

CHAPTER

7

**An overview of the
medical device industry**

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Chapter summary

Because Medicare does not pay directly for medical devices, the Commission has not historically studied medical devices in depth in its evaluation of Medicare payment policy. In response to recent Commissioner interest, however, this chapter provides an overview of the medical device industry and reviews how Medicare pays for medical devices.

The medical device industry makes an enormous number of products—ranging from surgical gloves to artificial joints to imaging equipment—and plays a crucial role in developing new medical technologies that can improve the ability to diagnose and treat illness. The industry has a relatively small number of large, diversified companies and a large number of smaller companies that are mainly engaged in research and development of new devices for specific therapeutic areas. The industry is distinctive both for its tendencies to make frequent, incremental changes to its products and its extensive ties with physicians.

Like prescription drugs, medical devices are regulated by the Food and Drug Administration (FDA). However, the regulatory framework that the Congress has established for medical devices is less stringent in many respects, due in part to underlying differences between medical devices and prescription drugs. Most low-risk devices can be marketed without prior FDA review, and most medium-risk devices are required to demonstrate only that they are

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“substantially equivalent” to an existing device before being marketed. Very few devices must demonstrate that they are safe and effective before being marketed. The FDA’s surveillance of devices after becoming available to the public has also been limited historically, although improvements are being made through initiatives such as requiring unique device identifiers on all devices.

The market dynamics for medical devices can vary greatly depending on the device. Markets for conventional devices such as surgical gloves and other routine surgical supplies are more competitive; companies compete heavily on price and often need high sales volumes to be profitable. In contrast, markets for advanced products like implantable medical devices involve opaque pricing, are harder to enter, and are less competitive, which allows device companies to charge higher prices and earn substantial profits. Large medical device companies are consistently profitable and typically have profit margins of 20 percent to 30 percent.

Medicare pays for medical devices indirectly by reimbursing providers when they use devices in the course of delivering care to beneficiaries. Medicare bundles the average cost of medical devices into its overall payment rate for many services, giving hospitals, for example, an incentive to use lower cost devices. However, physicians often do not have an incentive to use lower cost devices because physicians are generally not financially responsible for the cost of the device and may have financial connections to the device industry. Bundling also makes it harder to measure how much the program spends on medical devices, but Medicare cost report data for 2014 indicate that hospitals spent about \$14 billion on implantable devices and \$10 billion on medical supplies (e.g., handheld surgical instruments) for Medicare-covered services.

Because of the indirect manner in which Medicare pays for most medical devices, future changes designed to improve the quality of medical devices Medicare beneficiaries receive and to reduce their associated costs could focus on improving the availability of device- and provider-specific information and aligning provider incentives. Such improvements could entail adding more device-specific information to administrative claims, improving reporting by physician-owned distributors (PODs) under the Open Payments program, limiting the number of PODs, and more broadly allowing initiatives that encourage hospital-physician collaboration to reduce device costs. ■

Introduction

Medical devices play an important role in the delivery of many health care services. Defined broadly, medical devices are items that are used for the “diagnosis . . . cure, mitigation, treatment or prevention of disease” and are not absorbed or metabolized by the body.¹ The term applies to everything from common medical supplies such as latex gloves and syringes to advanced imaging equipment and implantable devices such as cardiac defibrillators. The medical device industry is thus an important component of the larger health care system and plays an essential role by developing new medical technologies that can improve the ability to diagnose and treat illness.

Most medical devices serve as inputs in the delivery of health care services and are usually not considered services by themselves. The major exceptions are medical devices that are used as durable medical equipment, prosthetics, or orthotics. As a result, Medicare has chosen to pay for many medical devices in an indirect manner, by including an amount for medical devices in its payment rates for services in which devices are used. For example, Medicare’s payment to a hospital or ambulatory surgical center for cataract replacement surgery includes an amount for the cost of the artificial lens.

Since Medicare does not pay directly for medical devices, the Commission has not historically studied medical devices in depth in its evaluation of Medicare payment policy. In response to Commissioner interest, however, this chapter provides an overview of the medical device industry by reviewing its overall size and composition, the development of new medical devices, the role of the Food and Drug Administration (FDA), and some key features of the medical device market. It also examines how Medicare pays for medical devices in greater detail.

Overall size and composition of the medical device industry

Because of the wide range of items that can be considered medical devices, there is no standard way of defining the medical device industry, and estimates of its overall size vary. For example, recent studies by the Congressional Research Service (CRS), BMI Research, and the Advanced Medical Technology Association (AdvaMed, the industry’s main trade association) have estimated that

total U.S. spending on medical devices was \$119 billion in 2011, \$125 billion in 2013, and \$172 billion in 2015, respectively (BMI Research 2015, Donahue and King 2015, Gravelle and Lowry 2015). All three studies are based on the same underlying data source—sales data from manufacturers that are collected by the Census Bureau—but differ by which sales are counted as medical devices and the adjustments made to convert sales data into estimates of overall U.S. spending.

These estimates indicate that medical devices account for roughly 4 percent to 6 percent of total U.S. spending on health care (BMI Research 2015, Donahue and King 2015). The AdvaMed study also found that the share of total U.S. spending on health care devoted to medical devices has changed very little over time, suggesting that spending on medical devices has grown at about the same rate as the broader health care sector (Donahue and King 2015).

Estimates of the total number of companies and employees in the medical device industry also vary somewhat. According to two studies that used data from the Census Bureau, there are roughly 5,300 to 5,600 U.S. companies in the industry, with approximately 330,000 to 365,000 employees (BMI Research 2015, International Trade Administration 2010). Medical device companies are located throughout the United States, but the industry has a larger presence in California, Massachusetts, and Minnesota.

International trade also plays a significant role in the medical device industry. Between 35 percent and 40 percent of domestic U.S. production is ultimately exported, and a similar share of domestic U.S. consumption is imported (Gravelle and Lowry 2015). Foreign sales represent 40 percent to 50 percent of overall revenues for U.S. medical device companies when sales by foreign subsidiaries are taken into account (Seligman 2013). The largest export markets for U.S. medical device companies have traditionally been the countries of the European Union and Japan (International Trade Administration 2010). The United States is the largest single market for medical devices and accounts for about 40 percent of worldwide sales (BMI Research 2015).

Most of the companies in the medical device industry are relatively small. One study that analyzed economic data from the Census Bureau found that 73 percent of medical device firms had fewer than 20 employees and that 88 percent had fewer than 100 employees (International

**TABLE
7-1****The 10 largest medical device companies, 2015**

Rank	Company	Country	Global medical device revenue (in billions)
1	Medtronic	United States	\$27.7
2	Johnson & Johnson	United States	27.5
3	GE Healthcare	United States	18.3
4	Baxter International	United States	16.7
5	Siemens Healthcare	Germany	15.8
6	Becton Dickinson	United States	12.3
7	Philips Healthcare	Netherlands	11.2
8	Cardinal Health	United States	11.0
9	Abbott Labs	United States	10.1
10	Stryker	United States	9.7

Note: Some companies shown in this table, such as Johnson & Johnson, generate substantial revenues in industries other than medical devices; the figures for these companies are for their medical device divisions only. Figures for Medtronic and Becton Dickinson reflect their acquisitions of Covidien and CareFusion, respectively. Since its acquisition of Covidien, Medtronic has been headquartered in Ireland for tax purposes.

