CHAPTER 5

# Public reporting of physicians' financial relationships

# RECOMMENDATIONS

**5-1** 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.

**COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

**5-2** 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 the related drug or device (if applicable); and
- year.

**COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

**5-3** 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.

**COMMISSIONER VOTES: YES 16 • NO 1 • NOT VOTING 0 • ABSENT 0**

**5-4** The Congress should require all hospitals and other entities that bill Medicare for services to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity (excluding publicly traded corporations). The Secretary should post this information on a searchable public website.

**COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

**5-5** The Congress should require the Secretary to submit a report, based on the Disclosure of Financial Relationships Report, on the types and prevalence of financial arrangements between hospitals and physicians.

**COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

CHAPTER 5

# Public reporting of physicians' financial relationships

## Chapter summary

Drug and device manufacturers have extensive financial relationships with physicians, academic medical centers, professional organizations, and other health care entities. These financial ties have led to many advances in medical research, technology, and patient care. However, they may also create conflicts between the commercial interests of manufacturers and physicians' obligation to do what is best for their patients.

Manufacturers inevitably interact with physicians, who play an important role in developing drugs and devices by overseeing clinical trials, inventing products, and providing expert advice. Moreover, manufacturers educate physicians about the use of their products through marketing efforts, training programs, and support of continuing medical education activities. Some relationships between manufacturers and physicians are explicitly commercial but others are more subtly so. There is evidence that at least some interactions are associated with rapid prescribing of newer, more expensive drugs and with physician requests that such drugs be added to hospital formularies (Wazana 2000). There is also concern that manufacturers' influence over

## In this chapter

physicians' education may skew the information physicians receive. The line between appropriate and inappropriate interactions may not always be clear, but there is no doubt that those relationships should be transparent. Transparency does not imply that all—or even most—of these financial ties undermine physician–patient relationships.

Requiring manufacturers to publicly report their financial relationships with physicians and other health care organizations should have several important benefits. It could discourage physicians from accepting gifts or payments that violate professional guidelines. It would help media and researchers shed light on physician–industry relationships and explore whether manufacturers and physicians are complying with industry and professional standards. In addition, CMS and other payers could use this information to examine whether physicians' practice patterns are influenced by their relationships with industry.

Given the potential benefits of public reporting, we recommend that the Congress mandate the reporting of comprehensive information on industry relationships with physicians and other health care entities and that the Secretary post this information on a public, searchable website.

## Recommendation 5-1

*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.*

**COMMISSIONER VOTES:**
**YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

## Recommendation 5-2

*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 the related drug or device (if applicable); and*
- *year.*

**COMMISSIONER VOTES:**
**YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

The reporting system should include the following parameters:

- Manufacturers should report payments or transfers of value to a recipient if the total value of payments made to the recipient exceeds $100 in a calendar year. This reporting threshold should be adjusted annually based on inflation.
- The following types of payments or transfers of value should be reported to the public database: gifts, food, entertainment, travel, honoraria, research, funding for education and conferences, consulting fees, investment interests, and royalties (but not discounts or rebates; product samples are addressed in Recommendation 5-3).
- Manufacturers should report the value, type, and date of each payment; the name, physician specialty (if applicable), Medicare billing number (if applicable), and business address of each recipient; and the name of the related drug, device, or supply (if applicable). Medicare billing numbers of physicians and other providers would be available only to researchers through a data use agreement with the Secretary.
- Manufacturers should be allowed to delay reporting of payments related to a clinical trial until the trial is registered on the National Institutes of Health website. Manufacturers should also be allowed to delay reporting of other payments related to the development of a product until the Food and Drug Administration approves or clears the product but no later than two years after the payment is made.
- This federal reporting law should preempt state reporting laws except those that collect information on additional types of payments or recipients.
- The Secretary should have the authority to assess civil penalties on manufacturers that fail to meet the law's requirements.
- The Secretary should monitor the impact of the law on potentially beneficial arrangements between physicians and manufacturers.

In 2005, pharmaceutical manufacturers provided free samples with a retail value of more than $18 billion to physicians and other providers (Donohue et al. 2007). Free samples may allow patients to start treatments sooner and help physicians evaluate a drug's effectiveness before a patient purchases

the full prescription. Samples also help some patients without insurance or with coverage limitations obtain medication. There are concerns, however, that samples may lead physicians and patients to rely on more expensive drugs when cheaper medications might be equally effective. In addition, several studies have found evidence that drug samples influence physicians' prescribing decisions. More information about the distribution of samples would enable researchers to study their impact on prescribing patterns and overall drug costs. It could also help payers and health plans target their counter-detailing programs, in which they provide information on drugs to physicians through educational visits. Therefore, the Commission recommends that the Congress require pharmaceutical manufacturers to report information about drug samples and their recipients. The Secretary would make this information available for research and legitimate business purposes through data use agreements.

## Recommendation 5-3

*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.*

**COMMISSIONER VOTES:**
**YES 16 • NO 1 • NOT VOTING 0 • ABSENT 0**

In addition to financial relationships with drug and device manufacturers, physicians may also have financial ties to health care facilities. There has been rapid growth in physician investment in hospitals and ambulatory surgical centers. Although physician ownership of facilities may improve access and convenience for patients, evidence suggests that physician-owned hospitals are associated with a higher volume of services within a market. Nevertheless, it is difficult for payers and researchers to obtain ownership information. The Commission recommends that the Secretary collect information on physician investment in hospitals and other health care providers and make it available in a public database, which would facilitate research on how physician ownership might influence patient referrals, quality of care, volume, and overall spending.

*The Congress should require all hospitals and other entities that bill Medicare for services to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity (excluding publicly traded corporations). The Secretary should post this information on a searchable public website.*

## Recommendation 5-4

**COMMISSIONER VOTES:**
**YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

Physicians have a wide variety of financial relationships with hospitals besides investment interests, yet we know very little about the prevalence of these arrangements and their impact on referral patterns, volume, quality, and cost. If information on these relationships were publicly available, payers and researchers could use it to examine these arrangements. Through the Disclosure of Financial Relationships Report, CMS plans to collect detailed data from a sample of hospitals on their ownership, investment, and compensation arrangements with physicians. We recommend that the Secretary use data from this survey to report to the Congress on the prevalence of various arrangements. This report could help guide future decisions on what types of physician–hospital relationships—in addition to ownership—should be publicly reported. The goal of hospital disclosure is to gain a better understanding of how physician–hospital relationships can affect the cost and quality of care. ■

*The Congress should require the Secretary to submit a report, based on the Disclosure of Financial Relationships Report, on the types and prevalence of financial arrangements between hospitals and physicians.*

## Recommendation 5-5

**COMMISSIONER VOTES:**
**YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

## Reporting physicians' financial relationships with drug and device manufacturers

With their authority to make decisions about diagnosis and treatment, physicians are the central actors in the health care delivery system. Several factors play a role in helping them determine which drug or device is best suited for a patient, such as their medical training and experience, information from peers and published literature, clinical guidelines, and ethical standards. As described in prior Commission reports, coverage and payment rules set by health plans and pharmacy benefit managers—such as formularies and tiered cost sharing—also influence which drug a patient receives (MedPAC 2005a, MedPAC 2004). In addition, manufacturers seek to affect physicians' treatment decisions through marketing and educational activities. This chapter focuses on the industry's interactions with physicians and the importance of making these financial ties more transparent.

As described in MedPAC's June 2008 report, financial relationships between physicians and pharmaceutical and device manufacturers are pervasive (MedPAC 2008a). Such interactions have led to many advances in medical research, technology, and patient care. However, they may also create conflicts between physicians' obligation to do what is best for their patients and the commercial interests of drug and device manufacturers. The line between appropriate and inappropriate interactions may not always be clear, but there is no doubt that these relationships should be transparent.

Medicare should be concerned about the potential for industry ties to influence physicians' treatment decisions because the program spent $48.6 billion on outpatient prescription drugs under Part D in 2007, about 11 percent of total benefits paid (Boards of Trustees 2008). In 2006, Medicare spent $10.6 billion on Part B drugs, which are primarily administered by physicians in their offices (MedPAC 2008b). Medicare also spends a significant amount on implantable medical devices, but it is difficult to estimate the precise value because the cost of a device is usually included in the payment rate for the associated surgery.

