CHAPTER 6

Public reporting of physicians' financial relationships

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Chapter summary

Physicians influence both the volume and the type of health care services Medicare beneficiaries receive. They recommend when patients should receive a specific drug or medical device or use a specific facility. Physicians are also involved in developing clinical protocols and researching new drugs and devices. Medicare and its beneficiaries depend on physicians, in carrying out these responsibilities, to act in the best interest of patients. However, physicians may have financial relationships with drug and device manufacturers and facilities that could compromise their independence and objectivity. Payers, plans, patients, and the general public are often not aware of these potential conflicts of interest. For example, physicians who serve on clinical guideline committees or publish research studies may have financial ties to pharmaceutical or device companies that are not fully disclosed.

According to physician surveys, state records, and legal cases, financial relationships between physicians and pharmaceutical and device manufacturers are pervasive (Campbell et al. 2007a, Department of Justice 2007, Ross et al. 2007). A physician survey conducted

In this chapter

in 2003 and 2004 found that more than three-quarters of physicians had received meals 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. 2007a). Manufacturers of medical devices, such as artificial joints and spinal implants, frequently pay physicians consulting fees and royalties to develop new products and subsidize their trips to attend conferences and training programs.

Although physician–industry relationships can lead to advances in medical technology and better patient care, 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. Physicians play an important role in developing drugs and devices by overseeing clinical trials, inventing products, and providing expert advice to manufacturers. Once a product is introduced, manufacturers' marketing efforts may lead to increased use of beneficial drugs. In addition, their training programs teach physicians how to safely use new devices. However, studies have shown that physician interactions with the pharmaceutical industry are associated with rapid prescribing of newer, more expensive drugs, decreased prescribing of generic drugs, and physician requests to add drugs to a hospital formulary (Chren and Landefeld 1994, 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).

Medicare should be concerned about the potential for bias because the program spent $48.6 billion on outpatient prescription drugs prescribed by physicians under Part D in 2007 and $10.1 billion on Part B drugs (which are primarily administered in physician offices) in 2005 (Boards of Trustees 2008, MedPAC 2007a). In addition, Medicare spends a significant amount on implantable medical devices.

Over the last decade, the federal government has initiated several criminal and civil cases against companies for allegedly giving physicians

inducements to prescribe their drugs or use their devices. In response to heightened scrutiny, industry associations, physician groups, and the Office of Inspector General developed ethical and legal guidelines for physician–industry relationships. However, some observers question whether the guidelines are sufficiently stringent and point out that compliance is not systematically measured and enforced (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007). Several hospital systems and physician organizations have implemented stricter policies to limit conflicts of interest (e.g., Stanford University Medical Center, the Permanente Medical Group). In addition, some states have enacted laws requiring pharmaceutical companies to report their financial relationships with physicians. However, these laws do not apply to device manufacturers and the information collected often is not easily available to the public.

A federal law that would require drug and device companies to publicly report their financial ties to physicians could encourage physicians to reflect on the propriety of those relationships, perhaps discouraging inappropriate arrangements. A public reporting system also would help the media and researchers shed light on physician–industry relationships and explore potential conflicts of interest. Payers (including Medicare) and health plans could use this information to examine physicians' practice patterns. In addition, industry and physician associations could use public reporting to refine their ethical standards.

Many physicians also have financial relationships with hospitals and ambulatory surgical centers (ASCs). The number of physician-owned specialty hospitals more than doubled from 2002 to 2006 (CMS 2006, MedPAC 2005). The number of Medicare-certified ASCs—most of which have at least some physician ownership—grew by 31 percent from 2002 to 2006 (MGMA 2006, MedPAC 2007a). There has also been an increase in joint venture facilities owned by physicians and hospitals. Currently, it is difficult for payers, health plans, the media, and the general public to

obtain information about physicians' financial relationships with hospitals and ASCs. Although Medicare patients were recently granted the right to obtain ownership information from physician-owned hospitals when they are admitted to them, this information is not available to plans, payers, and others (CMS 2007b). Information on other physician–hospital relationships, such as joint ventures and equipment leases, is also not publicly available. CMS has proposed requiring ASCs to disclose physician ownership interests to patients, but payers and researchers would not have access to this information (CMS 2007a). If payers, plans, and reporters had access to basic data about certain financial relationships between physicians and hospitals (as well as physicians and ASCs), they could use the information to examine the influence of these relationships on referral patterns and the overall volume of services.

In this chapter, we explore options for collecting data on physicians' financial relationships with drug and device manufacturers, hospitals, and ASCs. We describe three key design questions for a potential federal law requiring drug and device companies to report their financial ties with physicians: How comprehensive should the reporting system be? What size and types of payments should be reported? How can the data be made readily accessible to the public? Next, we examine possible reporting requirements for hospitals and ASCs. Under the approaches we describe, the responsibility for public reporting would rest with pharmaceutical and device manufacturers, hospitals, and ASCs rather than with physicians. Even if a reporting system were implemented, individual physicians, manufacturers, and facilities would continue to be responsible for ensuring that their financial relationships are ethical and improve patient care. ■

Reporting physicians' financial relationships with drug and device manufacturers

According to physician surveys, state data, and legal cases, financial relationships between physicians and pharmaceutical and device manufacturers are pervasive (Campbell et al. 2007a, Department of Justice 2007, Ross et al. 2007). In 2005, pharmaceutical companies spent nearly $7 billion on physician detailing (visits from sales representatives to physicians) and provided free samples worth $18 billion (Donohue et al. 2007). Manufacturers of medical devices such as artificial knees, cardiac defibrillators, and spinal implants frequently pay physicians consulting fees and royalties to develop new products and subsidize their trips to attend conferences and training programs.

Although such relationships can lead to advances in medical technology and better patient care, 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. Studies have shown that physician interactions with the pharmaceutical industry are associated with rapid prescribing of newer, more expensive drugs and decreased prescribing of generic drugs (Wazana 2000). More comprehensive information about physicians' financial relationships with drug and device manufacturers would help us better understand how they affect physician practice patterns.

Medicare should be concerned about the potential for bias 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 2005, Medicare spent $10.1 billion on Part B drugs, which are primarily administered in physician offices (MedPAC 2007a). 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.

In response to heightened legal and public scrutiny of physician–industry relationships, pharmaceutical and medical device associations, physician groups, and the Office of Inspector General (OIG) developed ethical and legal guidelines for these relationships. However, some observers question whether the guidelines are sufficiently stringent and point out that compliance is not systematically measured and enforced (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007). Several hospital systems and medical groups have responded to such concerns by implementing strict policies to limit potential conflicts of interest. In addition, some states have enacted laws requiring drug companies to report their financial relationships with physicians. However, these laws do not apply to device manufacturers and the information collected is not easily available to the public.

This section explores the potential benefits and limitations of adopting a federal law requiring drug and device companies to publicly report their financial relationships with physicians. We also explore key design questions for such a system. A public reporting system could encourage physicians to reflect on the propriety of their relationships with the industry, perhaps discouraging inappropriate arrangements. It also would help the media and researchers shed light on physician–industry relationships, explore potential conflicts of interest, and examine whether manufacturers and physicians are complying with voluntary industry and professional guidelines. Payers (including Medicare) and health plans could use this information to examine physicians' practice patterns.

Relationships among drug and device companies, physicians, and other entities

According to a survey of physicians in six specialties conducted in 2003 and 2004, most physicians (94 percent) had some type of recent relationship with the drug industry (Campbell et al. 2007a). Within the previous year, more than three-quarters of the respondents received meals or drug samples from manufacturers; more than one-third were reimbursed by companies for costs related to attending professional meetings or continuing medical education (CME) events; and more than one-quarter were paid for consulting, giving lectures, or enrolling patients in clinical trials. Physicians also reported frequent meetings with industry sales representatives, averaging—for example—16 meetings per month for family practitioners, 9 meetings per month for cardiologists, and 2 meetings per month for anesthesiologists. In general, the industry's marketing efforts appear to focus on physicians who are in a position to influence the prescribing practices of others, such as those who develop clinical practice guidelines and train new physicians (Campbell et al. 2007a).