Source: Medical Product Outsourcing 2015.

Trade Administration 2010). These figures suggest that companies with fewer than 100 employees account for roughly 15 percent to 20 percent of total employment in the medical device industry. CRS found a similar pattern when it looked at corporate tax return data for U.S. companies whose primary activity is making medical supplies and equipment: 83 percent of companies had less than \$1 million in assets, and 95 percent had less than \$10 million in assets (Gravelle and Lowry 2015). These smaller companies are engaged primarily in the development of new medical technologies and are often focused on relatively narrow therapeutic areas.

At the other end of the distribution, a relatively small number of large companies account for most of the medical device industry's overall employment and revenues. The same CRS study found that the top 1 percent of firms in the medical device industry accounted for 82 percent of total assets, with the top 0.2 percent of firms alone accounting for 56 percent of overall assets (Gravelle and Lowry 2015). These companies operate in many countries around the world and are highly diversified, making medical devices for several different therapeutic areas and often producing a broad range of medical devices within a therapeutic area. The 10 largest medical device companies, including those based outside the United States, are shown in Table 7-1.

The development of new medical devices

Large and small medical device companies both play a role in the development of new medical devices. Small medical device companies are engaged primarily in developing new medical technologies, and typically their work is narrowly focused on a specific therapeutic area. These companies have traditionally been funded by venture capital firms that hope to profit if the companies develop promising products. The prospects for these companies are uncertain given the challenges of securing enough start-up funding, developing the new medical device itself, figuring out how to manufacture the device in a cost-effective manner, obtaining the necessary regulatory approvals, and marketing the device to providers such as hospitals and physicians. These companies typically spend a large share of their revenues on research and development and may be unprofitable for years before developing a viable product or going out of business (Seligman 2013).

The overall amount of venture capital funding for medical device companies has declined somewhat in recent years. Between 2007 and 2009, the total amount that venture capital firms invested in medical device companies declined from \$3.7 billion to \$2.6 billion, and, since then,

annual investment has ranged between \$2.2 billion to \$2.9 billion. Similarly, the share of total venture capital funding going to medical device companies declined between 2007 and 2015, from 7.9 percent to 6.1 percent (PricewaterhouseCoopers and National Venture Capital Association 2016). Even with this recent decline, the total amount of venture capital funding going to medical device companies is still substantially higher than it was in 1992, when the industry received about \$400 million in venture capital funding (Advanced Medical Technology Association 2017). The recent drop in venture capital funding has been partly offset by greater funding from large medical device companies, which also invest in start-up device companies (Walker 2013). However, the decline has raised concerns that the industry's ability to develop new medical devices could suffer (Ernst & Young 2015).

Start-up companies that develop promising new products are often acquired by one of the large medical device companies.² These acquisitions benefit each side in a number of ways. Small companies can find it challenging to market their products, while major device companies have established distribution networks and relationships with hospitals and other providers. Large companies can also provide additional resources to further develop and improve new medical devices. An acquisition also allows the venture capital firms that supported the start-up company to withdraw their funding and realize a profit.³ For the large companies, acquisitions provide another way to conduct research and development and can either complement or substitute for the company's internal efforts. Large companies can also use acquisitions to branch out into new therapeutic areas or bolster existing product lines (International Trade Administration 2010, Moody's Investors Service 2015, Seligman 2013).

Although small companies play an important role in the initial discovery and development of new technologies, large medical device companies perform most of the industry's research and development. CRS found, based on corporate tax return data for U.S. companies that make medical supplies and equipment, that the 17 companies that had more than \$2.5 billion in assets claimed 56 percent of the tax credits for research and experimentation. The companies with more than \$500 million in assets claimed 80 percent of the credits (Gravelle and Lowry 2015).⁴

Research by financial analysts suggests that large medical device companies typically spend between 5 percent and

15 percent of their revenues on research and development, with most companies somewhere in the middle of that range (Fuhr et al. 2013, Moody's Investors Service 2015, Seligman 2013). Companies that make technologically sophisticated products such as implantable cardiovascular devices tend to spend more on research and development than companies that make less innovative products such as artificial joints (Moody's Investors Service 2015). The major medical device companies typically spend more on research and development as a share of sales revenue than other industrial firms (3 percent to 4 percent) but less than pharmaceutical manufacturers (15 percent) (Seligman 2013). However, these figures should be viewed with some caution because there is no standard way of defining which activities constitute research and development; some companies may classify activities as research and development that other companies or observers would not.

One notable difference between the medical device and pharmaceutical industries is that physicians are much more involved in the development of medical devices. Device makers often seek the input of physicians about the design and potential uses for new products and solicit feedback from physicians who use their products. In some cases, physicians bring their ideas for new or improved products to manufacturers. Research has found that physicians accounted for about 20 percent of the patents issued for medical devices between 1990 and 1996 (Seligman 2013). However, the extensive relationships between physicians and device companies have also raised concerns about the ability of device companies to influence physicians' treatment decisions (Ornstein and Weber 2011).

One particularly important feature of the medical device industry is its tendency to make "many incremental modifications of existing products, punctuated occasionally by an innovation that offers a significantly new mechanism of action, design, or risk profile" (Robinson 2015). Since medical devices are often modified, the life cycles for individual products can be relatively short compared with prescription drugs; the industry has said that most medical devices are replaced by a newer version every 18 to 24 months (Advanced Medical Technology Association 2015a). The shorter life cycle means that the payback period for research and development is also shorter, and that successful medical devices are typically not as profitable as blockbuster prescription drugs (Seligman 2013). Nevertheless, large medical device companies have been consistently profitable.

**TABLE
7-2****FDA classification and review of medical devices**

Category	Level of risk to patient	Examples	Type of review before device can be marketed
Class I	Low	<ul style="list-style-type: none"> Elastic bandages Examination gloves Handheld surgical instruments 	Most devices required only to register; a small share must submit a 510(k) notification.
Class II	Moderate	<ul style="list-style-type: none"> Powered wheelchairs Infusion pumps Surgical drapes 	Most devices must submit a 510(k) notification; a small share of devices are required only to register.
Class III	High	<ul style="list-style-type: none"> Heart valves Silicone breast implants Implanted cerebella stimulators 	Devices must submit a PMA application; in the past, a significant number of devices were able to submit a 510(k) notification.

Note: FDA (Food and Drug Administration), PMA (premarket approval).

Source: Johnson 2016.