Industry and physician groups have developed voluntary guidelines to manage interactions between manufacturers and physicians, but compliance is not systematically measured and enforced, and there is evidence that some prohibited relationships continue to occur. Recently, a growing number of academic medical centers have adopted stringent rules for interactions with the industry. In addition, several states require drug companies to report their financial relationships with physicians. Most of these laws, however, have significant weaknesses.

Comprehensive information about physicians' financial relationships with drug and device manufacturers would help payers, plans, and the general public better understand how they affect physician practice patterns and health care costs. Public reporting could also dissuade physicians from participating in arrangements that violate professional standards. Therefore, the Commission recommends that the Congress create a national database on industry relationships with physicians and other health care entities. Our support for greater transparency does not imply that all—or even most—of these financial ties are inappropriate or undermine physician–patient relationships.

### Manufacturers' financial ties to physicians and other health care entities

According to a survey of physicians, state data, and legal cases, financial relationships between physicians and pharmaceutical and device manufacturers are pervasive (Campbell et al. 2007, Ross et al. 2007, U.S. Attorney 2007). A physician survey conducted in 2003 and 2004 found that more than three-quarters of physicians had received food or drug samples from drug manufacturers in the preceding year, and more than a quarter were paid for consulting, giving lectures, or enrolling patients in clinical trials (Campbell et al. 2007). In 2005, pharmaceutical companies spent nearly $7 billion on physician detailing (visits from sales representatives to physicians) and provided free samples with a retail value of more than $18 billion (Donohue et al. 2007).

Reports in the media and legal cases suggest that medical device manufacturers often pay physicians consulting fees and royalties to develop products, subsidize their trips to attend training and conferences, pay them to conduct postmarketing research, and sometimes offer them investment interests in their companies (Abelson 2006a, Abelson 2006b, Burton 2005, Zuckerman 2005).[1] For example, according to a recent Department of Justice investigation of four orthopedic device companies, "surgeons who had agreements with the companies were typically paid tens to hundreds of thousands of dollars per year for consulting contracts and were often lavished with trips" (U.S. Attorney 2007). Investigators estimate that these four manufacturers paid physician consultants more

than $800 million under 6,500 consulting agreements from 2002 through 2006 (Demske 2008).

Many relationships between physicians and drug and device manufacturers 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 products, and providing expert advice to manufacturers (Abelson 2005, Campbell 2007). According to a recent study, physicians were listed as inventors on almost 20 percent of medical device patents filed from 1990 through 1996 (Chatterji et al. 2008). Once a product is introduced, manufacturers' marketing efforts may lead to increased use of beneficial drugs (Powell 2007). In addition, device companies often provide important hands-on training to physicians in how to safely use new devices, which may involve paying physicians to conduct training programs and subsidizing their travel costs to attend programs at centralized locations (AdvaMed 2003).

However, these relationships may also influence physicians' behavior in ways that undermine their independence and objectivity. Studies have shown that physician interactions with the pharmaceutical industry are associated with greater willingness to prescribe newer, more expensive drugs and physician requests that such drugs be added to hospital formularies (Chren and Landefeld 1994, Watkins et al. 2003, Wazana 2000). Research on human behavior suggests that providing gifts, food, and other favors creates a sense of indebtedness in recipients that may influence their decisions in subtle, unconscious ways (Dana and Lowenstein 2003, Katz et al. 2003). There is evidence of this dynamic in health care. For example, in a study of physicians who went on trips sponsored by a drug company to learn about two new drugs, most of the physicians said that the subsidized travel would not affect their prescribing behavior (Orlowski and Wateska 1992). After the trips, however, use of the new drugs at their hospital increased much faster than use of the same drugs at comparable hospitals, which suggests that the physicians who received the trips may have had an unintentional bias in favor of the new drugs.

In addition to their relationships with individual physicians, manufacturers also provide significant financial support to academic medical centers (AMCs) for education and research and are a major source of funding for continuing medical education (CME) activities. According to the Association of American Medical Colleges (AAMC), "medical schools … have become increasingly dependent on industry support of their core educational missions," in the form of gifts, meals, and travel expenses for students and residents; distribution of free drug samples to physicians; and payments for faculty to participate in speakers' bureaus (AAMC 2008a). The AAMC has expressed concern that such support may affect the objectivity and integrity of teaching, learning, and practice, based on evidence that gifts and other favors influence the recipients' decisions (AAMC 2008a).

A literature review concluded that about one-quarter of biomedical researchers at academic institutions receive funding from the industry, and approximately two-thirds of such institutions hold equity in start-up ventures that sponsor research conducted by their faculty (Bekelman et al. 2003). Many collaborations between investigators and the industry have benefited patients by translating research discoveries into new drugs and devices, but in some cases these relationships may create conflicts of interest (AAMC 2008b).

The Commission has previously expressed concern that clinical research funded by manufacturers is not always objective and publicly available (MedPAC 2007). Research has found that industry-sponsored studies are significantly more likely to reach conclusions favorable to the sponsor than non-industry-sponsored studies (Als-Nielsen et al. 2003, Jørgensen et al. 2006). Research also suggests that bias in industry-sponsored drug trials is common and such bias often favors the sponsor's product (Bekelman et al. 2003, Heres et al. 2006, Peppercorn et al. 2007). Sources of bias include the dose of the drug studied, the exclusion of certain patients from the study population, and the statistics and research methods used. Industry sponsorship is associated with publication bias (publishing positive results more frequently than negative results) and withholding data (Bekelman et al. 2003). In a recent article, researchers found that a drug manufacturer withheld data from clinical trials showing that the drug being tested (rofecoxib) was associated with a higher risk of mortality (Psaty and Kronmal 2008).

Both pharmaceutical and medical device manufacturers sponsor CME activities for physicians and other health professionals. Industry support for CME activities accredited by the Accreditation Council for Continuing Medical Education (ACCME) quadrupled between 1998 and 2006, from $302 million to $1.2 billion, growing from one-third to one-half of total CME revenue (ACCME 2006). Many CME programs are organized by medical schools and physician membership organizations, but for-profit publishing and education companies account for one-third of total CME revenue for accredited events (ACCME 2006).

Several entities have developed rules and guidelines for industry sponsorship of CME activities. The Food and Drug Administration (FDA) has issued guidelines to help ensure the independence of CME programs sponsored by companies (U.S. Senate 2007). For example, the FDA advises that educational providers maintain control over program content and discuss all relevant treatments for a condition. Similarly, the Office of Inspector General (OIG) of the Department of Health and Human Services recommends that manufacturers separate their grant-making functions from their sales and marketing departments and that industry funding of CME programs not involve control over the selection of content or faculty (OIG 2003). The ACCME, which accredits CME programs for physicians, has also designed standards to maintain the independence of CME activities from commercial sponsors (ACCME 2004).[2] For example, accredited CME providers must ensure that industry sponsors do not influence the selection or presentation of content or the selection of teachers. In addition, CME faculty must disclose their relevant financial relationships with the industry to participants.

Despite these standards, however, an investigation by the Senate Finance Committee found that industry sponsors improperly influence some CME activities (U.S. Senate 2007). For example, one commercial sponsor was involved in selecting faculty and other activities and another sponsor influenced where and how many presentations were scheduled. More broadly, there is a concern that the growth of commercial support for CME may skew the selection of topics by CME providers, resulting in a disproportionate focus on drugs, devices, and diagnostic tests (Steinbrook 2008).

## Efforts to manage physician–industry relationships

In response to heightened legal and public scrutiny of physician–industry relationships, organizations such as the American Medical Association (AMA), American College of Physicians, Pharmaceutical Research and Manufacturers of America (PhRMA), Advanced Medical Technology Association (AdvaMed), and AAMC have produced voluntary codes of ethics (AAMC 2008a, AdvaMed 2003, AMA 1998, Coyle 2002, PhRMA 2008, PhRMA 2002).[3] These guidelines—described more fully in a prior Commission report—set boundaries in areas such as the provision of gifts and meals to physicians, consulting arrangements, support of medical education, and sales presentations (MedPAC 2008a). In addition, the OIG issued guidance to help drug manufacturers identify practices that may lead to abuse and described ways to reduce the risk of violating the anti-kickback statute (OIG 2003). This statute prohibits companies from making payments to induce or reward the referral of items or services reimbursed by federal health programs.