A recent study estimated that drug manufacturers spent nearly $7 billion in 2005 on physician detailing and more than $400 million for advertising in professional journals (Donohue et al. 2007). The amount spent on detailing

excludes gifts, meals, and events. Manufacturers also provided free drug samples with a retail value of more than $18 billion. Adjusting for inflation, spending in these areas increased by 246 percent between 1996 and 2005.

Researchers have found that physician interactions with pharmaceutical companies start during the formative years of medical school and residency and continue thereafter (Wazana 2000). Most residents report having interactions with pharmaceutical representatives and receiving gifts, samples, and meals from the industry (Wazana 2000). In a survey of residents at an internal medicine program, a significant majority of residents considered it appropriate to accept pharmaceutical industry promotions such as conference lunches, dinner lectures, and social outings (Steinman et al. 2001). Even many residents who considered it inappropriate to receive such promotions reported accepting them anyway. 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; direct distribution of free drug samples to physicians; and paying faculty to participate in speakers' bureaus (AAMC 2008a). A recent newspaper article describes how some medical students feel pressure from their professors to attend dinners sponsored by drug manufacturers to promote their products (Emery 2007).

We are not aware of published studies that quantify the extent of relationships between medical device manufacturers and physicians. However, reports in the media and legal cases suggest that manufacturers often pay physicians consulting fees and royalties to develop new products, subsidize their trips to attend conferences, pay them to conduct postmarketing research, and sometimes offer them investment interests in their companies (Abelson 2006a, Abelson 2006b, Burton 2005, Zuckerman 2005). 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.…" (Department of Justice 2007). Investigators estimate that these manufacturers paid physician consultants more than $800 million under 6,500 consulting agreements from 2002 through 2006 (Demske 2008).

In addition to educational and marketing efforts directed at physicians, pharmaceutical and device companies also advertise directly to consumers. The text box discusses the growth and influence of direct-to-consumer advertising.

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). This funding goes to organizations that sponsor CME events, but physicians benefit through free or subsidized activities. Some observers have expressed concern that the dependence of CME on commercial support may lead to inappropriate industry influence over the topics, speakers, and content at educational events (Brennan et al. 2006, Hampton 2008, Steinbrook 2008).

The drug and device industry also plays a significant role in financing clinical research. A literature review concluded that financial relationships among manufacturers, scientific researchers, and academic institutions are widespread: About one-quarter of biomedical researchers at academic institutions receive funding from the industry, and approximately two-thirds of academic 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). As a result, two national higher education and research organizations have recommended that universities and medical schools develop policies to address institutional conflicts of interest.[1] However, a recent survey found that only 38 percent of medical schools have adopted policies to deal with the institution's financial interests, although a higher proportion have issued policies to address the financial interests of medical school officials, such as members of institutional review boards (Ehringhaus et al. 2008).

Although physician relationships with drug and device manufacturers can lead to improved patient care, there may also be negative effects. 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 2007b). Once a product is introduced, manufacturers' marketing efforts may lead to increased use of beneficial drugs (Powell 2007). In addition, device

Direct-to-consumer advertising

The pharmaceutical industry has rapidly increased its spending on direct-to-consumer (DTC) advertising in recent years, from $985 million in 1996 to $4.2 billion in 2005 (Donohue et al. 2007). This growth was driven in part by a change in Food and Drug Administration (FDA) policy that made it easier to advertise drugs on television (Wilkes et al. 2000). Although drug manufacturers spend more on physician detailing ($6.8 billion in 2005) than on DTC advertising ($4.2 billion), expenditures on consumer advertising are rising much faster (Donohue et al. 2007).

Although spending on DTC advertising by medical device manufacturers appears to have grown in recent years, it remains far less than such spending by drug companies. According to one estimate, device company expenditures on DTC advertising increased from almost nothing in 1996 to about $50 million in 2005 (Cutting Edge Information 2006). Several news articles have observed an increase in consumer advertising for devices such as stents, implantable cardioverter defibrillators (ICDs), artificial joints, and radioactive seeds (Feder 2007, Moylan 2007, Steinberg 2007). In 2007, for example, Medtronic—a manufacturer of ICDs—initiated a multimillion-dollar advertising campaign to raise awareness of sudden cardiac arrest (SCA) and the role of ICDs in preventing death from SCA (Medtronic 2007, Moylan 2007). Medtronic's effort—which involves print, television, and online advertising—encourages people who have had a heart attack or have been diagnosed with heart failure to visit a website where they can assess their risk for SCA (Medtronic 2007). Also in 2007, Cordis Corporation launched what is reportedly the first attempt to directly market a heart stent to consumers (Feder 2007).

Although DTC advertising for drugs can have positive effects by encouraging patients to talk to their physicians about undiagnosed conditions (e.g., high cholesterol, depression), it has also led to higher spending through increased use of the advertised drugs and other drugs used to treat the same condition (Donohue et al. 2007, GAO 2006).[2] DTC advertising appears to increase use by encouraging patients to ask their physicians for the advertised drugs. A recent survey found that DTC ads prompt nearly one-third of consumers to ask their physician about a drug; 44 percent of those who asked about an advertised pharmaceutical received a prescription for the drug, and 54 percent were prescribed a different drug (USA Today/Kaiser Family Foundation/Harvard School of Public Health 2008). There is evidence that DTC advertising may lead to greater use of underutilized drugs as well as higher use of an advertised drug when alternatives may be more appropriate (Donohue et al. 2007, GAO 2006). Because DTC advertising encourages patients to ask their physicians about new drugs, physicians and patients would benefit from having information that compares the effectiveness of new drugs with existing alternatives. The Commission has recommended that the Congress create an independent entity to produce and disseminate information about the comparative effectiveness of health care services (MedPAC 2007b).

DTC advertising has been criticized for stimulating demand for new drugs whose long-term safety has not been demonstrated (Donohue et al. 2007). Because some of the risks of new drugs are not known until they have been on the market for a period of time, the Institute of Medicine has recommended that the FDA restrict DTC advertising for new drugs during the first two years after approval (Committee on the Assessment of the U.S. Drug Safety System 2006). In addition, the American Medical Association has called for a temporary moratorium on advertising for newly approved drugs and devices to give physicians more time to understand their risks and benefits (AMA 2005). Some companies have voluntarily agreed to delay DTC ads for new drugs (Bristol-Myers Squibb 2005). ■

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).

Some of these relationships, however, may influence physicians' behavior in ways that undermine their independence and objectivity. According to several surveys, most physicians do not believe that accepting gifts and payments from drug manufacturers affects

their decision making (Gibbons et al. 1998, McKinney et al. 1990, Steinman et al. 2001). Two literature reviews suggest otherwise: Physician interactions with the pharmaceutical industry are associated with rapid prescribing of newer, more expensive drugs and decreased prescribing of generic drugs (Lexchin 1993, Wazana 2000).[3] Another study found that physicians who interacted with drug companies were much more likely than other physicians to request that drugs manufactured by those companies be added to a hospital formulary (Chren and Landefeld 1994). These interactions included meeting with sales representatives and accepting payments from manufacturers to speak at symposia or conduct research. Most of the drugs physicians wanted to add to the formulary represented little or no therapeutic advantage over drugs already on the formulary (Chren and Landefeld 1994). We are not aware of studies that examine the impact of relationships between physicians and device manufacturers on medical decisions. More comprehensive information about these financial ties would help researchers evaluate whether and to what extent they affect physician behavior.

Social science literature offers insights into how physician interactions with manufacturers may lead to bias. Providing gifts, food, and other favors creates a sense of indebtedness in recipients that tends to influence their behavior (Katz et al. 2003). Under the social rule of reciprocity, a gift recipient is expected to repay the giver, even if the value of the gift is small. According to the conventional understanding of conflicts of interest, people who are biased make a conscious decision to do something unethical to achieve personal gain. However, social science experiments show that, even when people try to be objective, "their judgments are subject to an unconscious and unintentional self-serving bias" (Dana and Lowenstein 2003).[4] This finding can be applied to conflicts of interest in medicine. For example, in a study of physicians who went on trips sponsored by a drug company to learn about two new drugs, most of them 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 went on the trips may have had an unintentional bias.