Like the pharmaceutical industry, medical device companies frequently obtain patents to prevent other companies from copying their products for a period of time. The U.S. Patent and Trademark Office has issued more than 75,000 patents for medical devices over the past 30 years. However, patents for medical devices are usually not as specific as patents for prescription drugs, which makes patents on medical devices easier to circumvent and lawsuits for patent infringement common. The shorter life cycles for medical devices also reduce the value of patents because many devices can become obsolete before their patent expires (Seligman 2013).

The role of the Food and Drug Administration

Before medical device manufacturers can market a new product, they must comply with the requirements of the FDA, which is responsible for regulating medical devices. When the FDA was created in the 1930s, its authority over medical devices was relatively limited. The agency could prosecute individuals who misused medical devices, but medical device manufacturers did not have to obtain FDA approval before marketing their products in the same manner as pharmaceutical manufacturers. This arrangement ended in 1976, when the Congress established a new system for the FDA to regulate medical devices (Seligman 2013). However, medical devices that

were already on the market were not required to comply with all aspects of the new regulatory system. This distinction between *preamendment* and *postamendment* devices—terms referring to the Medical Device Amendments of 1976—remains relevant 40 years later because many devices can enter the market by effectively demonstrating that they are similar to devices approved under the preamendment rules.

While the FDA now regulates both medical devices and prescription drugs, its regulation of medical devices is less stringent in many ways. To some extent, these regulatory differences reflect underlying differences between medical devices and prescription drugs. In particular, any regulatory scheme for medical devices must recognize that the number of medical devices on the market is much larger, that the level of risk associated with different kinds of medical devices varies more widely, and that medical devices typically evolve over time through a series of incremental improvements (Robinson 2015).

The FDA's regulation of medical devices can be divided into two broad areas: premarket requirements, which apply before devices can be marketed, and postmarket surveillance of devices after they enter the market.

Premarket requirements

The FDA's premarket requirements are based on the notion that the amount of scrutiny that should be given to a medical device before it can be marketed should reflect the

level of risk that the device poses to consumers. The FDA uses a three-tier system to categorize medical devices by risk (Table 7-2).

Medical devices that are considered low risk are categorized as Class I devices, which is the lowest tier in the FDA's system. Most medical devices in this category do not require any kind of FDA review before they can be marketed. However, the manufacturer of the device must notify the FDA beforehand by registering the device in a central database known as the FDA Unified Registration and Listing System and must follow a number of standard requirements that apply to the manufacturing of all medical devices, such as the need to use good manufacturing practices (Johnson 2016).

The 510(k) notification process

Medical devices that pose a moderate level of risk to consumers are categorized as Class II devices. Manufacturers of most Class II devices must get permission from the FDA before marketing them by submitting a premarket notification, which is more commonly known as a 510(k) notification, after the section of the Federal Food, Drug and Cosmetics Act that authorizes the process. Some Class I and Class III devices also use the 510(k) process (Johnson 2016).

Under the 510(k) process, a manufacturer must demonstrate that its device is “substantially equivalent” to another device that is already on the market, which is called the predicate device. Manufacturers decide which device to use as the predicate.⁵ The 510(k) process is different from the FDA's approval process for prescription drugs because the manufacturer usually does not have to demonstrate that the medical device is safe and effective.⁶ Instead, the manufacturer has to show only that the new device is substantially equivalent to an existing device. Since many predicate devices were themselves cleared through the 510(k) process through comparison with even older products, many medical devices that are cleared through the 510(k) process are ultimately being compared with devices that were first marketed before the enactment of the 1976 legislation that expanded the FDA's authority over medical devices.⁷ These so-called preamendment devices were not required to demonstrate their safety or efficacy (Johnson 2016, Robinson 2015).

The FDA reviews about 4,000 510(k) submissions each year and clears most of them in 3 months to 6 months (Johnson 2016, Seligman 2013). Between 2013 and 2016, the agency cleared between 79 percent and 85 percent

of 510(k) submissions within three months (Food and Drug Administration 2017a). The time needed to obtain FDA clearance has been a persistent concern for the medical device industry, and with the industry's backing, the Congress in 2002 authorized the FDA to collect user fees from medical device companies to help defray the agency's costs (Johnson 2016). However, wait times have continued to be an issue. Between 2005 and 2010, the average wait time for a 510(k) decision (mostly used for Class II devices) rose from 90 days to 154 days. The average wait time has decreased since then, reaching 128 days in 2014. The figures for wait times include time that the FDA spent reviewing the submission (typically 70 to 75 days in all) and time that medical device companies spent providing additional information (Food and Drug Administration 2017a).

The premarket approval process

The FDA's highest level of scrutiny is reserved for most Class III medical devices and is known as the premarket approval (PMA) process. Under the PMA process, manufacturers must submit clinical data that provide reasonable assurance that a device is both safe and effective.⁸ As part of its review, the FDA may convene an advisory committee of outside experts to help it evaluate the PMA application. Because of the requirement to demonstrate safety and efficacy, the PMA process is the area of medical device regulation that most closely resembles the regulation of prescription drugs, but there are some important differences (Johnson 2016).

First, the clinical data supporting a PMA application are often less robust than those of prescription drugs. One study found that about two-thirds of the PMA applications for implantable cardiovascular devices relied on clinical data from a single study and that most of those studies were not randomized controlled trials (RCTs) (Dhruva et al. 2009). The FDA has traditionally required data from two RCTs when it reviews a new drug, although about half of its approvals for new drugs between 2011 and 2015—mostly those used to treat rare diseases—were based on a single trial (Gassman et al. 2017).⁹

Second, once the FDA has approved a device, manufacturers can often make minor modifications to it without submitting new clinical data by filing a “supplement” to the previously approved PMA application instead of filing an entirely new application. Supplements have lower user fees and shorter review times than traditional PMAs, which makes it easier for device manufacturers to make incremental improvements

in a device. Some devices are modified dozens of times in this manner: One study examined the PMAs for implantable cardiovascular devices and found a median of 50 supplements for each original PMA (Rome et al. 2014). Once a device has been modified many times, the relevance and value of the original clinical data become less clear (Rabin 2014).

Very few medical devices enter the market through the PMA process. One study found that 67 percent of medical devices that entered the market between 2003 and 2007 were exempt from any FDA review (these are mostly Class I devices that need to be registered only before they can be marketed), 31 percent entered through the 510(k) process, and 1 percent entered through the PMA process (Government Accountability Office 2009). The FDA reviews about 40 original PMA applications each year (Maisel 2011). The FDA is supposed to make a determination on a PMA application within 180 days, but the process can often take longer: In 2014, the average wait time for a decision on a PMA application was 270 days (Food and Drug Administration 2017a). For medical device companies, the costs of submitting a PMA application are anywhere from 4 times to 10 times higher than the cost of submitting a 510(k) notification (Seligman 2013).

