congress should require the Secretary to make this information available under data use agreements to oversight agencies, researchers, payers, and health plans (Medicare Payment Advisory Commission 2009).

Free samples may allow patients to start treatments sooner and help physicians evaluate a drug's effectiveness before a patient purchases the full prescription (Chew et al. 2000). Samples also help some patients without insurance or with coverage limitations obtain medication. According to a study by Cutrona and colleagues, about 10 percent of uninsured patients reported receiving at least one free drug sample in 2003 (Cutrona et al. 2008). However, the same study found that wealthy and insured patients were more likely to receive free samples than poor and uninsured individuals. In addition, other research has found that physicians who receive samples of a new drug are more likely to prescribe it (Peay and Peay 1988), patients who receive samples have higher out-of-pocket spending on drugs than patients who do not receive samples (Alexander et al. 2008), and physicians are more likely to prescribe generic medications to uninsured patients after drug samples are removed from their office (Miller et al. 2008).

### **Oversight agencies, researchers, payers, and plans could use data on drug samples for research and counter-detailing programs**

Comprehensive data on the distribution of drug samples—combined with claims data on prescriptions—would enable further research on the effects of samples. Oversight agencies and researchers could examine questions such as:

- Does the use of samples vary by practice setting (e.g., office based vs. hospital based), physician specialty, or patient characteristics?
- Do practices that accept samples prescribe more expensive medications? Do they adopt newer drugs faster than other practices?
- Do the patients of clinicians who accept samples spend more on drugs or other health care services? Are they more likely to comply with treatment regimens?

Payers and plans could use information on practices' acceptance of drug samples to improve their counter-detailing efforts. For example, they could focus counter-detailing programs on practices that are more likely to accept samples of new drugs.

## **Manufacturers and distributors are required to collect and report information on drug samples to the Secretary**

Under the Prescription Drug Marketing Act of 1987 (PDMA), manufacturers and distributors are required to keep internal records of the drug samples they distribute to practitioners and pharmacies of hospitals and other entities. Section 6004 of the Patient Protection and Affordable Care Act of 2010 (PPACA) requires manufacturers and distributors to annually report to the Secretary much of the information they collect under PDMA (Food and Drug Administration 2014). This information includes the identity and quantity of drug samples requested and distributed; the name, address, and professional designation of the practitioner who requested the samples; and the name and address of the practitioner (or the practitioner's designee) who received the samples.<sup>4</sup> The Secretary delegated the authority to collect this information to the FDA, which has released industry guidance on the reporting process (Food and Drug Administration 2014).

The Commission recommended in 2009 that the Congress require manufacturers and distributors to report detailed information about drug samples to the Secretary, which the Secretary should make available through data use agreements (see text box, p. 188). Although the Congress adopted the first part of this recommendation in PPACA, the statute does not give the Secretary authority to release information on samples to researchers or others. Therefore, we reprint our recommendation that the Congress authorize and require the Secretary to make this information available to researchers, payers, and plans that sign confidentiality and data use agreements.<sup>5</sup> To foster legitimate use of the data, the process for requesting and obtaining the information should not be overly restrictive.

## **Collect more detailed data on manufacturers, GPOs, and research payments**

CMS should require companies to report whether they are GPOs or manufacturers, what type of products they make, and whether they are PODs. In addition, manufacturers should report the portion of a research payment that is related to physician compensation. CMS could likely use its existing statutory authority to require GPOs and manufacturers to report this information.

## **Require companies to report their company type**

Although the Open Payments database lists the name of each manufacturer or GPO that made the payment

or transfer of value, it does not indicate whether the company is a GPO or a manufacturer. Manufacturers do not report whether they produce drugs, biologics, devices, or supplies. Although some manufacturers are well known and users of the data may recognize whether they produce drugs, devices, or another product, some manufacturers are less well known. Moreover, some manufacturers report payments in the name of their subsidiaries.

In addition, GPOs do not report whether they are PODs (see p. 190 for the definition of PODs). According to CMS, PODs that purchase devices and other items for resale or distribution to groups of individuals or entities are considered a type of GPO and are therefore subject to the Open Payments reporting requirements (Centers for Medicare & Medicaid Services 2013). It is important to identify PODs because they have been the subject of reports and investigations by OIG and the Senate Finance Committee (Office of Inspector General 2013b, U.S. Senate Committee on Finance 2016). OIG warned that PODs are inherently suspect under the anti-kickback statute because they offer financial incentives to their physician-owners that may induce the physicians to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices sold by the PODs instead of other devices (Office of Inspector General 2013a). OIG's concerns are heightened because physicians, rather than hospitals or ambulatory surgical centers, strongly influence the choice of implantable medical devices used in procedures. OIG found that PODs supplied devices used in nearly one-fifth of spinal fusion surgeries paid for by Medicare in 2011 (Office of Inspector General 2013b). Among hospitals that purchased spinal devices from PODs, their rate of spinal surgery grew faster than the rate for hospitals overall.