Some observers question whether the industry and professional guidelines are sufficiently stringent and point out that compliance is not systematically measured or enforced (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007).[4] There also is evidence that some interactions prohibited by voluntary codes continue to occur. For example, a physician survey conducted between November 2003 and June 2004 found that more than one-third of physicians had, in the prior year, been reimbursed by the pharmaceutical industry for costs associated with professional meetings or CME events and 7 percent had recently received tickets from manufacturers to cultural or sporting events (Campbell et al. 2007). According to the PhRMA ethical code, which became effective in July 2002, manufacturers should not pay physicians to attend CME or educational events, unless they are faculty or consultants, and should not give them tickets to sporting events (PhRMA 2002).

In response to concerns about industry ties to medical students and faculty, a group of prominent physicians and researchers proposed that AMCs adopt stricter policies to regulate potential conflicts of interest (Brennan et al. 2006). Many of this proposal's recommendations were reflected in a report recently approved by the AAMC, which urges AMCs to:

- prohibit physicians affiliated with AMCs from accepting any gifts (regardless of value), free meals, or payments to attend meetings from manufacturers;
- restrict sales representatives' access to physicians and students;
- centrally manage the distribution of drug samples (to reduce the influence of samples on prescribing patterns); and
- strongly discourage the participation of faculty in industry-sponsored speakers' bureaus (AAMC 2008a).

According to a recent article, at least 25 AMCs have adopted strong conflict-of-interest policies (Rothman and Chimonas 2008). For example, Stanford University Medical Center bans industry sales representatives from patient care areas, prohibits its faculty from publishing

articles that have been ghostwritten by the industry, and no longer accepts industry funding for specific CME programs (Pizzo 2008, Stanford University School of Medicine 2006).[5]

In addition to efforts by AMCs, some physician organizations have also implemented stringent rules for physician–industry interactions. For example, the Permanente Medical Group prohibits physicians who have a financial interest in a manufacturer from being involved in purchasing decisions regarding that company's (or a competitor company's) products and forbids its physicians from accepting payments, gifts of any value, and travel expenses from the industry (Permanente Medical Group 2004). In addition, the Wisconsin Medical Society recently adopted a policy that physicians should not accept gifts, food, or travel reimbursement from drug or device companies (Wisconsin Medical Society 2008).

## State reporting programs

In an effort to increase the transparency of physician–industry interactions, five states and Washington, DC, have enacted laws requiring drug companies to report their financial relationships with physicians (Table 5-1). These laws require that the manufacturer—not the health care provider—disclose payments. Most statutes mandate disclosure of the recipient's name, credentials, amount of payment, form of payment (e.g., grant, donation, in-kind), and purpose of payment (e.g., honoraria, consulting, education). Most states require reporting of gifts, meals, travel expenses, and consulting fees but exclude reporting of payments for clinical trials and research. All states except Massachusetts specifically exclude reporting of free drug samples provided to physicians for patient use. The threshold for individual payments that must be reported ranges from $25 (Vermont, Maine, and Washington, DC) to $100 (Minnesota and West Virginia). All states require drug companies to report payments and transfers of value to health care professionals, whereas three states and Washington, DC, also mandate reporting of payments to hospitals, pharmacists, and nursing homes.

Most state reporting laws have significant weaknesses. All statutes except the Massachusetts law exclude payments from device manufacturers. The information collected under most state laws is usually not easily available to the public. Three states (Vermont, Maine, West Virginia) and Washington, DC, compile an annual report of payments in aggregate (Lurie 2007). However, only Vermont makes this report available on the Internet. Minnesota's is the only state law implemented thus far that makes public the names of individual physicians who receive payments, but this information is not yet available in a searchable electronic format.[6] The Massachusetts law, which has not yet been implemented, will make all disclosed data publicly available on a searchable database. In a recent article, researchers found that Minnesota's and Vermont's data are not complete and are difficult to analyze because payment categories are vaguely defined (Ross et al. 2007). Because Vermont aggregates its disclosures by pharmaceutical manufacturer, researchers had to negotiate with the Vermont Attorney General and submit a Freedom of Information Act request to obtain data at the individual physician level. In addition, Vermont permits manufacturers to designate information as "trade secrets," which are kept confidential by the state. In 2007, 72 percent of total payments were designated as trade secrets (Vermont Office of the Attorney General 2008).

Although state reporting laws have limitations, reporters and researchers have used information collected under the Minnesota law to shed light on potential conflicts of interest. Several recent articles have explored the financial relationships of physicians who serve on formulary and clinical guideline committees and prescribe expensive new drugs. For example, reporters used data from Minnesota to show that some physicians who coauthored clinical guidelines received significant funding from companies whose drugs were affected—in one case, a physician who served on panels that developed guidelines for the use of hypertension and cholesterol drugs received more than $200,000 from a manufacturer of these drugs (Harris and Roberts 2007).[7]

## Designing a national public reporting system

In this section, we consider the advantages, limitations, and costs of collecting national data on industry relationships with physicians and other health care entities. We then describe our recommendations for a public reporting law.

### Advantages of a national reporting system

A national public reporting system could have a number of potential benefits, including:

- encouraging physicians to reflect on the propriety of their relationships with the industry,
- helping the media and researchers shed light on physician–industry interactions and identify potential conflicts of interest,

**TABLE 5–1** **Disclosure requirements in state reporting programs**

| Disclosure requirement | MN | DC | VT | ME | WV | MA |
|---|---|---|---|---|---|---|
| Year of legislation | 1993 | 2001 | 2003 | 2003 | 2004 | 2008 |
| Disclose payment amounts greater than | $100 | $25 | $25 | $25 | $100 | $50 |
| Provide educational programs/materials | Yes | Yes | "any gift, fee, payment, subsidy or other economic benefit provided in connection with…marketing activities" | Yes | "gifts, grants, or payments of any kind" which are "provided directly or indirectly" | "any fee, payment, subsidy, or other economic benefit"** |
| Provide food/entertainment/payments | N/A* | Yes | | Yes | | |
| Pay travel expenses | N/A* | Yes | | Yes | | |
| Pay honoraria/consulting fees | Yes | Yes | | Yes | | |
| Pay for clinical trials/research | Yes | No | No | No | No | |
| Provide free samples for patients | No | No | No | No | No | |
| Sponsor CME | Yes | Yes | Yes | Yes | No | |
| Provide drug rebates/discounts | N/A* | Yes | No | Yes | No | |
| Disclose payments made to | Practitioners | Health care professionals, plans, pharmacies, hospitals, nursing facilities, and clinics | Physicians, hospitals, nursing homes, pharmacists, anyone authorized to prescribe, dispense, or purchase prescription drugs | Health care professionals, plans, pharmacies, hospitals, nursing facilities, and clinics | Prescribers (physicians and other professionals) | Physicians, hospitals, nursing homes, pharmacists, plan administrators, anyone authorized to prescribe, dispense, or purchase drugs or devices |
| Is information publicly available? | Yes | No | Yes (aggregate payments only) | No | No | Yes (after program is implemented in 2009) |

Note: N/A (not applicable), CME (continuing medical education).
*These payments are banned under Minnesota law if in excess of $50.
**The Massachusetts law does not list specific payment categories. It is unclear which categories will be included or excluded when the program is implemented in 2009.

Source: Lurie 2007, MedPAC analysis of state laws.

- enabling payers and health plans to examine whether and to what extent industry ties influence physicians' practice patterns,
- allowing AMCs to verify the financial interests of their clinical investigators,
- enabling hospitals to check whether physicians who recommend the purchase of specific drugs and devices have financial ties to the manufacturer, and
- facilitating the refinement of ethical standards by industry and physician organizations by providing information on the prevalence of various arrangements (MedPAC 2008a).

Requiring manufacturers to publicly report the payments they make to physicians might encourage physicians to critically examine their relationships with the industry. The American College of Physicians' code of ethics recommends that physicians ask themselves what their patients and colleagues would think about an arrangement with a manufacturer and how they would feel if the relationship were disclosed through the media (Coyle 2002). The possibility that colleagues, patients, and the general public might learn about their financial relationships with the industry could give physicians an incentive to carefully consider these questions, perhaps discouraging arrangements that are not consistent with professional standards.

The media and researchers could draw on national data to investigate potential conflicts of interest related to clinical guideline committees, formulary committees, prescribing practices, and clinical trials. As discussed earlier, recent articles have used data from Minnesota's public reporting law and other sources to shed light on physician–industry interactions.