Postmarket surveillance

The FDA's regulation of medical devices continues after they enter the market. The agency can never fully assess the safety and effectiveness of medical devices before market entry, so postmarket surveillance is an important element in regulating medical devices. However, devising an effective system of postmarket surveillance can be challenging because devices typically evolve over time as manufacturers make incremental changes to their designs.

The FDA uses a variety of methods to monitor the performance of medical devices after they enter the market. For example, medical device manufacturers and health care facilities such as hospitals are required to report to the FDA any adverse events that involve the use of a medical device. The agency can also require manufacturers to study a device's safety and effectiveness after it enters the market, but research has found that these studies can take a long time to complete and may be of limited value (Colvin et al. 2014, Lenzer and Brownlee 2010, Reynolds et al. 2014).

The agency is also planning to more actively monitor the safety of medical devices through an initiative known as

the National Evaluation System for health Technology (NEST). Under NEST, the FDA would gain access to and analyze many different sources of electronic health data such as claims, electronic health records, and registries to generate more timely and complete information on medical device performance (Food and Drug Administration 2017d). For example, NEST could make it easier for the FDA to assess reports of safety problems with individual medical devices and reduce the need for medical device companies to conduct postmarket surveillance studies. The incorporation of unique device identifiers (see next section) into electronic health information is a key requirement for the development of NEST (Califf 2016).

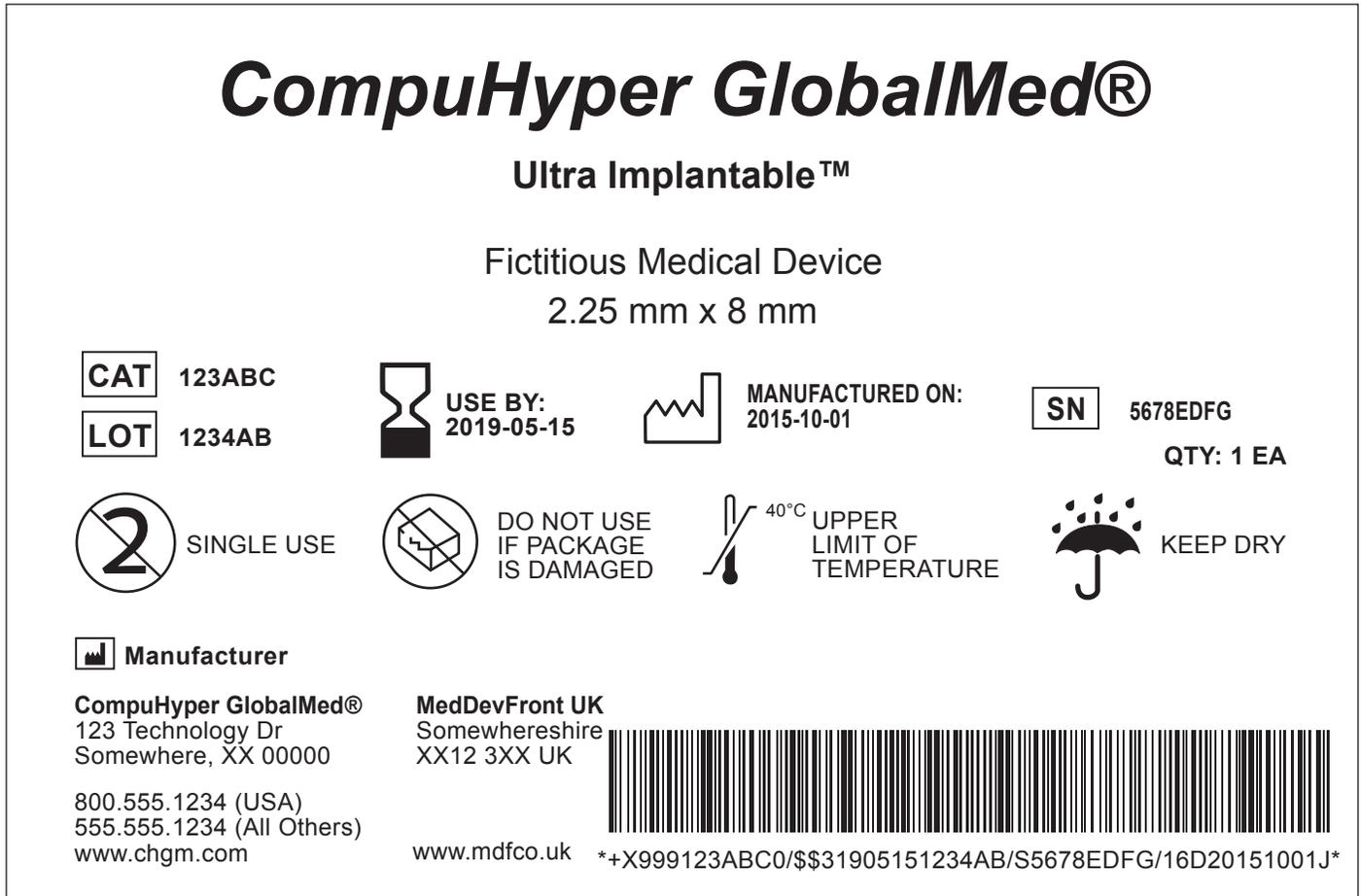
The FDA can also order product recalls for medical devices that are found to pose a health risk. For example, the FDA recalled two widely used types of leads for implantable defibrillators (leads are wires that transmit electric shocks from the defibrillator to the heart to keep it beating properly) that were found to be prone to failure, which could result in the defibrillator delivering unnecessary shocks or not functioning at all. Most recalls are carried out with the cooperation of the device manufacturer (Johnson 2016). In fiscal year 2016, the agency issued recalls for about 2,900 products. The FDA classifies its recalls based on the degree of health hazard involved; about 4 percent of the product recalls that occurred in 2016 fell into the most serious category, in which the use of a medical device poses a serious risk (Food and Drug Administration 2017c).

Unique device identifier

Another initiative designed to improve the FDA's postmarket surveillance is the requirement that all medical devices have a unique device identifier (UDI), unless an exception or alternative has been granted.¹⁰ The Food and Drug Administration Amendments Act of 2007 directed the Secretary to establish a UDI system for medical devices (Johnson 2016).¹¹ The FDA issued a final rule to establish the UDI system in September 2013, with UDI adoption occurring gradually. For example, all Class III medical devices were required to have a UDI on their label and package (but not on the device itself) as of September 24, 2014, and the labels and packages of all implantable, life-supporting, and life-sustaining devices were required to bear a UDI by September 24, 2015 (Food and Drug Administration 2017b). The full transition, which includes requiring UDIs for additional lower risk devices and fully implementing UDIs as a permanent marking on the device itself (as opposed to the packaging) for certain devices, is

**FIGURE
7-1**

Illustrative example of a device label with a unique device identifier



Source: Health Industry Business Communications Council sample unique device identifier label (Health Industry Business Communications Council 2017).