In addition, the Commission has previously expressed concern that clinical research funded by manufacturers is not always objective and publicly available (MedPAC 2007b). 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). 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 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 a drug being tested (rofecoxib) was associated with a higher risk of mortality (Psaty and Kronmal 2008). In a safety report to the Food and Drug Administration (FDA) in 2001, the company used a statistical technique that minimized the appearance of mortality risk from the drug. However, the sponsor had conducted a different, more comprehensive analysis, which revealed that rofecoxib was associated with a three-fold increase in mortality. These results were not submitted to FDA until 2003 and were not described in published articles about the drug (most of the articles' authors were employees of the manufacturer).

Moreover, some industry-sponsored research appears to serve promotional, rather than scientific, purposes. For example, the OIG has alleged that a device company paid several physicians $5,000 each to test five patients with a new spinal cord stimulation product (Demske 2008). According to the OIG, this program did not provide clinical value and the manufacturer's research department did not use the data collected through the program. Instead, the effort was allegedly used as a marketing tool to increase sales. Further, some Phase IV (post-FDA approval) studies of pharmaceuticals appear to be aimed at encouraging physicians to prescribe new drugs rather than to collect useful information (Angell 2005). Although many Phase IV studies serve legitimate purposes—to examine whether a new drug is safe and effective for additional uses or to ensure that a new product is safe for its approved uses—in some cases companies pay physicians to start patients on new drugs and answer questions that have very little clinical relevance, such as whether the physician is pleased or not pleased with the drug (Angell 2005).

Efforts to regulate physician–industry relationships

In the last several years, physician associations, drug and device organizations, individual companies, and the OIG have attempted to develop ethical and legal guidelines for interactions between physicians and industry. The primary factors motivating these efforts include:

- increased spending on prescription drugs and medical devices,
- growing awareness of the negative influence that some physician–industry relationships may have on patient care, and
- prosecutions of drug and device manufacturers under federal fraud and abuse laws (Chimonas and Rothman 2005, Department of Justice 2007, Studdert et al. 2004).

Although these guidelines attempt to set boundaries for ethical behavior and proscribe the most extreme practices, critics argue that the guidelines are too vague, are not stringent enough, and lack mechanisms to measure and ensure compliance (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007). In response, some health systems, physician organizations, and medical groups have adopted much stricter policies to limit potential conflicts of interest. In addition, some states have enacted laws requiring that drug companies report their financial relationships with physicians, and one state (Minnesota) has limited the size of gifts that can be given to physicians.

Prosecutions of drug and device manufacturers under fraud and abuse laws

In the late 1990s, the federal government began prosecuting some drug manufacturers for providing illegal inducements to physicians to use their products. Several of these cases led to convictions and very large settlements. In the case against TAP Pharmaceuticals, for example, the government alleged that the company induced urologists to prescribe Lupron (an injectable drug) by providing them with free samples and encouraging them to bill Medicare for the samples, employing physicians as consultants without requiring services in return, and awarding them educational grants with no strings attached (Studdert et al. 2004).[5] Prosecutors charged that these arrangements were intended to induce physicians to prescribe Lupron and were therefore illegal kickbacks. This case, which TAP settled for $875 million, led to several similar cases against other drug companies (Studdert et al. 2004).

Federal prosecutors have also charged several device manufacturers with violating fraud and abuse laws by providing inducements to physicians to use their products. In 2006, Medtronic agreed to pay $40 million to settle allegations that it had paid kickbacks to surgeons to use its spinal implants, which may have cost as much as $13,000 per surgery (Abelson 2006a, Abelson 2006b). The Department of Justice alleged that these kickbacks took the form of "sham consulting agreements, sham royalty agreements, and lavish trips to desirable locations" (Department of Justice 2006). According to a whistle-blower lawsuit against Medtronic, one physician received $700,000 in consulting fees in 2005 and another physician received $400,000 annually for eight days of consulting per year (Abelson 2006b). Recently, four large orthopedic device manufacturers paid the government a total of $311 million to settle cases alleging that they had paid surgeons thousands of dollars per year in consulting fees to induce use of their artificial hip and knee implants (Department of Justice 2007).[6] The investigation found that some payments to physicians were not related to physicians' actual work for the companies but instead were kickbacks designed to influence their decisions. According to an OIG official, for example, the companies sponsored consultant meetings at resort locations, covered the physicians' travel expenses, and paid them $5,000 per day, even though they attended meetings only a few hours each day (Demske 2008).

Under the settlement, the companies agreed to adopt corporate compliance procedures, including requiring physicians with whom they have a financial arrangement to disclose the arrangement to their patients and affiliated hospitals. The companies also agreed to post on their websites all payments made to physicians in 2007. However, the websites do not identify whether payments were for consulting, clinical studies, royalties, honoraria, or other purposes. The websites do not permit users to perform searches, and it is very difficult to print information from three of the websites. Despite these limitations, we were able to analyze data from the websites of two companies and found that they made payments to 311 physicians in 2007 (Biomet 2007, Smith & Nephew 2008). Across both companies, half the physicians received annual payments of more than $19,000. At least 53 individual physicians received total payments of $100,000 or more (roughly one-fifth of all physicians who received payments). Nine individual physicians received total payments of at least $1 million in 2007 (3 percent of the 311 physicians who received any payments).

Development of guidelines for physician–industry relationships

In response to heightened scrutiny of physician–industry interactions, manufacturer and physician groups have adopted or revised ethical codes of conduct. These codes are voluntary and compliance is not monitored. A representative of the Advanced Medical Technology Association (AdvaMed) recently stated that the association lacks the resources to enforce its code (Weiland 2008). In addition, antitrust laws may limit the ability of industry associations to enforce compliance with their codes.

The American Medical Association's (AMA's) code, which was developed in 1992 and updated in 1998, allows physicians to accept gifts (e.g., textbooks) as long as the gifts primarily benefit patients and are not of substantial value (AMA 1998). According to the code, physicians should not accept payments or subsidies from the industry to attend educational meetings or conferences, unless they are consultants or faculty. However, manufacturers may provide subsidies to conference sponsors, which can use the money to defray physicians' registration fees.

In 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted a new code of ethics that is similar to the AMA code and significantly stronger than the older guidelines it replaced (PhRMA 2002, Studdert et al. 2004). The PhRMA code states that manufacturers' relationships with physicians "are intended to benefit patients and to enhance the practice of medicine" and recognizes that physicians' decisions should be based "solely on each patient's medical needs" (PhRMA 2002). Therefore, "no grants, scholarships, subsidies, support, [or] consulting contracts … should be provided or offered to a health care professional in exchange for prescribing products."

In general, the PhRMA code attempts to limit the most egregious activities that previously led to legal problems and negative publicity. The code describes appropriate and inappropriate conduct in several important areas, such as gifts, support for CME activities, consulting arrangements, and sales presentations. Under the code, companies are permitted to provide gifts to physicians on an occasional basis if they are primarily for patients' benefit (e.g., an anatomical model) and are worth $100 or less. In addition, companies may give physicians items of minimal value that are associated with their practice, such as pens and notepads. Gifts that are not related to patient care, such as artwork or tickets to sporting events, are discouraged.

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. Manufacturers are allowed to pay physicians reasonable compensation, travel, lodging, and meals for bona fide consulting relationships. A bona fide arrangement must involve a written contract that specifies the services to be provided. When physicians attend a sales presentation, manufacturers may offer occasional, modest meals in an appropriate venue, but not entertainment or recreational events. Spouses and guests should not be invited to these presentations.

AdvaMed, which includes many device manufacturers, adopted a code of ethics in 2003 (AdvaMed 2003). This code is quite similar to PhRMA's code. Companies are permitted to provide physicians modest meals, lodging, and hospitality in connection with legitimate training, education, and sales meetings. Companies may have bona fide consulting arrangements with physicians. Occasional, modest gifts are allowed, but "repeated gifts to the same person, each with a value below the $100 threshold, could violate the spirit of the Code" (AdvaMed 2005).

In 2002, the American College of Physicians (ACP) adopted a new ethical code, which states that: "Recent studies show that accepting industry hospitality and gifts, even drug samples, can compromise judgment about medical information and … patient care" (Coyle 2002). Before accepting gifts, hospitality, and subsidies from manufacturers, the ACP code encourages physicians to ensure that their objectivity (or perceptions of their objectivity) will not be affected by asking themselves the following questions:

- What would my patients/the public/my colleagues think about this arrangement?
- How would I feel if the relationship were disclosed through the media?
- What is the purpose of the offer?