A public reporting system would enable payers, plans, and researchers to examine whether physicians' financial relationships with manufacturers affect their practice patterns (Campbell 2008). For example, do financial ties to companies influence which drugs physicians prescribe and which devices they use? Do patients treated by physicians with certain types of industry relationships have higher costs for an episode of care? CMS and researchers could link information on physician–industry relationships to Part D claims data to evaluate the impact of these interactions on prescribing practices. Some plans in Minnesota are using state information on physician–industry relationships to review physician prescribing behavior (Wyckoff 2008).

Public information on physician–industry relationships would allow AMCs to verify the financial disclosures of their clinical investigators. Institutions—such as AMCs—applying for Public Health Service grants must obtain financial disclosure statements from investigators who plan to participate in the research and must manage, reduce, or eliminate significant financial interests that could be affected by the research (42 CFR 50, subpart F). The institution must also report the existence of conflicting financial interests to the government agency that awards the grant and assure the agency that the interest has been managed, reduced, or eliminated. Institutions rely on researchers to honestly disclose their financial interests.

In some cases, however, it appears that researchers did not fully report the extent of their financial relationships with manufacturers. According to a recent article, for example, congressional investigators found that three child psychiatrists who were awarded federal research grants received several hundred thousand dollars in consulting fees from drug companies, which they failed to report to their university (Harris and Carey 2008). In another case, investigators learned that a psychiatrist who was in charge of a large federal research grant failed to report $1.2 million in consulting fees he received from a drug manufacturer (Harris 2008). It is difficult for AMCs to identify and manage financial relationships if clinical investigators do not fully report them.

### Limitations and costs of a national reporting system

It is also important to recognize the limitations and potential costs of a public reporting system:

- Information on financial relationships may be of limited use to individual patients.
- Public disclosure might discourage beneficial arrangements between physicians and industry.
- Mandatory reporting would not eliminate conflicts of interest.
- A federal reporting law would impose compliance costs on manufacturers (to report financial information) and administrative costs on the government (to implement and enforce the law).

It is unclear whether information about physicians' financial ties to drug and device manufacturers would help patients make better medical decisions because patients frequently lack medical expertise and usually trust their physicians. Thus, they are unlikely to know how their physicians' financial interest could bias their advice or whether their physicians' recommendations are appropriate (Cain et al. 2005). In addition, physician disclosure to patients may lead both parties to believe the disclosed relationship will not bias physician decision making (Brennan et al. 2006, Cain et al. 2005). However, patients may benefit if public reporting leads to more appropriate use of drugs and devices.

There are concerns that a public reporting system might discourage physicians and other providers from having legitimate research, consulting, education, and training arrangements with manufacturers that benefit patients

and pose little risk of abuse. For example, AdvaMed has warned that a reporting system that does not allow companies to explain the context of their payments to physicians could discourage physicians from participating in efforts to develop new devices (White 2008). Thus, a reporting system should allow companies to report clarifying details about payments. In addition, the Secretary should monitor the impact of a public reporting law on potentially beneficial arrangements between manufacturers and physicians, such as industry funding of clinical research, medical education, and physician training in the use of medical devices.

Some observers have noted that, although public reporting would shed light on physician–industry interactions, it would not eliminate potential conflicts of interest (Prescription Project 2007). Physicians would still be able to accept gifts, consulting fees, meals, royalties, and other payments from manufacturers. As discussed earlier, however, public disclosure could discourage physicians from accepting payments that violate professional guidelines. In addition, a public database could help payers and researchers examine the prevalence of different types of relationships and their impact on clinical decisions, which could inform future efforts to devise rules in this area.

Manufacturers would incur costs to comply with a federal reporting law. However, a comprehensive federal law that discourages states from enacting their own reporting laws may reduce companies' overall compliance costs; it should be less costly to comply with a single reporting requirement than multiple requirements.

The government agency that would implement a potential reporting law would require resources to develop rules, collect data, maintain an electronic database, and enforce the law. According to two states with public reporting laws (Minnesota and Vermont), the cost of collecting information from the industry and posting it on a website is minimal (Lunge 2008). However, these states do not have databases that are searchable electronically, which might increase costs. We also lack data on costs incurred by states to monitor and enforce compliance with their reporting laws.

### Recommendations for a public reporting system

In this section, we make two recommendations for a comprehensive federal law to require that drug and device companies publicly report their financial relationships with physicians and other entities. The following subsections address several important design issues:

- Who should report the information?
- How comprehensive should the public reporting system be? For example, which types of manufacturers should be included? Should payments to academic medical centers and other organizations be reported?
- What should the dollar threshold be for reporting payments?
- What types of relationships (e.g., gifts, meals, consulting deals, investment interests) should be reported?
- What type of information about the payments and recipients should be disclosed?
- Should manufacturers be required to report payments related to the development of new products?
- Should a federal reporting law preempt state laws?
- How should the information be made accessible to the public?
- What implementation questions need to be addressed?

**Manufacturers should report payment information** The first question is whether the manufacturers or the individuals and entities that receive payments should be required to report payment information. In most cases, such as journal articles and clinical trials, the recipients of payments are required to disclose their financial ties. Under a comprehensive reporting system, however, it is more reasonable to have manufacturers submit the information because there are many fewer manufacturers than there are physicians and other providers. Larger organizations can realize economies of scale in developing systems to track and report payment data. It should also be easier for the government to monitor compliance among a smaller number of entities. Finally, many manufacturers have gained experience tracking and reporting payments under state reporting laws.

**The reporting system should apply to a broad set of manufacturers and recipients** Policymakers would need to determine which types of manufacturers should be subject to a public reporting law and which recipients of industry payments should be included. Although most state reporting laws apply only to drug manufacturers,

a comprehensive federal system should also include manufacturers of biological products, medical devices, and medical supplies because these companies may also have extensive relationships with physicians. A comprehensive law should apply to small as well as large companies to achieve a level playing field. It should include subsidiaries of manufacturers to prevent companies from evading reporting requirements by setting up subsidiaries to pay physicians. The law should also apply to wholesale distributors of drugs, devices, and supplies because they may have financial ties to physicians.

Manufacturers have financial relationships with individuals and entities that deliver health care services, discover and develop new treatments, and educate patients and practitioners. To enhance the public's understanding of these financial ties, companies should be required to report the payments they make to a broad set of recipients:

- physicians, physician groups, and other prescribers (e.g., nurse practitioners and physician assistants);
- pharmacies and pharmacists;
- health plans, pharmacy benefit managers, and their employees;
- hospitals and medical schools;
- organizations that sponsor CME;
- patient organizations; and
- professional organizations.

The reporting law should include health plans, pharmacy benefit managers, and their employees because they may have financial relationships with manufacturers, such as research contracts. The law should include hospitals and medical schools because drug and device companies provide them with significant support for education and research.

Because industry funding accounts for half of total revenue for CME providers accredited by the ACCME, we recommend including grants to CME organizations. The ACCME requires CME providers to disclose their commercial support to participants, but this information is not publicly available except in a highly aggregated form (ACCME 2004). The ACCME reports total commercial support by type of CME organizer (e.g., medical schools, hospitals, physician membership organizations, publishing and education companies). However, it does not separately report funding by industry type (e.g., drug manufacturers or device manufacturers) or by company name. A public reporting system would capture this information and enable researchers to track industry support of CME in much greater detail. For example, researchers would be able to examine the growth of CME funding by cardiac device manufacturers for events at medical schools.

Because patient and professional organizations may receive grants from drug and device companies for education, research, and fellowships, these payments should also be reported. Although at least one manufacturer has begun disclosing this information voluntarily, and other companies have pledged to do so, it is unclear whether all companies will follow suit and whether the data will be provided in a format that is easily accessible and searchable (see text box).

Many physicians and organizations have productive, beneficial relationships with manufacturers. Therefore, the Secretary should monitor the impact of a reporting law on potentially beneficial arrangements, such as industry funding of clinical research, medical education, and hands-on physician training in the use of devices.

**Threshold for payments that should be reported** To balance the reporting burden on companies and the number of records in a public database with the goal of collecting comprehensive information, payments should be reported when the total value of payments from a manufacturer to a recipient during a year exceeds $100. When manufacturers calculate whether this threshold has been reached, they should include all payments or transfers of value. This reporting threshold should be adjusted annually based on inflation. Once this threshold is reached, all payments or transfers of value to the recipient should be disclosed, regardless of the amount. We do not support a per payment reporting threshold because that could lead companies to divide a single payment or gift into smaller individual payments to avoid reporting this information. A federal law that would collect data on all payments above $100 (regardless of size) is one factor we consider in supporting preemption of state laws that collect information on the same types of payments and recipients as a federal law (see discussion below).