expected to be complete by September 24, 2020 (Food and Drug Administration 2017b).¹²

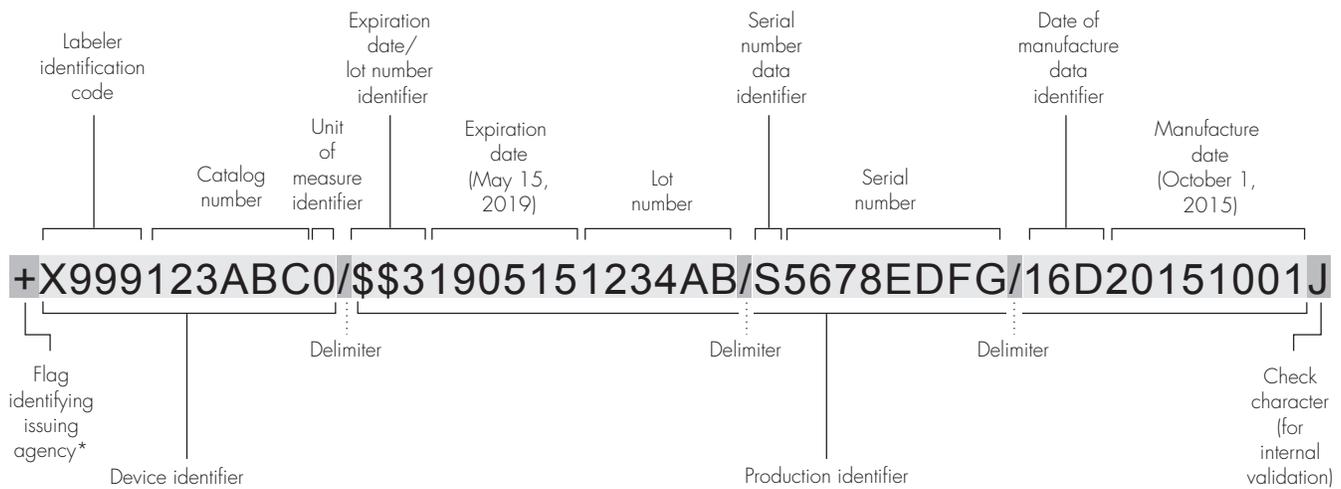
The UDI has two components: (1) a device identifier that indicates the manufacturer and specific model of the device and (2) a production identifier that contains additional, more specific information about the device. Currently, there are three FDA-accredited issuing agencies that assign UDIs to devices.¹³ The UDIs assigned by each of the three issuing agencies have their own structure, so the device identifier and full UDI can be of varying lengths and structures depending on the agency that assigned it. Currently, across the 3 issuing agencies, the device

identifier can contain up to 23 characters, and the full UDI can contain up to 75 characters. Figure 7-1 is an example of how a UDI might appear on a device label. (In this example, the UDI is located below the bar code.)

Providers are able to identify a number of device characteristics based on the UDI, which will be present in human-readable format (e.g., a string of numbers and characters) and automatic identification and data capture technology (e.g., a bar code) on device labels once UDIs are fully implemented. For instance, using the example above and the standards that each issuing agency publishes, a provider is able to tell the manufacturer,

FIGURE 7-2

Breakdown of illustrative unique device identifier



Note: *Issuing agency in this example is the Health Industry Business Communications Council.

Source: MedPAC analysis of illustrative device label and Health Industry Business Communications Council standards (Health Industry Business Communications Council 2017, Health Industry Business Communications Council 2016).

model, date of manufacture, lot number, and more by scanning the UDI. (See Figure 7-2 for a complete breakdown of the illustrative UDI.) Providers can also obtain more device attributes, such as the name of the company that produces the device and whether the device is compatible with magnetic resonance imaging procedures, by looking up the device identifier portion of the UDI in the Global Unique Device Identification Database, an FDA-maintained database that serves as a reference catalog for every device with an identifier.

UDIs should make it easier to identify medical devices that are unsafe or defective, conduct product recalls, and compare the effectiveness of different device models if UDIs are incorporated throughout the health care system (in data sources such as electronic medical records and administrative claims data). All of these activities have historically been challenging in the device market. For example, manufacturers have often experienced difficulties locating all of their recalled products. A 2011 Government Accountability Office (GAO) report found that firms were unable to correct or remove all products in roughly half of the completed or terminated recalls studied (Government Accountability Office 2011). In one particular case, GAO found that 1,732 of 23,987 pacemakers for which the device’s seal may degrade (allowing excess

moisture within the pacemaker) could not be recalled because no implant records were available (Government Accountability Office 2011).

There is broad agreement that UDIs can be a valuable addition to data sources like electronic health records and medical device registries, but there has been debate about including UDIs on administrative claims. The FDA and other stakeholders have supported adding UDIs to claims data, particularly for implanted devices, but others, including CMS, expressed opposition because of the cost and complexity of updating claims processing systems (Burton 2015, Centers for Medicare & Medicaid Services 2015a, Thibault 2016). For example, CMS said that UDIs on claims would be prone to errors because there are an estimated 300,000 UDIs just for high-risk implantable medical devices (IMDs), UDIs have different formats (depending on the issuing agency), and payers would not be able to validate UDIs submitted on claims against any external data source (Centers for Medicare & Medicaid Services 2015a).¹⁴

In response to concerns about the costs and complexity of adding UDIs to claims, a proposal was put forth to incorporate just the device identifier portion of UDIs for high-risk IMDs, which is supported by CMS, the FDA, the Office of Inspector General (OIG) of the Department of Health and Human Services, and others.

Specifically, on January 31, 2017, the American National Standards Institute's X12 Incorporated (X12) released draft revisions to the claim forms used by hospitals and physicians that included the addition of a device identifier field (X12 Incorporated 2017).¹⁵ The proposal calls for claims to include the device identifier and a flag for whether the device was implanted or explanted in certain situations. Those situations are the implantation of a high-risk implantable device or the removal of a high-risk implantable device because of safety concerns about premature failure. In both situations, the information is to be exchanged only if the provider and payer have mutually agreed to exchange the data or are mandated by state or federal governments to do so. A list of what constitutes a high-risk implantable device has not been established.

The proposal to add device identifiers to hospital and physician claims is just one part of the larger process to update these claim forms, which involves seeking input from multiple stakeholders and can take years to complete. Stakeholders estimate, based on previous updates to the claim forms, that the change to the claim forms, including the potential addition of the device identifier field, will not be in effect until approximately 2022. For example, before being implemented, the changes must be approved by X12 after a comment period; be approved by the Designated Standard Maintenance Organizations; be reviewed by the National Committee on Vital and Health Statistics, which holds hearings, solicits input from numerous organizations, and ultimately makes a recommendation to the Secretary; and go through a formal rule-making process and implementation period. This process would be just to approve the changes to the claim forms. If CMS wanted to require providers to input actual data into the device identifier field on Medicare claims, the Secretary would likely need to issue additional regulations.