The Senate Finance Committee found evidence that many PODs do not report their physician ownership interests to Open Payments, and some PODs have changed how they compensate physicians to circumvent the reporting requirements (U.S. Senate Committee on Finance 2016). The Committee reviewed Open Payments data from the last five months of 2013 and found that many PODs did not appear in the data. According to the Committee's report, an increasing number of PODs are reclassifying physicians as employees instead of owners to avoid reporting physician ownership interests. In addition, physicians who invest in PODs sometimes request that payments from the POD be made to close family members or friends instead of the physician-owners. However, the Open Payments statute requires that ownership or

investment interests by physicians *or their immediate family members* must be reported.

In our work, we engaged in a time-consuming process using websites and other sources to identify whether each company in the Open Payments database was a drug manufacturer, device manufacturer, producer of both drugs and devices, a traditional GPO (not a POD), a POD, or another type of company. In particular, it was difficult to identify PODs because they typically lack public websites, and some PODs try to obscure their financial relationships with physicians (U.S. Senate Committee on Finance 2016).

CMS should require each manufacturer or GPO that reports data under Open Payments to indicate:

- whether it is a manufacturer or GPO;
- whether, if a manufacturer, it produces drugs, biologics, devices, supplies, or a combination of products; and
- whether, if a GPO, it is a POD.

In addition, CMS should conduct outreach to PODs (or companies suspected of being PODs) to remind them of their obligation to report physician ownership information and to assess penalties on PODs that do not comply with the statute. CMS should coordinate its efforts with OIG, which identified PODs that sold spinal devices to hospitals for its report on PODs (Office of Inspector General 2013b). Including more information on the types of companies that have financial relationships with physicians and teaching hospitals would enable patients and researchers to better understand these relationships.

### **Require manufacturers to separately report the portion of a research payment related to physician compensation**

Research payments are reported separately from general payments because research is a unique activity and payments for research do not necessarily represent a personal payment to physicians (Centers for Medicare & Medicaid Services 2013). Research payments are often very large and cover a variety of activities included in the written agreement or research protocol, such as examinations and tests for patients, the drugs or devices that are studied, other in-kind items provided by the

manufacturer, and the time spent by physicians treating patients and managing the study. Because manufacturers may not know the details of how a research payment was spent, CMS does not require them to itemize the cost of specific activities (Centers for Medicare & Medicaid Services 2013).

However, it would be helpful for users of the data to be able to distinguish between the portion of the payment that included the physician's compensation for conducting the research study and the portion of the payment associated with other costs (e.g., patient care and the cost of drugs or devices). Because physician compensation for managing a study represents a direct payment to a physician, it is similar to other physician payments reported by manufacturers, such as consulting fees, royalties, and speakers' fees. Therefore, payments for these various activities could be compared and aggregated if manufacturers reported the portion of a research payment that was related to the physician's compensation. CMS should require manufacturers to separately report this information, and the agency should explore how manufacturers could obtain it.

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## **Conclusion**

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The Open Payments program has shed significant light on industry ties to over 600,000 physicians and over 1,000 teaching hospitals. The database contains information on financial interactions valued at \$7.3 billion in 2015, including payments for research, royalties, speaking fees, meals, and ownership interests in companies. However, the program should be expanded to include additional providers and organizations that have relationships with manufacturers. In addition, the Secretary should make information reported by manufacturers to the FDA about free drug samples available to oversight agencies, researchers, payers, and health plans. CMS should also require companies to report whether they are GPOs or manufacturers, the type of products they make, whether they are PODs, and the portion of a research payment that is related to physician compensation. These changes would make the data easier to use and increase the transparency of companies' financial relationships with providers and organizations. ■

## Endnotes

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- 1 The initial reporting thresholds for 2013 were \$10 for individual payments and \$100 for the aggregate amount transferred by a manufacturer to a recipient during the year. These thresholds are adjusted each year based on the change in the consumer price index.
- 2 CMS defines GPOs as companies that purchase, arrange for, or negotiate the purchase of medical products for a group of individuals or entities. A company that purchases a product for a single entity, rather than a group of entities, is not considered a GPO.
- 3 CMS released the initial files with data from 2015 in June 2016 and released updated files in January 2017. Because the total value of payments in the general payments file did not change significantly between June 2016 and January 2017, we used the June 2016 version of this file for the detailed analysis of general payments that appears in Table 6-4 (p. 193), Table 6-5 (p. 194), Table 6-6 (p. 195), and Table 6-7 (p. 195).
- 4 According to the regulations implementing the PDMA, drug samples may be requested only by practitioners licensed in their state to prescribe the requested drugs. The practitioner may authorize someone else to receive the drug samples and sign for them.
- 5 This recommendation would not apply to free drugs provided by manufacturers under prescription assistance programs to low-income, uninsured patients because drugs provided under these programs are not considered samples.

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