**Types of payments that should be reported** A public reporting system should collect detailed information on a wide variety of financial relationships between manufacturers and physicians as well as other entities. These relationships include gifts, food, entertainment, travel, honoraria (including speakers' fees), research, funding for medical education and conferences, consulting

## Some manufacturers plan to voluntarily disclose educational grants and other payments

Some drug manufacturers have recently decided to publicly disclose their educational grants to organizations and some of their payments to physicians. Eli Lilly began voluntarily disclosing its educational grants and charitable contributions on its website in 2007 (Eli Lilly 2008). These disclosures include the name of the recipient, amount, and program title. Recipients include physician membership organizations, patient advocacy groups, academic institutions, and continuing medical education companies. Beginning in 2009, Eli Lilly also intends to list on its website payments to physicians that exceed $500 for speaking and consulting services and plans to eventually disclose payments for travel, entertainment, and gifts (*Kaiser Daily Health Policy Report* 2008). Merck has also announced that it will disclose speakers' fees paid to physicians (*New York Times* 2008). In addition, a dozen drug and device manufacturers intend to publicly disclose their medical education grants; some of these companies also plan to disclose payments to patient advocacy groups (Freking 2008). ■

fees, investment interests in a manufacturer, and product royalties. Many of these categories are included in at least some existing state laws (Table 5-1, p. 325). The categories of financial relationships should be clearly defined and standardized so that the information is consistently reported.

However, we exclude reporting of discounts, rebates, and free drug and device samples for patient use from Recommendation 5-1. Discount and rebate information is considered very proprietary, and public reporting of discounts and rebates would make it difficult for purchasers to negotiate price reductions. In addition, CMS collects discount and rebate data for Part B drugs on a confidential basis to calculate Medicare payment rates. We make a separate recommendation related to reporting free drug samples on p. 335.

**Manufacturers should report detailed information about payments and recipients** To facilitate in-depth analyses of the industry's relationships with physicians and other health care entities, manufacturers should report detailed information about payments and recipients, including:

- the value, type, and date of each payment;
- the name, business address, physician specialty (if applicable), and Medicare billing number (if applicable) of each recipient; and
- the name of the related drug, device, or supply (if the payment was related to marketing, research, or education about a specific product).

Collecting the name, address, and physician specialty of each recipient would allow users to calculate total payments received by a physician, organization, or specialty. Collecting the Medicare billing numbers—known as National Provider Identifiers (NPIs)—of recipients who participate in Medicare would permit researchers to link information on providers' financial relationships to Medicare claims data. Manufacturers can obtain NPIs and physicians' specialties through a public website. As we discuss later, the Secretary should provide NPIs only to researchers who sign a confidentiality and data use agreement.

If the payment was related to marketing, research, or education about a specific product, the company should also report the name of the product. This information would enable research on payments connected to specific drugs, devices, and supplies. This particular requirement should apply only to products that have been approved or cleared by the FDA. Companies should be allowed to report additional clarifying details about the context for a payment (e.g., to explain that it was related to training other physicians in the proper use of an implantable device).

Each payment made to each recipient should be itemized to allow for analyses of the size and frequency of individual payments. For example, it would be useful to track how frequently manufacturers provide gifts and meals to physicians and to examine whether more frequent interactions influence prescribing patterns.

To keep the database up to date, the law should require that companies report information electronically on an

annual basis. If recipients notify manufacturers of errors in the data they have submitted to the Secretary, companies should be required to investigate and correct the errors in a timely fashion.

**Guidelines for reporting payments related to product development** Policymakers would need to determine whether to allow companies to withhold information that they deem to be proprietary. On the one hand, companies may wish to shield details of their research, product development, education, and marketing programs from competitors. For example, public disclosure of certain payments to physicians could make it difficult for manufacturers to keep their product development efforts confidential. On the other hand, the public has a legitimate interest in learning about the industry's financial relationships with physicians. A recent analysis of the role of physicians in medical device innovation recommended that a public reporting law include physicians' financial relationships with manufacturers during the discovery stage of a product's life cycle (Chatterji et al. 2008). In addition, a policy that would allow manufacturers to withhold any information they designate as proprietary could significantly restrict the amount of data available to the public, as evidenced by the experience with the Vermont reporting law. Vermont allows manufacturers to prevent the public release of information by designating it as a "trade secret," but this policy resulted in 72 percent of payments being designated as trade secrets in 2007 (Vermont Office of the Attorney General 2008).

To balance these considerations, the Commission recommends that a reporting law allow delayed reporting of payments that are related to the development of new products. First, we support allowing manufacturers to withhold information on payments related to clinical trials until the trial is registered on a public website maintained by the National Institutes of Health (http://clinicaltrials.gov/). Manufacturers are legally required to register Phase II and Phase III clinical trials of drugs and devices on this website.[8] Second, reporting of other payments related to new product development—such as paying physicians to serve as clinical advisers or licensing a product invented by a physician—could be linked to FDA approval or clearance of the product. If, however, a manufacturer makes payments related to a new product that is never approved or cleared, these payments would remain hidden from the public. Thus, there should be a time limit on how long reporting may be delayed. In other words, reporting of payments related to the development of a new product (other than for clinical trials) could be delayed until the earlier of FDA approval or clearance or the time limit is reached. We believe a two-year time limit is reasonable.

**A federal reporting law should preempt equally or less stringent state laws** An important issue to address is whether a federal reporting law should preempt existing or future state reporting laws (five states and Washington, DC, currently have such laws).[9] On the one hand, preemption would reduce the compliance costs for manufacturers because they would need to comply with only one uniform federal law rather than several state laws (AdvaMed 2008). In addition, a single source of information could reduce confusion among users. Because a federal law with a relatively low aggregate reporting threshold would collect data on most payments, there would be less need for individual state laws. On the other hand, preemption would limit state autonomy and the potential for the federal government to learn from state laws. We support preempting existing and future state laws that collect data on the same types of payments and recipients as a federal law, even if a state law has a lower aggregate reporting threshold than the federal law (we recommend a $100 threshold for a federal law). For example, a state law that required companies to report all gifts worth $10 or more would be preempted. If, however, a federal law excluded reporting of discounts and rebates, a state law could collect this information.

**Making the data useful and easily accessible** Making the data as useful as possible and easily available to the public are significant issues, given the difficulties of accessing information collected under state laws. In a recent article, for example, researchers found that data collected by Minnesota and Vermont were not complete and were difficult to analyze because payment categories are vaguely defined (Ross et al. 2007). Minnesota is currently the only state that makes public the names of individual physicians who receive payments, but this information is not in a searchable electronic format.

To further the goal of accessibility, the Secretary should post payment information on the Internet in an electronic format that is easy to search and download. The website should allow users to search for and aggregate payments by manufacturer (or distributor), recipient, physician specialty (if applicable), name of the related drug or device, geographic location of recipients, type of payment, and year. As described earlier, researchers should be able to obtain each provider's NPI through a data use agreement process. Analysts could use the NPI to link information on industry payments to a provider to

Medicare claims data. Through such a linkage, researchers could examine whether gifts, meals, consulting fees, and other payments influence the type and amount of drugs physicians prescribe and the volume of surgical procedures they perform.

**Implementing a federal reporting law** The Commission believes that the Congress should allow the Secretary to choose which agency should administer a public reporting law. Although the FDA could be an option to implement the law because it regulates products made by drug and device manufacturers, the agency currently faces severe resource constraints and growing demands (Subcommittee on Science and Technology 2007). Similarly, CMS could be an appropriate choice because Medicare and Medicaid are major purchasers of drugs and devices, but CMS also has funding and staffing constraints. A third option would be the OIG because it has responsibility for investigating financial relationships that may violate the anti-kickback statute. States with reporting laws delegate this responsibility to various types of agencies. In Minnesota, for example, the supervisory agency is the Board of Pharmacy, whereas the state attorney general supervises the reporting law in Vermont.

The Secretary will require resources to develop rules for a reporting system, maintain an electronic database, monitor the impact of the law on financial relationships, and enforce the statute. According to two states with public reporting laws (Minnesota and Vermont), the cost of collecting information from the industry and posting it on a website is minimal (Lunge 2008). However, these states do not have databases that are searchable electronically, which would increase costs. We also lack data on costs incurred by states to monitor and enforce compliance with their reporting laws. The Congress should provide the Secretary with adequate resources to implement a public reporting system. The Congress should also give the Secretary the authority to assess civil penalties on manufacturers that fail to meet the law's reporting requirements.