Proponents of adding device identifiers to administrative claims contend that incorporating such information would be a valuable part of the country's postmarket surveillance system. Including device identifiers in claims would not obviate the need to incorporate UDIs in many other data sources such as electronic health records and clinical registries. Rather, including device identifiers in administrative claims would leverage the scale, availability, and longitudinal nature of claims data to improve postmarket surveillance. Including device identifiers in claims could also produce other tangible benefits for the Medicare program and others. Examples of the specific benefits that proponents believe will flow from including device identifiers on claims include:

- **Improved ability to detect potential issues at the manufacturer/model level.** Device identifiers on claims could be used by NEST, payers, academic researchers, and others to compare quality and detect potential problems at the manufacturer/model level. For example, a longitudinal study of Medicare fee-for-service beneficiaries who received a total knee replacement could be conducted to determine whether the revision rates for certain types of knee implants increased over time or were higher for some implant models compared with others. Such studies could reveal important quality information (e.g., whether one model performs better than another) and alert researchers of a possible problem (e.g., whether revision rates spiked for the same model or manufacturer over time).
- **Reduced Medicare expenditures by improving adherence to current device credit policy.** Not all manufacturers offer warranties for their products. In these cases, Medicare ultimately pays for the cost of failed devices and for the replacement device. However, hospitals that do receive device credits from a manufacturer (e.g., a credit when a device fails while still under warranty) are required to report the credit to Medicare, and Medicare's payment for the revision surgery is subsequently reduced. OIG has found that hospitals often do not abide by this policy (see text box on costs of failed devices, p. 218). Including the device identifier on claims for the implanted and explanted devices could allow for easier identification of cases where device failures occur and, therefore, increase adherence to the current policy.
- **Improved understanding of long-term device costs and aid in the development of value-based insurance designs.** Failed and recalled devices likely cost Medicare billions of dollars (see text box on costs of failed devices, p. 218). In addition to the cost of the actual surgeries to implant or explant devices, the downstream costs for follow-up care, monitoring, post-acute care, additional surgeries, and other costs are likely substantial. Including the device identifier on claims could aid in more precisely understanding the long-term costs of certain devices. The information could also assist in any related cost-recovery efforts (Office of Inspector General 2016). Additionally, such information on costs, coupled with the quality data discussed above, could be used by payers to create value-based purchasing initiatives to help ensure patients receive the most appropriate device.

Cost of failed devices in Medicare

Medicare regulations currently require a reduced payment for certain inpatient and outpatient procedures if hospitals receive a device credit from a manufacturer for a faulty device. However, the Office of Inspector General (OIG) of the Department of Health and Human Services has found that hospitals often fail to seek and report device credits. Further, the lack of device-specific information on claims makes it difficult to quantify the total costs to Medicare and beneficiaries of device failures, including the cost of the surgeries themselves and downstream costs.

Hospitals are currently required to report the value of a device credit associated with a replacement device on outpatient claims if the hospital received a credit of 50 percent or more of the cost of the replacement device. In addition, when a device credit is received, hospitals must also indicate whether the replaced device was part of a known recall or whether the device was replaced earlier than the device's typical life cycle (Centers for Medicare & Medicaid Services 2017b). A similar policy applies to the hospital inpatient setting. In their compliance review of 145 hospitals nationwide, OIG

found approximately \$10 million in overpayments to hospitals for device credits that hospitals received but did not report to Medicare (about 75 percent of the \$10 million) or for credits that were available under the terms of the manufacturers' warranties but not obtained by hospitals (about 25 percent of the \$10 million) (Office of Inspector General 2015).

In addition to the cost of the device, Medicare spends substantial resources on the costs of the procedures related to failed devices and other downstream costs. However, quantifying these costs is difficult because of the lack of device-specific information on Medicare claims. In a letter to CMS informing the agency of preliminary results, OIG said that the lack of device-specific information in Medicare claims data impedes the ability of CMS to readily identify and track Medicare's total costs related to the replacement of recalled or defective devices (Office of Inspector General 2016). After implementing complex audit procedures (which involved subpoenaing manufacturers), OIG found \$1.5 billion in Medicare payments and \$140 million in beneficiary copayments and deductibles for services and procedures associated with seven recalled or failed devices. ■

- **Other benefits.** Proponents of adding device identifiers to claims have suggested other benefits, such as helping to implement recalls that affect an entire product (e.g., when a device's design is flawed, as was the case with metal-on-metal artificial hips), improving innovation (as more quality information becomes widely available), and enhancing the ability to monitor the effects of payment changes on the utilization of specific devices (e.g., monitoring shifts in device utilization that could occur when payments are bundled).

Opponents of including device identifiers on claims contend that doing so would have limited value for postmarket surveillance, be costly to implement and maintain, and could have other negative consequences. Some of the most prominent criticisms include:

- **Device identifiers cannot be used to effectively identify certain issues or implement all recalls.** Opponents contend that device identifiers are not granular enough to detect issues that affect only a portion of devices within a model. For example, a manufacturing problem could affect only certain groups of devices within a model or devices produced in a certain time period. In such cases, the full UDI (which can include the date of manufacture) may be used to precisely identify the problem and implement a recall, but the device identifier alone could be insufficient. One prominent device failure in which certain batches of a device were more prone to failure involved the Björk-Shiley convexo-concave prosthetic heart valve (Blot et al. 2005). Over 600 of these valves that were implanted were known to have fractured, often with catastrophic outcomes for the patients

(including death) (Blot et al. 2005). While multiple factors were subsequently shown to contribute to failure, valves produced within a certain time frame were shown to be more likely to fail compared with those produced at other times (Blot et al. 2005).

- ***Including device identifiers on claims could be administratively complex and costly.*** Some suggest that physicians, hospitals, payers, and others would incur substantial costs to ensure that device identifiers were accurately submitted on claims and that claims with device identifiers could be efficiently processed. Costs could involve redesigning workflows to ensure device identifiers were correctly submitted on claims and updating numerous computer systems to accept and validate the data for a large number of device identifiers. CMS has said the agency would require additional funding and resources to update legacy computer systems to accommodate device identifiers (Centers for Medicare & Medicaid Services and Food and Drug Administration 2016).
- ***Efforts to improve postmarket surveillance should focus on electronic health records and registries.*** Opponents suggest that resources should be deployed to improve and expand clinical registries and ensure UDIs are incorporated into electronic health records. As one part of a postmarket surveillance strategy, the FDA has promoted the development of device registries, although the agency said that registries might be economically feasible for only a subset of devices because of the significant costs associated with registry development and maintenance (Food and Drug Administration 2012). Certain programs, such as the Electronic Health Record Incentive Program, encourage the adoption and use of UDIs. However, some electronic health records currently cannot record UDIs, and challenges remain to make electronic health records useful repositories for UDIs, such as ensuring that records are interoperable and that providers consistently input UDIs into the records.
- ***Conclusions drawn from claims could be erroneous and could be used to restrict provider choice.*** Because administrative claims lack the clinical context often available in clinical registries or electronic health records, some contend that conclusions about a particular device's effectiveness drawn from claims alone could be erroneous. Opponents of including device identifiers on claims believe such conclusions

could lead patients and physicians to make misguided device choices and could allow payers to implement overly restrictive device formularies or utilization review.