Although the ACP recognizes that even small gifts can affect clinical judgment, the code permits physicians to accept low-cost gifts of an educational or patient-care nature and modest hospitality connected with education. However, the code states that physicians should not accept commissions for articles that are ghostwritten by the industry and should not participate in postmarketing studies that are "thinly disguised promotional schemes" (Coyle

2002). In addition, they should disclose their industry ties to potential participants in clinical research studies.

The American Academy of Orthopaedic Surgeons (AAOS) recently adopted standards for physician–industry relationships that set limits on gifts, consulting agreements, and subsidies to attend CME and other educational events, and recommend disclosures to patients and institutions (AAOS 2007). For example, the standards require surgeons to disclose to patients any financial arrangement with a manufacturer that relates to their treatment, such as royalties, stock options, or consulting agreements. In addition, surgeons who influence the selection of products for an entity must disclose their relationships with the industry to the entity.

In 2003, 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 law prohibits companies from making payments to induce or reward the referral of items or services reimbursed by federal health programs. According to OIG's guidance, when a manufacturer provides something of value to a physician, the company should examine whether it is providing a benefit to the physician with the intent to induce the use of its products. If a company identifies an arrangement that may be problematic, the company should ask several questions, such as:

- Does the arrangement have the potential to interfere with clinical decision making (e.g., is the payment based on referrals)?
- Does it have the potential to increase the risk of overutilization or inappropriate use?
- Does it raise patient safety or quality-of-care concerns?

The OIG encourages manufacturers to try to fit arrangements with physicians within a safe harbor; safe harbors are specific types of payment arrangements that protect entities against prosecution under the anti-kickback law. With regard to the funding of research and education, the guidance recommends that manufacturers separate their grant-making function from their sales and marketing function to reduce the risk that grants would be awarded to increase the use of a product. The guidance also recommends that industry funding of CME programs not involve control over the selection of content or faculty.

The OIG also warns against several practices that are highly suspect under the law, such as paying physicians as consultants for attending meetings and conferences and paying them for time spent listening to sales representatives. Although providing travel, meals, and gifts may potentially violate the anti-kickback statute, the guidance states that "compliance with the PhRMA code will substantially reduce the risk of fraud and abuse" but will not protect a company as a matter of law under the statute (OIG 2003).

The AAMC convened a task force to develop general principles for academic medical institutions to manage industry support of educational activities (AAMC 2008a). In forming the task force, the AAMC was motivated by concern about the increasing dependency of academic institutions on the industry for financing of education and evidence that such support can influence the objectivity of teaching, learning, and practice. The task force recently issued its final report (AAMC 2008a).

Concerns about effectiveness of guidelines

Although the development of ethical and legal guidelines has led to some positive changes in physician–industry relationships, critics point out that the guidelines lack mechanisms to measure and ensure compliance. There also is evidence that interactions prohibited by voluntary codes continue to occur (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Grande 2007, Prescription Project 2007, Sade 2007).

Drug companies appear to be ramping up their compliance efforts in response to the 2003 OIG guidance. Many manufacturers are developing official compliance policies, elevating the status of compliance officers, and transferring responsibility for CME and grant funding from sales and marketing staff to medical education or general business units (Chimonas and Rothman 2005, U.S. Senate 2007a). Spending for lavish gifts and entertainment has declined in favor of more resources for educational programs (Chimonas and Rothman 2005). Some physicians have lamented the end of the "golden era" when companies gave physicians tickets to sporting events and invited their spouses to industry-sponsored dinners (Chimonas et al. 2007).

Nevertheless, no mechanism exists to systematically monitor compliance with industry or OIG guidelines, as mentioned earlier (Chimonas and Rothman 2005). Companies are not required to report their financial relationships with physicians (with the exception of a

few states that mandate reporting, as described later). In fact, there is evidence that some noncompliant practices have continued. As noted earlier, the government has alleged that, from 2002 through 2006, four orthopedic implant manufacturers made payments to physicians that were kickbacks designed to influence their clinical decisions (Demske 2008). A physician survey conducted in late 2003 and early 2004 found that more than one-third of physicians had recently 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. 2007a). According to an FDA official, some pharmaceutical manufacturers were still inviting physicians on cruises and to exotic resorts, free of charge (Harris 2005). The PhRMA code states that manufacturers should not pay physicians to attend CME or educational events, unless they are faculty or consultants, and discourages them from giving physicians tickets to sporting events (PhRMA 2002). Similarly, the AMA's position is that physicians should not accept subsidies from the industry to attend a CME conference or professional meeting or accept gifts unless they primarily benefit patients (AMA 1998).[7]

An investigation by the Senate Finance Committee found that industry sponsors improperly influence some CME activities (U.S. Senate 2007a). For example, a commercial sponsor was involved in selecting faculty and other activities and another sponsor influenced where and how many presentations were scheduled. According to standards set by the ACCME, PhRMA, AMA, and OIG, CME activities should be independent of commercial sponsors.

Some organizations have adopted stricter policies on relationships

According to some critics, the only way to ensure that physicians are not biased by their relationships with the industry is for physicians to not accept anything of value, even trivial items, from drug manufacturers (Blumenthal 2004). Groups that support this position include the American Medical Student Association and No Free Lunch, an organization of physicians who pledge to not accept gifts or hospitality from the drug industry (American Medical Student Association 2008, No Free Lunch 2008).

A group of physicians and researchers has proposed that academic medical centers (AMCs) adopt stricter policies to regulate conflicts of interest between physicians and industry (Brennan et al. 2006). Under this proposal, for example, physicians affiliated with AMCs would be unable to accept from manufacturers any gifts (regardless of value), free meals, or payments to attend meetings. The proposal would prohibit companies from directly providing drug samples to physicians; instead, manufacturers could provide vouchers to low-income patients. Physicians who have financial relationships with manufacturers would not be able to serve on hospital formulary committees. AMC faculty would be forbidden from serving on industry speakers' bureaus and from publishing articles that were ghostwritten by the industry. The proposal would allow legitimate consulting arrangements and research grants from the industry to AMCs as long as they were disclosed publicly on the Internet.

Elements of this proposal are reflected in policies adopted by several AMCs, health systems, and medical groups, and in a recent AAMC report (AAMC 2008a). For example:

- The University of Massachusetts Medical Center recently approved rules that prohibit its physicians from accepting gifts and meals from manufacturers, ban physicians from joining companies' speakers' bureaus, and prevent physicians who receive grants or consulting fees from companies from serving on hospital formulary committees (Kowalczyk 2007).
- Stanford University Medical Center bans industry sales representatives from patient care areas and prohibits its faculty from publishing articles that have been ghostwritten by the industry (Stanford University School of Medicine 2006).
- A health system in Minnesota limits sales representatives' access to its clinics and has purged its hospitals and clinics of all pens, notepads, and other promotional items received from drug companies (Karnowski 2008).
- 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, or travel expenses from the industry (Permanente Medical Group 2004).

State efforts to regulate relationships

Some states have designed laws to make physician–industry relationships more transparent and to place limits on those relationships. Four states and Washington, DC, have enacted laws requiring that drug manufacturers report to the

state any cash and in-kind payments made to physicians. Seventeen other states introduced similar bills last year, but none became law (Medicine & Health 2008). Minnesota bans drug companies from giving food and gifts worth more than $50 to physicians, which reportedly has led to a decline in visits by sales representatives to primary care physicians (Harris 2007).[8] Iowa and Massachusetts have considered a complete ban on all gifts from drug manufacturers to physicians (Ross et al. 2007). In addition, Washington, DC, prohibits drug manufacturers from offering gifts or remuneration to a member of a government formulary committee (District of Columbia 2008).

To date, four states (Minnesota, Vermont, Maine, and West Virginia) and Washington, DC, mandate reporting of pharmaceutical manufacturers' financial relationships with physicians, and California requires that manufacturers specify annual limits on the value of items provided to physicians.[9] Minnesota is the only state to make public the names of individual physicians who receive payments, but this information is not in a searchable electronic format. Vermont, Maine, and Washington, DC, require disclosure of payments over $25, whereas Minnesota and West Virginia require disclosure of payments over $100 (Table 6-1, p. 154).