## RECOMMENDATION 5-1

**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.**

As described earlier, the public reporting law should be designed as follows:

- Manufacturers should report payments or transfers of value to a recipient if the total value of payments made to the recipient exceeds $100 in a calendar year. This reporting threshold should be adjusted annually based on inflation.
- The following types of payments or transfers of value should be reported in a public database: gifts, food, entertainment, travel, honoraria, research, funding for education and conferences, consulting fees, investment interests, and royalties (but not discounts or rebates; product samples for patient use are addressed in Recommendation 5-3).
- Manufacturers should report the value, type, and date of each payment; the name, physician specialty, Medicare billing number, and business address of each recipient; and, if the payment is related to a specific drug, device, or supply, the product's name. Medicare billing numbers of physicians and other providers would be available only to researchers through a data use agreement with the Secretary.
- Manufacturers may choose to delay reporting of payments related to clinical trials until the trial is registered on the National Institutes of Health website. Manufacturers may also choose to delay reporting of other payments related to the development of a new product until the FDA approves or clears the product, but no later than two years after the payment is made.
- The federal reporting law should preempt existing and future state reporting laws except those that collect information on additional types of payments or recipients.
- The Secretary should have the authority to assess civil penalties on manufacturers that fail to meet the law's reporting requirements.
- The Secretary should monitor the impact of the law on potentially beneficial arrangements between physicians and manufacturers.

## RATIONALE 5-1

The intent of a public reporting law is to improve the appropriate use of drugs and devices by increasing the transparency of the industry's financial ties to physicians and other health care entities. Greater transparency does not imply that all—or even most—of these financial ties are inappropriate or undermine physician–patient relationships. Requiring manufacturers to report information on their financial relationships with physicians and other entities could discourage arrangements that violate industry and professional guidelines. A public reporting system also would help media and researchers shed light on physician–industry interactions. Payers (including Medicare) and health plans could use this information to examine whether and to what extent industry ties influence the drugs physicians prescribe and the procedures they perform. In addition, industry and physician organizations could use public reporting to refine their ethical standards.

## IMPLICATIONS 5-1

### Spending

- There would be administrative costs for the government to implement and enforce the reporting law.
- Medicare expenditure implications are indeterminate. Although the Congressional Budget Office (CBO) was unable to estimate the impact of public reporting on Medicare spending, it believes that disclosure has the potential to reduce Medicare spending over time (CBO 2008).

### Beneficiary and provider

- Although the information may be of limited direct use to beneficiaries, they would benefit indirectly if public reporting leads to more appropriate use of drugs and devices.
- Hospitals, AMCs, and health plans should benefit from a source of information on physicians' financial interests.
- Manufacturers will incur costs to comply with a reporting law; however, if a uniform federal law replaces multiple state reporting laws, manufacturers' overall compliance costs should decline.
- Physicians and other providers who receive large payments from manufacturers may receive public scrutiny.

## RECOMMENDATION 5-2

**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 the related drug or device (if applicable); and**
- **year.**

## RATIONALE 5-2

To maximize the accessibility and usability of data submitted by manufacturers, the Secretary should post payment information on the Internet in a format that is easy to search and download. The public should be able to search and aggregate the data in a variety of ways.

## IMPLICATIONS 5-2

### Spending

- There would be administrative costs for the government to establish and maintain a public database.
- Medicare expenditure implications are indeterminate. Although CBO was unable to estimate the impact of public reporting on Medicare spending, it believes that disclosure has the potential to reduce Medicare spending over time (CBO 2008).

### Beneficiary and provider

- Although the information may be of limited direct use to beneficiaries, they would benefit indirectly if public reporting leads to more appropriate use of drugs and devices.
- Hospitals, AMCs, and health plans should benefit from access to information submitted by manufacturers.
- Physicians and other providers who receive large payments from manufacturers may receive public scrutiny.

## Collecting data on free drug samples

The pharmaceutical industry provides free samples worth billions of dollars to providers every year; according to a recent estimate, the retail value of free samples equaled $18.4 billion in 2005, far more than the $6.8 billion

spent by the industry on visits from sales representatives to physicians (Donohue et al. 2007). According to a physician survey, 78 percent of physicians received samples in the last year (Campbell et al. 2007). Although samples clearly offer benefits for many patients, they may also lead physicians and patients to rely on more expensive drugs when cheaper products may be equally effective. More information about the distribution of samples would enable researchers to study their impact on prescribing patterns and overall drug costs. Such data could also help payers and health plans target their counter-detailing programs. Therefore, the Commission recommends that the Congress require manufacturers and distributors of pharmaceuticals to report information about drug samples and their recipients. The government would make this information available under data use agreements for research and legitimate business purposes.

### Drug samples benefit patients but may also influence prescribing decisions

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. About 10 percent of uninsured patients reported receiving at least one free drug sample in 2003 (Cutrona et al. 2008).[10] According to beneficiary focus groups conducted by the Commission in 2007, some beneficiaries rely on free samples when they reach the coverage gap under Medicare Part D (Hargrave et al. 2008).

On the other hand, some researchers have pointed out that free samples may increase total drug spending by leading to the use of more expensive drugs instead of cheaper generics that may be equally effective (Brennan et al. 2006, Miller et al. 2008, Piette 2005). Several studies have found evidence that drug samples influence physicians' prescribing decisions. In one study, researchers examined how the availability of free samples influenced physicians' prescribing practices in three clinical scenarios (Chew et al. 2000). Of the physicians who said that they would provide free samples to patients, between 49 percent and 95 percent (depending on the clinical scenario) reported that they would dispense a sample that differed from their preferred drug choice. Another study found that physicians who received samples of a new drug were more likely to prescribe it (Peay and Peay 1988). According to a survey of physicians, more than half believed that accepting drug samples would be likely to affect their prescribing behavior (Gibbons et al. 1998). In another survey, one-third of obstetrician-gynecologists said that accepting samples would probably influence their prescribing decisions (Morgan et al. 2006).

### Potential uses of data on drug samples

Comprehensive data on the distribution of drug samples would facilitate further research on their effects and could also help payers and plans target their counter-detailing efforts. Although the studies cited above offer evidence that free samples influence prescribing behavior, they are limited because they rely on surveys in which physicians report their acceptance of samples and their treatment decisions. An independent source of data on drug samples, combined with information from claims on prescriptions and other health care services, would enable far more detailed research on the impact of samples. Researchers could examine questions such as:

- Does the use of samples vary by practice setting (e.g., office based vs. hospital based), physician specialty, patient mix, or geographic location?
- Do practices that accept samples prescribe more expensive medication? Do they adopt newer drugs faster than other practices?
- Do the patients of practices that accept samples spend more on drugs or other health care services? Are they more likely to comply with treatment regimens? Are they more likely to reach the Part D coverage gap? Do they have better outcomes?
- How does the distribution of samples influence overall spending trends for newer versus older drugs?

Several payers and health plans use counter-detailing programs (also known as academic detailing) to provide information on drugs to physicians through educational visits by clinicians (Hoadley 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. Some peer-reviewed studies have found that counter-detailing efforts reduce the use of targeted drugs and reduce spending (Avorn and Soumerai 1983, Yokoyama et al. 2002). Payers and plans might be able to 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 are required to keep records of samples

Under the Prescription Drug Marketing Act of 1987, manufacturers and distributors are required to keep internal records of the drug samples distributed to practitioners and pharmacies of hospitals and other entities. To distribute samples by mail or by sales representatives (also known as detailers), companies must maintain written request forms and receipts from the practitioners who receive the samples (21 CFR 203.30–203.31). The request form must include:

- the name and address of the practitioner who requests the samples;
- the practitioner's state license or authorization number (and, in some cases, the Drug Enforcement Administration number);
- the name, strength, and quantity of the drug samples being requested;
- the name of the manufacturer; and
- the date of the request.

If the samples are distributed to a pharmacy, the request must also contain the pharmacy's name and address. The written receipt must include similar information about the recipient and samples. If the samples are received by a physician's office, the records contain only the name of the practitioner who requested and signed for the delivery of samples, rather than the names of all physicians in the practice who may dispense samples to patients.[11] Manufacturers and distributors must retain these requests and receipts for three years and make them available to the FDA and other government agencies upon request.