Key features of the medical device market

Once medical device manufacturers have received the FDA's permission to market their products, they are primarily engaged in selling medical devices to health care providers like hospitals, physicians, and nursing homes rather than individual consumers. The market dynamics for medical devices vary significantly depending on the device, but at a high level, devices can be divided into two groups: conventional devices and high-technology devices (Seligman 2013).

Conventional devices are products such as surgical apparel, regular wound dressings, and surgical trays. These devices are fairly easy to manufacture, with relatively few barriers to entry for new companies and relatively little product differentiation (i.e., purchasers such as hospitals can switch from one company's version to another company's version with minimal difficulty). These devices are thus treated much like commodities, and their manufacturers compete with each other based on price. Profit margins are relatively low, and manufacturers often need high sales volumes to be profitable. As a result, the ability to secure long-term supply contracts with large institutional purchasers such as hospital chains is very important (Seligman 2013).

The market dynamics for high-technology devices—such as IMDs, advanced diagnostic imaging, and some types of surgical instruments—are very different. Manufacturers typically face greater barriers to entry, such as significant research and development costs, the presence of patents, and greater regulatory scrutiny from the FDA. As a result, competition in this segment is more limited and these kinds of devices can garner higher profits than conventional devices (Seligman 2013).

Because large medical device companies are highly diversified, they sell a mix of conventional and high-technology devices. This diversification has a number of benefits. Companies can use their flagship high-technology products to boost sales of their other, more

conventional medical devices. At the same time, profits from the sale of conventional devices help provide the cash flow that companies need to conduct research and development for their high-technology products (Seligman 2013).

The remainder of this section reviews six key features of the medical device market: coverage determinations, group purchasing organizations, IMDs, the relationships between medical device companies and physicians, physician-owned distributors, and the financial performance of medical device manufacturers.

Coverage determinations

Medicare and other third-party health care payers are not required to cover every medical device that has been cleared or approved by the FDA. Health care providers are much more likely to use new forms of medical technology that are eligible for reimbursement, so ensuring coverage and payment are key considerations for device companies. Medicare's coverage decisions have particular weight because they are often followed by private health insurers (Johnson 2016).

Medical device companies can apply for Medicare coverage of new devices that do not fit into an existing service code by requesting either a national coverage determination (NCD) from CMS or a local coverage determination (LCD) from a Medicare administrative contractor (MAC) for the procedure that involves the device. NCDs apply nationwide, while an LCD applies only to the states within the jurisdiction of the MAC that issued it. CMS and the MACs make coverage decisions by determining whether the available evidence for a device supports the requested coverage. The processes for developing both NCDs and LCDs give external stakeholders the opportunity to share their views and allow the public to review and comment on draft coverage determinations. As of August 2013, there were about 300 active NCDs and 1,700 active LCDs (Office of Inspector General 2014).

There are some indications that private health insurers have tightened their standards for covering new technology in recent years. For example, some have suggested that private insurers now require device companies to provide stronger evidence of the clinical benefits of new devices and information on how their performance compares with existing products (Advanced Medical Technology Association 2015a, A. T. Kearney 2014, Rice 2014).

Group purchasing organizations

Many providers purchase medical devices with the help of entities known as group purchasing organizations (GPOs). GPOs are intermediaries that negotiate purchasing contracts with medical device companies (and other suppliers) on behalf of the providers who are members of the GPO, using their combined purchasing power to obtain lower prices. GPOs do not purchase anything themselves and play no role in distributing products from manufacturers to purchasers. GPOs play a larger role in the purchase of conventional devices than in the purchase of high-technology devices, which is often done outside of GPO contracts.

There are approximately 600 GPOs in all, but the sector has been steadily consolidating and is now highly concentrated (Government Accountability Office 2010). The top five GPOs currently account for about 90 percent of all GPO sales (Government Accountability Office 2014b). The ownership structure of GPOs varies; some are owned by their customers, while others are not. Virtually all hospitals in the United States use GPOs to purchase at least some of their supplies (many hospitals use different GPOs to buy various products), and GPO purchases represent about 75 percent of total hospital supply purchases (Government Accountability Office 2010).

As part of a GPO contract, medical device manufacturers and other suppliers pay “contract administrative fees” to the GPO. These fees typically equal a share of the sales price on items sold through the GPO contract; the fees for the five largest GPOs in 2012 were between 1 percent and 2 percent of their overall sales volume. These fees are GPOs' main funding source and can represent more than 90 percent of their overall revenues. GPOs use some of the fees to cover their operating expenses and typically distribute a significant portion of the fees to the hospitals that are their customers. In 2012, the five largest GPOs distributed about 70 percent of the \$2.3 billion that they received in fees. The fees could be prohibited under the federal anti-kickback statute as an inducement to obtain business if certain conditions were met, but the Congress enacted a “safe harbor” exception in 1986 that allows GPOs to collect them (Government Accountability Office 2014b).

Although GPOs benefit from their customers' bulk purchasing power, the prices on GPO contracts may not always be the lowest possible. GPOs generally award contracts to at least two manufacturers of a particular

product, and hospitals are usually not required to make all of their purchases through the GPO contract. As a result, medical device manufacturers may not always offer a GPO the lowest prices because they cannot be certain of receiving a sufficient volume of sales in return. Individual hospitals can obtain lower prices for some products by directing their GPO to negotiate customized contracts in which the hospital agrees to purchase all of those products from a single manufacturer or supplier (Advisory Board Company 2013, Government Accountability Office 2014b).¹⁶

There has been some debate over whether a business model based on administrative fees is an appropriate way to structure GPOs. Critics of the current model argue that GPOs do not always have an incentive to negotiate the lowest possible price; since administrative fees are based on overall sales volume, lower prices also result in lower fees for the GPO. Supporters of the current model note that hospitals can switch GPOs if they wish and argue that competition among GPOs for hospitals' business mitigates any potential conflict of interest. Little empirical research has been done on the issue. Experts disagree on whether other business models for GPOs would be viable (for example, GPOs could be funded entirely by fees paid by member hospitals), but agree that the transition from the current model to another business model would be disruptive for both GPOs and hospitals (Government Accountability Office 2014b).

Implantable medical devices

IMDs are a segment of the medical device industry that has received significant attention from researchers, financial analysts, and others over the years. IMDs include devices such as pacemakers, coronary stents, artificial hips and knees, and artificial lenses. Although IMDs are used in many different kinds of surgery, they feature most prominently in cardiac and orthopedic procedures.