All existing statutes require that the pharmaceutical manufacturer, not the health care provider, disclose payments. Most statutes mandate disclosure of the recipient's name, credentials, amount, form of payment (e.g., grant, donation, in-kind), and purpose of payment (e.g., honoraria, consulting, education). However, states vary considerably regarding disclosure of each provider's license number, address, and affiliated facility.

States also vary regarding which types of providers are included in a reporting mechanism. All states require that drug companies report payments and transfers of value to health care professionals, and two states and Washington, DC, also mandate reporting of payments to hospitals and nursing homes (Table 6-1). With regard to the types of payments that must be disclosed, all statutes exempt pharmaceutical samples intended to be free for patients, and most exempt payments related to clinical trials and other research (Table 6-1). Vermont's statute allows pharmaceutical manufacturers to broadly designate payments as "trade secrets."[10] As a result of this designation, the state withholds all information relating to these payments. In fiscal year 2006, 72 percent of manufacturers' payments to Vermont providers were designated "trade secrets" and withheld from public disclosure (Vermont Office of the Attorney General 2007).

Each state's statute varies in its supervisory agency and enforcement mechanisms. In Minnesota, the supervisory agency is the Board of Pharmacy, whereas the attorney general supervises disclosures in Vermont. Washington, DC, and Maine require manufacturers to pay an annual reporting fee. Fines for each violation or false submission range from $1,000 to $10,000, depending on the state. 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 does not publish an aggregate report, but scanned copies of each manufacturer's disclosure forms are available online (Minnesota Board of Pharmacy 2007). When Minnesota switches to electronic filing in fiscal year 2009, it may become the first state to post a searchable list of manufacturer payments to health care providers online (Wyckoff 2008).

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). This study found that, over 3 years, manufacturers made 6,238 payments exceeding $100 each to physicians in Minnesota, for a total of $22.4 million; the median payment was $1,000. Over 2 years, manufacturers reported providing 2,416 payments exceeding $100 each to health care providers in Vermont, for a total of $1.0 million; the median payment was $177. The authors reported several problems with data completeness, accessibility, and quality:

- 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.
- To obtain access to some of the payments designated as "trade secrets" under Vermont's law, the authors had to sue 18 pharmaceutical manufacturers.
- Because of vague definitions of payment type and purpose, researchers had difficulty differentiating between payments for gifts and those for contracted services.
- In Vermont, the physicians' complete names were available for only 25 percent of the payments included in the state's annual report.

TABLE 6–1 **Disclosure requirements in state reporting programs**

Disclosure requirement	MN	DC	VT	ME	WV
Year of legislation	1993	2001	2003	2003	2004
Disclose payment amounts greater than	$100	$25	$25	$25	$100
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"
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)

Note: N/A (not applicable), CME (continuing medical education).
*These payments are banned under Minnesota law if in excess of $50.

Source: Lurie 2007, MedPAC analysis of state laws.

Should the federal government require public reporting of financial relationships between physicians and manufacturers?

Current public reporting laws on physician–industry financial relationships are limited to a few states and do not provide complete information that is easily accessible. Three bills were recently introduced in the Congress to create a national system in which drug and device manufacturers would be required to report all payments and gifts above $25 or $50 to physicians; this information would be publicly available in an online database (U.S. House 2008, U.S. House 2007, U.S. Senate 2007b). The following subsections examine the potential uses and limitations of a federal reporting system and identify key design issues for such a system.

Potential uses of data on physician–industry relationships

A national public reporting system could:

- encourage physicians to reflect on the propriety of physician–industry relationships, perhaps discouraging inappropriate arrangements;
- help the media and researchers shed light on physician–industry interactions, explore potential conflicts of interest, and examine whether manufacturers and physicians are complying with industry and professional guidelines;
- enable payers (including Medicare) and health plans to examine whether and to what extent industry ties influence physicians' practice patterns;

- allow hospitals to check whether physicians who recommend the purchase of specific devices and drugs have financial ties to the manufacturers;
- help manufacturers demonstrate their compliance with industry guidelines;
- assist industry and physician associations in refining their ethical standards; and
- highlight individual physicians, medical groups, and academic institutions that have decided to limit certain financial relationships with the industry.

Public reporting of payments from manufacturers to physicians might encourage physicians to critically examine their relationships with the industry. The ACP's 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 by the media (Coyle 2002). The possibility that colleagues, patients, and the general public might learn about their financial relationships with drug and device companies could give physicians an incentive to carefully consider these questions, perhaps discouraging arrangements that may compromise their objectivity.

Recent articles that used data from Minnesota's public reporting law and other sources to shed light on physician–industry interactions demonstrate how reporters and researchers could draw on national data to investigate potential conflicts of interest. These articles have explored the financial ties of physicians who serve on formulary and clinical guideline committees, lead clinical trials, and prescribe expensive new drugs. They have also evaluated manufacturers' compliance with industry guidelines.

According to a survey of physicians who helped write clinical guidelines, almost 60 percent of them had a financial relationship with companies whose drugs were considered in the guideline they authored (Choudhry et al. 2002). However, only 2 of the 44 guidelines studied in the article included a disclosure of the authors' financial arrangements with the drug industry. Only 7 percent of the authors with a financial relationship believed they were influenced by their relationship, but 19 percent of these physicians believed their coauthors' recommendations were influenced by such interactions. These potential conflicts of interest are significant because clinical guidelines influence the treatment recommendations of many physicians (Choudhry et al. 2002, Harris and Roberts 2007). Reporters used data from Minnesota's public reporting system to show that some physicians who coauthored clinical guidelines received significant funding from companies whose drugs were affected (Harris and Roberts 2007). For example, 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.

Physicians who serve on drug formulary committees for hospitals, health plans, and states influence which drugs are purchased or covered. Hospitals generally require that physicians who serve on such committees disclose their financial interests and in some cases prohibit physicians with financial interests from serving on these committees (American Society of Health-System Pharmacists 2000, Kowalczyk 2007). Some—but not all—state formulary committees have similar rules. Until recently, Minnesota's formulary committee, which recommends the drugs that should be covered by the state Medicaid plan, did not have a disclosure policy. Using data from Minnesota's disclosure records, a reporter found that a physician who served on the committee received more than $350,000 from companies whose drugs were considered by the panel (Lohn 2007).

When manufacturers apply for approval of a new drug or device, the FDA requires that they identify certain financial interests of researchers who performed clinical trials on the product (FDA 2001). According to a recent article, however, several researchers involved in a clinical trial of a new artificial spinal disk had invested in the product's manufacturer, yet this information may not have been disclosed to the FDA before the device was approved (Abelson 2008). The reporter obtained confidential data on the researchers' investment interests from a patient lawsuit. A public reporting system could make such information more easily available to the public.

A recent *New York Times* article used data from Minnesota on physician–industry relationships to examine psychiatrists' use of a new class of expensive drugs (atypical antipsychotics) for children covered by Medicaid (Harris et al. 2007). The use of these drugs for children has been controversial because of safety risks and scarce evidence that they are effective for children. The analysis found that psychiatrists who accepted significant payments (at least $5,000) from manufacturers of these drugs prescribed them to children much more frequently than psychiatrists who accepted less or no money.

Public information on physician–industry relationships could also be used to track compliance with voluntary

industry guidelines on interactions with physicians. For example, are companies providing only occasional gifts worth less than $100 to physicians? Do companies offer only modest meals and hospitality? Researchers using data from Minnesota's reporting law identified many payments to physicians that may have violated industry guidelines on modest gifts and meals (Ross et al. 2007).

A public reporting system would enable payers (including Medicare) and plans to examine whether physicians' practice patterns are affected by their financial relationships with manufacturers. For example, what factors—including financial ties to drug companies—influence which drugs physicians prescribe? Do patients treated by physicians with industry relationships have higher costs for an episode of care? Some plans in Minnesota have been using state information on physician–industry interactions to review physician prescribing behavior (Wyckoff 2008). Plans could also use this information to tier providers or make other network decisions.