Samples distributed by sales representatives are subject to an additional requirement that does not apply to samples sent by mail: Manufacturers must maintain an inventory of these samples and conduct an annual reconciliation process that documents their distribution (21 CFR 203.31). The reconciliation report must include each recipient's name and address; the drug sample's name, dosage, and number of units; and the date of shipment. Although the FDA and other government agencies have the right to request these records to ensure that companies are following the law, there is no requirement to report this information to the government on a regular basis (FDA 1999).

### Reporting information on samples to the Secretary

Much of the data that manufacturers are currently required to collect on samples that are mailed or distributed by representatives should be reported to the Secretary, including:

- the name and address of the practitioner (or entity) who receives the samples;
- the name, dosage, and quantity of the drug samples;
- the name of the manufacturer; and
- the date of delivery.

However, to make this information more useful for research, the companies should also collect and report additional data on sample recipients. Because manufacturers collect the name and address of only the practitioner who requests and receives the samples, it will be difficult to examine the use of samples by practices. Therefore, for samples distributed to physicians, companies should also have to collect and report the name and specialty of the physician practice. To enable researchers to link data on samples to Medicare claims data, manufacturers should also collect and report the Medicare billing number of the practitioner or entity that receives the samples. We expect that this additional information on practice name, specialty, and billing number would be self-reported by the sample recipients and should not have to be verified by the manufacturers. We recognize that, even with this additional information, it will still be difficult to examine the use of samples at the physician level because we will not have data on the samples dispensed by individual physicians. Nevertheless, researchers could analyze the distribution of samples at the practice, specialty, and geographic level.

The Secretary should make the data on samples available for research and legitimate business purposes (e.g., counter-detailing) to entities that sign confidentiality and data use agreements. To foster legitimate use of such data, the process for requesting the information should not be overly restrictive.

We recognize that manufacturers would have to redesign their data collection systems to report comprehensive information on samples to the government. For example, manufacturers would have to revise their written request and receipt forms to collect additional data on sample recipients (e.g., Medicare billing numbers). In addition, companies would have to create and populate a database

on samples to submit reports to the government. To accomplish this task, manufacturers' inventories of samples distributed by sales representatives could be expanded to include samples sent by mail.

The following recommendation differs from Recommendation 5-1 because manufacturers would not be required to report the value of free samples and because data on samples would be available only for research and legitimate business purposes, rather than being posted on a public website.[12]

**RECOMMENDATION 5-3**

**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.**

**RATIONALE 5-3**

The pharmaceutical industry provides free drug samples worth billions of dollars to providers every year. Although samples clearly offer benefits for many patients, they may also lead physicians and patients to rely on more expensive drugs when cheaper products may be equally effective. Requiring pharmaceutical manufacturers to report information on free samples to the Secretary would enable in-depth research on the impact of samples on physicians' prescribing patterns and overall drug spending. Payers and health plans could also use the information to improve their counter-detailing programs.

**IMPLICATIONS 5-3**

### Spending

- There would be administrative costs for the government to collect information on free samples and make it available for research and other purposes.
- Medicare expenditure implications are indeterminate.

### Beneficiary and provider

- Beneficiaries may indirectly benefit from research evaluating the impact of free samples on physicians' prescribing behavior and overall drug spending.
- Although manufacturers currently collect much of this information, they will incur administrative costs to collect the additional data and report the data to the government in a standard format.

## Reporting physicians' financial relationships with hospitals and other providers

Physician investment in hospitals, ambulatory surgical centers (ASCs), and other providers serving Medicare patients has grown rapidly. Although physician ownership of facilities may improve access and convenience for patients, there is evidence that the presence of physician-owned hospitals is associated with a higher volume of services in a market (MedPAC 2006, Nallamothu et al. 2007). In addition, physician ownership of ASCs may influence referral patterns (Gabel et al. 2008). Nevertheless, it is difficult for payers and researchers to obtain information about these financial ties. Collecting information on physician investment in hospitals and other entities and making it available in a public database would enable further research on how these financial ties might influence patient referrals, quality of care, volume of services, and cost of care.

The number of physician-owned specialty hospitals more than tripled from 2002 to 2008, from 46 to roughly 175 (CMS 2008c, CMS 2006, MedPAC 2005b). While physician-owned specialty hospitals are small and represent only 4 percent of the nation's hospitals, they represent roughly 40 percent of all the hospitals formed during the last five years. The number of Medicare-certified ASCs—most of which have at least some physician ownership—grew by more than 60 percent from 2000 to 2007, from about 3,000 to almost 5,000 (ASC Coalition 2004, MGMA 2006, MedPAC 2008b).[13] There has also been an increase in joint venture facilities owned by physicians and hospitals, such as imaging centers and cardiac catheterization labs (Berenson et al. 2006). The Commission supports certain physician–hospital arrangements, such as shared savings (also known as gainsharing), that have the potential to improve the coordination of care and control the volume and cost of services (MedPAC 2008a). However, the Commission has expressed concerns that some physician–hospital relationships may be designed to increase the volume of services without improving the quality and coordination of care (MedPAC 2008a).

## Reporting physician investment information

Hospitals and other providers have to comply with CMS rules that require disclosure of physician ownership, but none of the required disclosures is comprehensive or available to the general public.

### Current rules for reporting ownership information to CMS

Under federal disclosure requirements, hospitals and other entities such as ASCs, independent diagnostic testing facilities, radiation therapy centers, clinical laboratories, dialysis facilities, skilled nursing facilities, and hospices have to report certain ownership information to CMS (CMS 2008a, CMS 2008b). Entities that are structured as partnerships must identify all partners, regardless of their percentage interest, when they enroll in Medicare. In addition, entities that are structured as corporations must identify individuals who own 5 percent or more of the facility, either directly or indirectly. Many investors in physician-owned specialty hospitals have less than a 5 percent interest and therefore would not be identified. The general public does not have access to this information, which is maintained in a CMS database called the Provider Enrollment Chain Ownership System.

### Disclosing ownership information to patients

CMS requires physician-owned hospitals and ASCs to disclose ownership information to Medicare patients, but this information is not available to health plans, researchers, or members of the public who are not patients at these facilities. Physician-owned hospitals must inform patients that the hospital is physician owned and provide patients with a list of physician owners upon request. In addition, hospitals with physician owners must require all physicians with staff privileges to disclose their ownership to patients when a referral is made (CMS 2008c).[14] ASCs must also notify patients of physician ownership before the date of the procedure (42 CFR 416.50).[15]

### CMS plans to collect data on physician–hospital financial relationships

CMS plans to require a sample of hospitals to report detailed data on their ownership, investment, and compensation relationships with physicians (CMS 2008c). This effort—called the Disclosure of Financial Relationships Report (DFRR)—could include up to 500 hospitals, though CMS may reduce that number to limit hospitals' administrative burden. According to CMS, the agency's statutory authority for the DFRR is based on Section 1877 of the Social Security Act (the Stark self-referral law) (CMS 2008c).[16] CMS plans to use the DFRR to identify arrangements that may not be in compliance with the physician self-referral rules and to help shape future changes to these rules. In contrast, the Commission's interest in the DFRR is not centered on enforcement of self-referral rules. We believe that information collected through the DFRR could provide insights into what types of physician–hospital relationships should be publicly disclosed. The goal of disclosure is to facilitate research on the impact of those arrangements on the cost and quality of care.

CMS has stated that information collected through the DFRR may be shared with other federal agencies (such as the OIG) and congressional committees but does not mention congressional support agencies such as the Commission (CMS 2007). In addition, CMS intends to protect individual-specific information collected under the DFRR from public disclosure, to the extent permitted by the Freedom of Information Act (CMS 2007).

### Publicly reporting all physician owners of hospitals and other Medicare providers

Building on the existing requirement for hospitals and other entities to report to CMS the identity of at least some investors, we recommend that the Congress require that facilities billing Medicare annually report information on all physicians who directly or indirectly own an interest in the facility (excluding owners of publicly traded stock). An example of indirect ownership would be if a physician owns a 10 percent share of a group practice, and that group practice owns a 40 percent share of a hospital. The hospital would then report the physician's 4 percent indirect ownership share in the hospital.

An ownership interest refers to a partnership interest, stock (not publicly traded), stock options, or other form of equity ownership.[17] The disclosed information should include the physician's name, specialty, Medicare billing number, business address, and ownership share. For companies with more than one class of stock (e.g., preferred and common stock), the facility should report the physician's share of each type of security.