Hospitals make important decisions about which drugs to include in their formularies and which devices to purchase. Physicians can request that a hospital add a pharmaceutical to its formulary or purchase an expensive new device, such as an artificial hip or cardiac stent. Surgeons have a great deal of discretion when deciding which implant to use in a patient. Although physicians are generally motivated by their patients' best interests when recommending a drug or device, financial incentives at times may play a role. Hospitals may be unaware if physicians have financial relationships with manufacturers and may have difficulty obtaining this information (Abelson 2005). A public reporting system would allow hospitals to check whether physicians who request that the hospital add a drug to its formulary or purchase an expensive device have financial ties to the manufacturer. Hospitals could use this information when deciding which drugs to include in a formulary and which devices to purchase, as well as when negotiating prices.

Potential limitations and costs of public reporting

When exploring a public reporting system, it is important to recognize potential limitations and costs:

- Information on financial relationships may not be useful to many patients.
- Mandatory reporting would not eliminate conflicts of interest.
- A federal reporting law may impose compliance costs on manufacturers (to report financial information) and some 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. Patients frequently lack medical expertise and usually trust their physicians and thus are unlikely to know how their physicians' financial interest could bias their advice or whether their physicians' recommendations are appropriate (Cain et al. 2005). If a patient's physician makes the disclosure, this may actually increase the patient's level of trust. For example, if a physician tells a patient that he or she is paid by a manufacturer to give speeches about a drug, the patient's trust may deepen because the physician has been honest. In addition, physician disclosure to patients may lead both parties to believe there is no longer a possibility for the disclosed relationship to bias physician decision making (Brennan et al. 2006, Cain et al. 2005). Disclosure may be more useful to those with medical expertise, such as providers, when they need to evaluate physicians' independence and objectivity.

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, research funding, consulting fees, meals, royalties, and other payments from manufacturers. However, public disclosure could discourage physicians from having relationships 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.

Existing state laws require that manufacturers—not physicians—report information on physician relationships. PhRMA has expressed concern that a potential federal reporting law would impose a burden on manufacturers (Bloedorn 2007). 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. One option for reducing the reporting costs of manufacturers and the administrative costs of the government is to require that manufacturers start by reporting higher value arrangements with physicians and then, over time, begin reporting smaller gifts and payments.

Key design questions for a federal reporting system

In this section, we examine three key design questions for a potential federal law requiring public reporting of physician–industry relationships:

- How comprehensive should the reporting system be?
- What size and types of payments should be reported?
- How can the data be made readily accessible to the public?

We also examine which agency should administer a potential public reporting law and whether a federal law should preempt existing state laws.

How comprehensive should the reporting system be?

Policymakers would need to determine which types of manufacturers should be subject to a public reporting law, which recipients of industry payments to include, and whether to allow companies to withhold information that they deem to be proprietary. Although state reporting laws apply only to drug manufacturers, a comprehensive federal law could also include manufacturers of biological products, medical devices, and medical supplies because these manufacturers often have extensive relationships with physicians and federal health programs spend a lot of money on these products. In addition, a comprehensive law could apply to small as well as large companies to achieve a level playing field.

An important question is whether payments made to entities other than physicians should be included in a public reporting law. Although including payments to other entities would increase transparency, it also would add complexity to a public reporting system. Manufacturers provide support for education and research to AMCs, so there may be a public interest in obtaining information on the nature and extent of financial relationships between companies and medical schools and teaching hospitals. In addition, industry support for CME organizations accredited by the ACCME amounted to $1.2 billion in 2006, half of their total income (ACCME 2006). This dependence on commercial support has led to concerns about inappropriate industry influence over CME activities and prompted a recent recommendation that CME funding should be disclosed through an online registry (Steinbrook 2008). Therefore, it may be important to include manufacturer payments to CME organizations in a public reporting system. Finally, medical societies and other organizations of health care professionals may receive grants and subsidies from drug and device companies for education and fellowships, which could also be included in a reporting law.

Eli Lilly, a pharmaceutical manufacturer, 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 CME companies. Further, a dozen drug and device manufacturers recently announced that they intend to publicly disclose their medical education grants; some of these companies also plan to disclose payments to patient advocacy groups (Freking 2008).

Should manufacturers be required to report information they consider to be proprietary? On the one hand, companies may wish to shield details of their research, product development, education, and marketing programs from competitors. On the other hand, the public has a legitimate interest in learning about the industry's financial relationships with physicians. Vermont permits manufacturers to designate information as a "trade secret" that is not released to the public, but this policy resulted in 72 percent of payments being withheld from public disclosure in 2006 (Vermont Office of the Attorney General 2007). AdvaMed contends that, to protect proprietary information about a product under development from competitors, consulting arrangements with physicians should not be disclosed until a product is approved by the FDA (AdvaMed 2008).

What size and types of payments should be reported?

A public reporting system could collect detailed information on a wide variety of financial relationships between manufacturers, physicians, and possibly other entities. In designing a law, policymakers would need to set a dollar threshold for payments that must be reported and define which types of payments and what details must be reported.

State laws have different dollar thresholds for payments that must be reported, ranging from $25 to $100. Although

a low threshold would result in the collection of more information on small gifts and meals, this additional information should be weighed against the greater reporting burden on manufacturers.

Several types of payments or transfers of value could be included in a reporting requirement, ranging from smaller items to significant financial arrangements: free product samples intended for patients, gifts, food, entertainment, honoraria, payments or subsidies related to medical conferences, consulting fees, speakers' fees, funding for research, investment interests in a manufacturer, profit distributions, and product royalties. Most state reporting laws exclude payments for clinical trials and other research, although there is evidence that industry-sponsored research can be biased and some industry-sponsored studies appear to serve promotional, rather than scientific, purposes (Angell 2005, Bekelman et al. 2003, Demske 2008, Psaty and Kronmal 2008).

An important question is whether to require the reporting of free product samples intended for patients (the laws in four states and Washington, DC, exclude this category). On the one hand, because manufacturers frequently provide free samples to physicians, mandatory reporting of samples would increase both the complexity of a law and the compliance costs for companies. According to a physician survey, 78 percent of physicians received samples in the last year (Campbell et al. 2007a). PhRMA contends that free samples make it easier for patients to find the right drug and to start treatment sooner, and they help uninsured patients obtain medication (PhRMA 2008). 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 enable sales representatives to gain access to physicians and lead physicians and patients to rely on branded drugs instead of cheaper generics that may be equally effective (Brennan et al. 2006). A recent study found that poor and uninsured individuals are less likely to receive free samples than wealthy and insured patients (Cutrona et al. 2008). Finally, researchers have estimated that the retail value of free samples provided by drug manufacturers 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). Including free samples in a reporting system would provide the public a more complete picture of industry promotional activities.

Regardless of which payment categories are included in a reporting system, it is important that they be clearly defined and standardized so that the information is consistently reported. Each payment made to each physician or entity could be itemized to allow researchers to examine the size and frequency of individual payments. In addition, manufacturers could be required to report the name and address of the physician or entity to whom a payment or transfer of value was made, the value of each payment, the type of payment (e.g., gift, meal, or consulting fee), and the date (or range of dates) of the payment. Companies could be allowed to report additional clarifying details about a payment (e.g., payment for training other physicians in the proper use of an implantable device). To keep the database up to date, policymakers could require that companies report information on a regular schedule, such as quarterly or annually.

How can the data be made readily accessible to the public? Making data easily available to the public is a significant issue, given the difficulties of accessing information collected under state laws (Ross et al. 2007). To further this goal, information on payments to physicians and other entities could be posted on the Internet in an electronic format that is easy to search and download. The website could allow users to search for and aggregate payments by type, amount, physician or entity, date, and manufacturer. Manufacturers could be required to report payment information electronically to facilitate the creation of a database.

Other issues Policymakers would need to decide which agency would be best suited to administer a reporting law. Although the FDA could be an option 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. As noted earlier, two states with public reporting laws spend very little to collect information from the industry and post it on a website, but the costs of monitoring and ensuring compliance are uncertain (Lunge 2008).

An important question is whether a potential federal reporting law should preempt existing or future state reporting laws. On the one hand, preemption would

reduce the compliance costs for manufacturers because they would need to comply with only one federal law rather than several state laws (AdvaMed 2008). A single source of information could also reduce confusion among users. On the other hand, preemption raises concerns about state autonomy. A potential compromise would be to allow state laws that require reporting of information not collected under a federal law. In other words, a federal law would constitute a minimum floor. For example, if a federal law excluded reporting of free samples, a state law could require such reporting. If this approach leads to multiple state laws, however, it would likely not reduce the industry's compliance costs.

Reporting physicians' financial relationships with hospitals and ambulatory surgical centers

The number of physician-owned specialty hospitals more than doubled from 2002 to 2006, from 46 to 128 (CMS 2006, MedPAC 2005). The number of Medicare-certified ambulatory surgical centers (ASCs)—most of which have at least some physician ownership—grew by 31 percent from 2002 to 2006, from 3,600 to 4,700 (ASC Coalition 2004, Medical Group Management Association 2006, MedPAC 2007a). There has also been an increase in joint venture facilities owned by physicians and hospitals, such as imaging centers, cardiac catheterization labs, and specialty hospitals (Chapter 3 in this report provides additional information on joint ventures). Although physician ownership of hospitals and ASCs may offer benefits to physicians and patients, there is evidence that the presence of physician-owned specialty hospitals is associated with a higher volume of surgeries in a market (MedPAC 2006, Nallamothu et al. 2007). In addition, a recent study suggests that physician ownership of ASCs may influence referral patterns (Gabel et al. 2008).

Currently, it is difficult for the general public to obtain information about physicians' financial relationships with hospitals and ASCs. CMS requires hospitals to disclose to patients whether they are owned by physicians and has proposed the same requirement for ASCs, which may help patients make informed decisions about their care. However, this information is not available to payers, plans, and researchers (Table 6-2, p. 160). Creating a searchable electronic database with information on physicians' financial relationships with hospitals and ASCs would help payers, plans, and researchers examine the influence of these relationships on referral patterns and the overall volume of services.

Physicians may also own health care facilities that provide physical therapy, radiation therapy, diagnostic imaging, clinical laboratory tests, and other ancillary services. Some might wonder whether these providers should also be required to publicly report their financial arrangements with physicians. However, the Stark law prohibits physicians from owning or investing in a facility to which they refer their Medicare or Medicaid patients for diagnostic tests or other ancillary services, with some exceptions.[11] According to one of those exceptions, physicians may provide these services to patients in their offices as long as the services are billed by the referring physician or the group practice and other conditions are met.[12] Therefore, CMS should know if a physician or group practice is providing ancillary services because the provider's billing number appears on the Medicare claim. In addition, patients may be aware that their physicians have a financial interest in ancillary services provided in their offices. Thus, it is probably not necessary to create a database that identifies physicians who own entities providing tests or other ancillary services.

Impact of physician ownership of hospitals and ASCs on volume and referrals

By giving physicians more control over their work environment, physician-owned hospitals and ASCs allow physicians to hire specialized staff, customize operating rooms for specific procedures, and schedule surgeries more efficiently (MedPAC 2005). Physician-owned facilities may also improve access and convenience for patients. However, the growth in the number of physician-owned facilities could also lead to a higher volume of services in a market through additional capacity and by creating financial incentives for physicians to refer patients for more procedures. First, if additional hospitals and ASCs increase overall capacity in a market, this may lead to greater use of supply-sensitive services, such as diagnostic tests and minor procedures. With supply-sensitive care, the capacity of the health care system drives the amount of services delivered. For example, a new cardiac hospital may be associated with an increased number of coronary angioplasties provided in a market. Second, physicians who invest in facilities have a financial incentive to refer patients for additional admissions or procedures, as long as those services are profitable.

With their authority to make decisions about diagnosis and treatment, physicians are the central actors in the health

TABLE 6–2 **Under current and proposed federal disclosure rules for hospitals and ambulatory surgical centers, information is limited and often not publicly available**

	Hospitals	ASCs
Current rules	• Report physicians who own 5 percent or more of hospital to CMS, but information not publicly available • Inform Medicare patients whether hospital is physician owned when they receive preadmission information or arrive for outpatient services	• Report physicians who own 5 percent or more of ASC to CMS, but information not publicly available • ASCs that comply with anti-kickback safe harbor must disclose physician ownership to patients
Recent CMS and IRS proposals	• A sample of hospitals would report to CMS physician ownership and other financial relationships (unclear if information would be publicly available) • Would require physicians with admitting privileges to disclose ownership in hospital to patients when they are referred to hospital • Nonprofit hospitals would report certain joint ventures with physicians on IRS Form 990, but not names of physician investors	• Would disclose physician financial interests in ASC, including ownership, to patients

Note: ASC (ambulatory surgical center), IRS (Internal Revenue Service). The general public does not have access to information on physician ownership disclosed to patients.

Source: CMS 2008a, CMS 2008b, CMS 2007a, CMS 2007b, IRS 2008, OIG 1999.

care delivery system. When they recommend services to patients, professional ethics and concern for their patients' best interest are powerful motivations. However, financial incentives may also influence some physicians' decisions, particularly with regard to services that lack evidence-based guidelines (Wennberg et al. 2002). For example, there is not much evidence in the medical literature on the appropriate indications for hospitalizations and use of diagnostic tests.

In MedPAC's 2006 specialty hospital study, we found that the opening of a physician-owned cardiac hospital resulted in additional cardiac surgeries in a market (MedPAC 2006). For the average heart hospital with a market share of 26 percent, total cardiac surgeries in the market were estimated to increase by 6 percent. A recent article confirmed these findings (Nallamothu et al. 2007). Likewise, another study examined physician-owned spine hospitals and found increases in spinal fusion after these facilities opened (Mitchell 2007). The Commission's research also found that physician-owned specialty hospitals generally treat less severe cases (expected to be relatively more profitable than average); concentrate on particular diagnosis related groups, some of which are relatively more profitable; and tend to have smaller shares of Medicaid patients than community hospitals (MedPAC 2005).

Although the relationship between physician investment in ASCs and the overall volume of surgical services has not been examined, evidence from a recent study indicates that physician ownership of ASCs may influence referral patterns (Gabel et al. 2008).[13] This article examined data from Pennsylvania and found that physicians who sent many patients to physician-owned ASCs were much more likely to refer their commercial/Blue Cross patients to a physician-owned ASC than their Medicaid patients; these physicians referred more than 90 percent of their commercial/Blue Cross and Medicare patients to a physician-owned ASC but only 55 percent of their Medicaid patients (Gabel et al. 2008). This finding raises a concern that physicians who invest in ASCs may refer more lucrative patients to their facilities and less lucrative patients to hospitals. This study has two main limitations, however:

- Physicians might have been more likely to refer their Medicaid patients to hospitals because Medicaid managed care plans might not cover surgeries in ASCs.

- Because the authors lacked public information on physicians who own or invest in ASCs, they used a proxy measure for ownership based on physicians who accounted for 50 percent of referrals to physician-owned ASCs.

With regard to the first limitation, physicians who sent many patients to non-physician-owned ASCs were also more likely to refer their commercial/Blue Cross patients than their Medicaid patients to an ASC, but the magnitude of this difference was smaller than that for physicians who referred patients to physician-owned ASCs.[14] This finding suggests that physician ownership of an ASC may have influenced referrals independent of Medicaid coverage policies. With regard to the second limitation, public information on physician ownership of ASCs would allow more robust research on whether and to what extent physician investment influences referral patterns and total volume in a market.

Reporting financial relationships between physicians and hospitals

Hospitals currently have to comply with two (or potentially three) CMS rules that require disclosure of physician–hospital relationships, but none of the required disclosures is comprehensive or available to the general public (Table 6-2).[15] Under one federal disclosure requirement, a hospital enrolling in Medicare must identify individuals—including physicians and their Medicare provider numbers—who own 5 percent or more of the hospital. 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 contained in the CMS database on provider ownership and enrollment in Medicare.

Under a second CMS requirement, a physician-owned hospital must inform its Medicare patients that the hospital is physician owned and that the patient can request a list of all physician owners of the facility (CMS 2007b). The hospital must notify patients of physician ownership when they receive their preadmission packet of information or arrive for outpatient services.[16] However, CMS does not receive this notification information.

Under a third reporting mechanism proposed by CMS, hospitals would be required to report physician ownership and details of other financial relationships with physicians to CMS, including the value of compensation arrangements and copies of agreements (CMS 2008a). However, this proposed data collection—called the Disclosure of Financial Relationships Report (DFRR)—would include a sample of only 500 hospitals, and it is not clear that any of the data would be available to other payers, plans, patients, or researchers.