Other than the Medicare billing number, the Secretary should post this information on a public website in a format that is searchable by facility or physician name, facility or physician location, physician specialty, and year. Medicare billing numbers would be used to link ownership interests in different entities to a single physician and to link ownership data to claims data. However, billing

numbers would be available only to researchers who sign a confidentiality and data use agreement with CMS. Information on ownership would help plans, payers, and researchers analyze whether and to what extent physician ownership of hospitals and other entities affects referral patterns, quality of care, the volume of procedures or admissions, and total costs for an episode of care. For example, CMS and the Commission could link ownership data to Medicare claims to examine whether physician ownership influences where patients are referred.

The Secretary has authority under Section 1877 of the Social Security Act to collect information from hospitals and other entities that receive Medicare payments on their financial relationships with physicians. It is unclear, however, if CMS has the authority to disclose this information to the general public. Thus, we recommend that the Congress give the Secretary clear authority to publicly disclose information on physician investment in hospitals and other providers.

**RECOMMENDATION 5-4**

**The Congress should require all hospitals and other entities that bill Medicare for services to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity (excluding publicly traded corporations). The Secretary should post this information on a searchable public website.**

**RATIONALE 5-4**

There has been rapid growth in physician investment in hospitals and other entities to which they may refer patients. Although physician ownership may improve access and convenience, there is evidence that physician-owned hospitals are associated with a higher volume of services in a market. Nevertheless, it is difficult for payers and researchers to obtain data on physician investment. Collecting this information and making it available in a public database would enable further research on how physician investment might influence patient referrals, volume, quality of care, and cost of care. This recommendation builds on the existing requirement for hospitals and other entities to report to CMS the identity of at least some investors.

**IMPLICATIONS 5-4**

### Spending

- Because CMS already collects some data on physician investment in hospitals and other providers, the additional administrative costs to collect complete investment information and post it on a website should be minimal.
- Medicare expenditure implications are indeterminate.

### Beneficiary and provider

- Although the information would be of limited direct use to patients, beneficiaries may benefit indirectly from further research on how physician investment might influence patient referrals, volume, costs, and quality of care.
- Hospitals and other providers are currently required to report some information on physician investment interests, and the additional costs of reporting more complete data should be minimal.

## Reporting information on additional financial relationships between physicians and hospitals

Physicians may have a wide variety of compensation relationships with hospitals besides investment interests, such as leasing arrangements involving space or equipment, employment, and payments for providing emergency on-call services. If data on these relationships were publicly available, payers and researchers could examine whether different types of financial ties influence patient referrals, resource use for an episode of care, and overall volume of services in a market. For example, researchers could evaluate whether physicians refer more patients to a hospital for imaging studies when they lease an imaging machine to that hospital. They could also evaluate whether changes in admission patterns are related to changes in physicians' financial relationships with hospitals.

It may be difficult at this point to decide what financial relationships other than ownership should be publicly reported. Therefore, before requiring more extensive public reporting, it would be prudent to wait for a review of the information that CMS will collect from hospitals through the DFRR. When conducting the DFRR, CMS should be cognizant of hospitals' administrative burden. CMS should consider limiting the types of relationships that hospitals must report. For example, it may be more important to collect data on equipment leasing arrangements and medical directorships than on market-rate leases for office space or small on-call payments. In addition, CMS should try to limit the number of hospitals sampled to a number necessary for solid statistical inference. Because different stakeholders may have different objectives in using the DFRR data, we encourage

CMS to convene a panel on how to make the data most useful to researchers and government agencies.

Our intent is to use the information from the DFRR to make better decisions on what physician–hospital relationships should be reported. The goal of public reporting is to gain a better understanding of how these relationships can affect the cost and quality of care. Some of the relationships may be beneficial and should be encouraged, while others may not support the goal of increasing the value of care beneficiaries receive.

The Commission recommends that the Secretary submit a report to the Congress on the types and prevalence of physician–hospital arrangements, using data from the DFRR. After this report is published, the Commission could review it and potentially recommend which types of relationships—in addition to ownership—should be publicly reported by all hospitals on a regular basis. The Commission's evaluation of which arrangements hospitals should disclose would not be limited to those that will be collected in the DFRR. For example, even if CMS chooses not to collect data on physician employment, the Commission could still determine that employment information would be valuable for research and should therefore be disclosed.

## RECOMMENDATION 5-5

**The Congress should require the Secretary to submit a report, based on the Disclosure of Financial Relationships Report, on the types and prevalence of financial arrangements between hospitals and physicians.**

## RATIONALE 5-5

If information on physician–hospital relationships were publicly available, payers and researchers could use it to examine their impact on referral patterns, volume, quality, and cost. A report from the Secretary on the prevalence of various arrangements could inform future decisions on what types of relationships—in addition to ownership—should be publicly reported by all hospitals.

## IMPLICATIONS 5-5

### Spending

- Because CMS already plans to collect data on physician–hospital arrangements, the agency's administrative costs to submit a report based on this information should be minimal.
- There will be no implications for Medicare expenditures.

### Beneficiary and provider

- The impact on beneficiaries is indeterminate because we do not know how the report will influence future disclosures of physician–hospital relationships.
- There will be no impact on hospitals because CMS already plans to require a sample of hospitals to fill out the DFRR. ■

# Endnotes

1 We are not aware of published studies that quantify the extent of relationships between medical device manufacturers and physicians.

2 In addition, the code of ethics issued by the Pharmaceutical Research and Manufacturers of America, which is discussed in the next section, addresses manufacturer funding of CME activities. Manufacturers may provide support to third-party companies that organize CME conferences, but the CME organizers must control the selection of content, faculty, venue, and materials (PhRMA 2008).

3 PhRMA's ethical code was adopted in 2002 and revised most recently in 2008.

4 PhRMA's revised ethical code recommends that companies adopt procedures to ensure adherence to the code and also seek external verification that they have such procedures in place (PhRMA 2008). However, it is difficult for the general public to evaluate whether manufacturers are complying with industry and corporate guidelines.

5 Although Stanford Medical School will no longer accept industry funding for specific subjects, courses, or programs, industry may provide CME funding for broadly defined fields. Such funding would be distributed by a central CME office (Pizzo 2008).

6 When Minnesota switches to electronic filing in fiscal year 2009, it plans to post on its website a searchable list of manufacturer payments to health care providers (Wyckoff 2008).

7 Additional examples of articles that use Minnesota data on physician–industry relationships are described in MedPAC's June 2008 report (MedPAC 2008a).

8 Phase II trials are designed to evaluate the effectiveness of a drug or device for a particular indication in patients with the disease under study and to discover common risks or side effects with short-term use. Phase III studies are expanded controlled or uncontrolled trials designed to determine the relationship between benefit and risk after preliminary evidence has suggested that the product is effective (21 CFR 312.21).

9 There are precedents for federal preemption of state laws relating to health care. For example, federal law preempts most state laws related to the regulation of Medicare Advantage plans. In addition, the Employee Retirement Income Security Act preempts state laws that relate to employee benefit plans (Congressional Research Service 2008).

10 However, this study found that wealthy and insured patients were more likely to receive free samples than poor and uninsured individuals (Cutrona et al. 2008).

11 The practitioner's designee (instead of the practitioner) may sign for the delivery of samples (42 CFR 203.31).

12 In addition, Recommendation 5-3 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.

13 According to an industry survey conducted by the Federated Ambulatory Surgery Association in 2004, about 90 percent of ASCs have at least some physician ownership (ASC Coalition 2004). According to a survey conducted by the Medical Group Management Association, 64 percent of ASCs are owned by physicians, and 31 percent are owned by joint ventures, which may include physician ownership (MGMA 2006).

14 In addition to Medicare's disclosure rules, 16 states require physicians who own a specialty hospital to disclose their ownership interest to patients they refer to that hospital (CMS 2006). Although one state (Texas) requires that physicians disclose ownership interests in a specialty hospital to the state, none of the state laws makes such information available to the general public.

15 A number of states require physicians who own facilities (including ASCs) to disclose their ownership interests to patients they refer to the facility, but this information is not available to the general public.

16 This provision requires health care entities to submit information on their financial relationships with referring physicians in the form and manner specified by the Secretary (42 CFR 411.361).

17 Investors who own more than a 5 percent interest in publicly traded corporations would continue to have to report their ownership interests to the Securities and Exchange Commission (SEC), as is the case under current SEC regulations. That information is available on an SEC website.

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