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 the 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.

To improve the transparency of physicians' financial relationships with hospitals, CMS could collect information on certain relationships from all hospitals and make the data publicly available on a searchable website that could be updated regularly. A database containing this information could include the hospital name and identification number, physician name and identification number, type of financial relationship, and, for physician owners, the ownership percentage. CMS would have to determine which relationships to include in a reporting requirement. The agency could begin by asking hospitals to report data on physician ownership, equipment and space leases, and joint ventures and later collect information on physician employment. To minimize the reporting burden on hospitals, CMS could exclude details of agreements between hospitals and physicians from the database. CMS could proceed with the DFRR on a sample basis to obtain more detailed data on physician–hospital relationships.

Payers and researchers could use information from a public database on physician–hospital relationships to examine whether different types of relationships influence patient referrals, resource use for an episode of care, or overall volume of services in a market. Patients could use such a database to learn about physician ownership before they select a physician and hospital. (Currently, they can request a list of physician owners only after they receive their preadmission packet of information for their scheduled admission or when they arrive for an outpatient service).

Reporting physician investments in ambulatory surgical centers

Most ASCs have at least some physician ownership, but there is no comprehensive public database that identifies all physicians who invest in ASCs.[17] As with hospitals,

ASCs must identify physicians and others with a 5 percent or more ownership interest when they enroll with Medicare (CMS 2008b) (Table 6-2, p. 160). However, this information is not publicly available, and physicians with smaller ownership interests are not reported to the agency. A requirement for physician ownership to be disclosed to patients applies to at least some—but not all—physician-owned ASCs, and CMS has proposed a new disclosure-to-patients rule that would apply to all ASCs. However, the current and proposed requirements have weaknesses that could be remedied by creating a public database.

Physician-owned ASCs that wish to comply with a safe harbor to the anti-kickback statute are required to meet a physician ownership disclosure requirement: Patients referred to the ASC by a physician investor must be fully informed of the physician's ownership interest in the ASC (OIG 1999).[18] However, it is unclear whether patients must be informed at the time of referral or when they arrive for surgery. This rule applies to physician-owned ASCs that comply with the anti-kickback safe harbor, but not all physician-owned ASCs are eligible for the safe harbor. For example, the safe harbor covers surgeon-owned, single-specialty, multispecialty, and hospital–physician ASCs that meet certain conditions, but not ASCs jointly owned by physicians and a corporate chain. In addition, this information is not reported to a federal agency or made available to the public.

As part of its proposal to update the ASC conditions of coverage, CMS has proposed requiring that ASCs disclose physician financial interests in the ASC (including ownership) to patients before their visit to the ASC (CMS 2007a).[19] However, this information would not be available to plans, payers, the media, researchers, and other members of the public. 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.

Creating a public database on the CMS website that included the names of all physicians who invest in ASCs and their ownership percentage would help plans, payers, and researchers analyze whether and to what extent ASC ownership affects referral patterns and the number of procedures performed. This information could be part of a database on hospital–physician financial relationships.

Conclusion and future work

In this chapter, we described the financial relationships between drug and device manufacturers and physicians, academic institutions, and medical education organizations. Although these financial ties can lead to advances in medical technology, they may also create conflicts between physicians' obligation to do what is best for their patients and the commercial interests of manufacturers. If physicians' decisions are not fully objective and independent, this may lead to increased Medicare spending and suboptimal care for beneficiaries. Requiring manufacturers to publicly report information on their financial relationships with physicians could encourage physicians to reflect on the propriety of those relationships and perhaps discourage inappropriate arrangements. A public reporting system also would help payers, plans, researchers, and reporters shed light on physician–industry interactions and examine physicians' practice patterns. In future work, we plan to further explore key questions in designing such a system, such as which types of manufacturers to include, whether payments made to entities other than physicians should be reported, and which types of payments to include.

We also examined the rapid growth of physician-owned specialty hospitals and ASCs. Currently, it is difficult for the general public (other than patients) to obtain information about physicians' financial relationships with hospitals and ASCs. Information on other physician–hospital relationships, such as joint ventures and equipment leases, is also not publicly available. If payers, plans, and researchers had access to basic data about certain physician relationships with hospitals and ASCs, they could use this information to examine the influence of these arrangements on referral patterns and the overall volume of services. In the future, we intend to examine which types of relationships should be publicly reported. ■

Endnotes

1 These groups are the Association of American Universities and the Association of American Medical Colleges.

2 We are not aware of research that examines the effects of DTC advertising for medical devices on patients' requests for devices and use of devices.

3 Several factors other than marketing by drug manufacturers may also affect physicians' prescribing decisions, such as published literature, information from peers, CME activities, clinical guidelines, health plan formularies, and utilization management programs.

4 In one study, for example, individuals were assigned to the role of plaintiff or defendant in a lawsuit and asked to neutrally rate the importance of arguments favoring either side (Dana and Lowenstein 2003). Participants showed a strong tendency to favor the arguments of the side to which they had been assigned. This result demonstrates that it is difficult for people to be objective when they have a vested interest in reaching a conclusion.

5 Physicians who administer drugs to patients in their offices bill Medicare for the drugs under Part B.

6 A fifth orthopedic device company entered into a nonprosecution agreement with the government, under which it agreed to implement the same reforms as the other four companies but was not part of the financial settlement.

7 The PhRMA and AMA codes allow manufacturers to support CME and other educational activities indirectly through a third-party sponsor.

8 Minnesota's ban does not apply to manufacturer payments to physicians for educational programs, honoraria, and consulting fees.

9 California's statute mandates that each pharmaceutical manufacturer develop a comprehensive compliance program that specifies an annual dollar limit on gifts, promotional materials, and items or activities that the pharmaceutical company may provide to an individual medical or health care professional. These comprehensive compliance programs must conform to OIG guidelines and the PhRMA code (California Health and Safety Code 2004). Annual dollar limits set by pharmaceutical manufacturers range from $300 per health professional for McKesson to $3,000 per health professional for Novartis (McKesson 2005, Novartis 2008). Drug samples, financial support for CME, and consulting fees are exempt from the annual limit on payments.

10 Trade secrets are defined in 1 V.S.A. 317(b)(9) as "including, but not limited to, any formulae, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it" (Vermont Office of the Attorney General 2005).

11 The Stark law, also known as the Ethics in Patient Referrals Act, was enacted in two phases. Stark I covered financial relationships between physicians and clinical laboratories. Stark II covered relationships between physicians and entities that provide nine other services: diagnostic imaging, radiation therapy, physician and occupational therapy, durable medical equipment, parenteral and enteral nutrients, prosthetics and orthotics, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.

12 Ancillary services performed by a group practice in its office must also be performed or supervised by the referring physician or another physician in the group practice and done in the same building where the referring physician (or another physician in the group) provides patient care or in a "centralized building" used by the group for ancillary services.

13 A study by the Florida Health Care Cost Containment Board of physician-owned ASCs did not examine whether physician ownership influenced the overall volume of surgeries because the number of ASCs was relatively small (State of Florida 1991).

14 Top-referring physicians to non-physician-owned, for-profit ASCs sent 78 percent of their commercial/Blue Cross patients and 61 percent of their Medicaid patients to the ASC. The comparable numbers for physicians who referred many patients to physician-owned ASCs were 92 percent and 55 percent (Gabel et al. 2008).

15 In addition, beginning in 2009, the Internal Revenue Service plans to require that nonprofit hospitals report certain joint ventures with physicians on Form 990 (IRS 2008). However, the draft form does not require that hospitals report the names and provider numbers of physicians who invest in the joint venture.

16 In the proposed inpatient hospital rule for fiscal year 2009, CMS has proposed mandating that hospitals require physicians with admitting privileges to disclose their ownership or investment interests in the hospital to patients when they refer them to the hospital (CMS 2008a).

17 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).

18 The anti-kickback statute prohibits health care providers from receiving or paying anything of value to influence the referral of services covered by federal health programs. The OIG has published safe harbor regulations that protect physicians who invest in ASCs from prosecution under the anti-kickback statute, if certain conditions are met.

19 The ASC conditions of coverage are the rules that ASCs must follow to participate in Medicare (CMS 2007a).

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