As a group, IMDs are often technologically advanced and provide innovative ways to treat conditions such as heart arrhythmia and chronic arthritis. They are also expensive; the purchase price for an IMD can equal 30 percent to 80 percent of an insurer's payment to a hospital for a procedure (Robinson 2008).

The market for IMDs has several distinctive features and is similar in many respects to the market for brand-name prescription drugs. First, companies face numerous barriers to entering the market, such as high research and

development costs, the need to win regulatory approval, the presence of patents, and the difficulty in convincing hospitals to purchase their products (Seligman 2013). Most markets for particular IMDs thus have relatively few competitors. For example, three companies account for about 90 percent of pacemaker sales, and four companies account for about 95 percent of knee and hip implant sales (Collins 2016, Hollmer 2014). In economic terms, these markets are oligopolies, where the number of sellers is small and each company has some degree of control over the prices it charges for its products (Pauly and Burns 2008).

The degree of competition between companies is often limited by other factors, including differences in competing products that make switching difficult, physician preferences, and lack of pricing information. Regarding product differences, manufacturers of IMDs differentiate their devices from those made by competing firms. For example, one company's knee implant may have features or capabilities different from a competitor's knee implant, and physicians may need to use different techniques to implant each device. The short life cycles that are common in the medical device industry help manufacturers keep their products differentiated over time. Some differences among competing devices may have a clinical or therapeutic benefit, but in other cases, the benefits are unclear. However, this kind of product differentiation makes it harder for physicians to switch suppliers (because of the time required to learn how to use a new device properly) and helps limit the extent to which manufacturers have to compete on price.

Physician preferences can also dampen competition. Although hospitals are the entities that actually purchase IMDs, physicians have traditionally had significant influence on their purchasing decisions. Most physicians prefer to use a particular company's devices in their procedures, and hospitals have been willing to accommodate those preferences because of physicians' ability to control where their patients are admitted and the profitability of surgical lines such as orthopedic procedures. These devices are thus also known as *physician preference items* (Robinson 2015). Physicians have typically had little incentive to consider differences in cost when deciding which devices to use because the hospital bears the cost.

The prices that manufacturers of IMDs charge for their devices can vary considerably from hospital to hospital. Manufacturers often require that their prices be kept

**TABLE
7-3****Prices paid by hospitals for common orthopedic and cardiac devices varied substantially, 2008**

IMD	Minimum	25th percentile	Median	75th percentile	Maximum
Artificial knee implants	\$3,380	\$4,463	\$4,925	\$6,549	\$10,944
Artificial hip implants	\$3,828	\$5,425	\$6,238	\$7,262	\$10,640
Lumbar spine implants	\$3,397	\$5,425	\$6,238	\$7,262	\$29,311
Cardiac pacemakers	\$4,925	\$5,709	\$6,197	\$7,024	\$10,790
Cardiac defibrillators	\$19,150	\$22,870	\$25,066	\$28,599	\$34,961

Note: IMD (implantable medical device). Prices are for 2008 and were taken from a study that collected data from 61 hospitals in 8 states. Figures are the actual prices paid by the hospital, as opposed to the manufacturer's list price.

Source: Robinson 2015.

confidential and have in the past filed lawsuits to prevent the disclosure of pricing data. This lack of information makes it harder for hospitals to compare their prices with those paid by other facilities. GPOs face the same challenge in trying to evaluate prices (Government Accountability Office 2012, Robinson 2008).¹⁷

Manufacturers have list prices for their IMDs, but those prices indicate what the “least sophisticated part of the market will pay” and typically serve as a starting point for subsequent negotiation (Robinson 2015).

Some studies have examined variation in IMD prices, although they are now somewhat dated. One study that collected price information for 2008 for several common orthopedic and cardiac IMDs found that the maximum prices for IMDs were often more than twice as high as the minimum prices (Table 7-3). Some of that variation could be due to outlier hospitals that paid unusually high or low prices, but there was also substantial variation in the middle of the distribution: The prices paid by hospitals at the 75th percentile were 23 percent to 47 percent higher than the prices paid by hospitals at the 25th percentile (Robinson 2015). GAO also found significant variation in the prices for cardiac and orthopedic IMDs when it examined the prices that some hospitals paid in fiscal year 2010 (Government Accountability Office 2012). As with prescription drugs, hospitals are more likely to negotiate favorable prices when they can promise significant sales in return. Hospitals have typically tried to do this by negotiating longer contracts and limiting the number of suppliers they use for a particular device, but the latter strategy may not be feasible for hospitals where physicians

have strong preferences about which IMDs they use (Robinson 2015).

The prices for a particular model of an IMD can rise or fall over time, depending on a number of factors. Manufacturers of devices that can demonstrate clinical superiority over competing products may be in a stronger position to increase prices, or at least keep them stable (Seligman 2013). In contrast, prices for a specific model can decline over time if other manufacturers enter the market or launch newer versions of existing products (where the newer versions “catch up” by incorporating features found in existing devices, introduce entirely new features, or both). Manufacturers also have an incentive to lower prices and reduce their inventory of devices that will soon be replaced by a newer model.¹⁸ The manufacturer then typically launches the new model at a higher price. Manufacturers may also lower prices if concerns are raised about the safety of a particular procedure, and physicians become more conservative in their treatment choices (Seligman 2013). A study funded by AdvaMed found that the average prices of seven types of IMDs declined between 2007 and 2011 by 5 percent to 25 percent. The AdvaMed study looked at average prices across all IMD models, so the change in prices for specific models could have been different (Long et al. 2013). Concerns about safety and overuse could have contributed to the decline in prices for two of those IMDs—coronary stents and implantable defibrillators (iData Research 2015, Seligman 2013).

Several recent changes in the health care sector have given hospitals more ability to negotiate favorable prices for

IMDs. First, the hospital industry has had a significant number of mergers and acquisitions in recent years, which has given some hospital systems control over larger volumes of IMD purchases. Second, the number of physicians employed by hospitals or hospital systems has increased in recent years. The shift toward hospital employment has reduced the influence of physician preferences and given hospitals greater control over device purchases. Hospitals are increasingly trying to negotiate lower prices on IMDs by purchasing from only two or three manufacturers. These efforts are often overseen by “technology assessment committees” that are composed of hospital management and physicians from the relevant specialties and that consider both cost and clinical benefit in their decision making (A. T. Kearney 2014, Robinson 2015).¹⁹

Price transparency for IMDs

Another facet of the IMD market is the extent to which prices are opaque. Some IMD price information is commonly known, such as list prices, but the market is far from transparent. Our work on IMDs provides an overview of what IMD price information is known by various actors in the IMD market, arguments for and against increasing IMD price transparency, and other issues to consider regarding increased IMD price transparency.

Our review of what each actor in the IMD market knows about prices focuses on manufacturers, hospitals, physicians, patients, and the Medicare program.²⁰ First, of all these actors, patients have the least information about IMD prices. The procedure summaries patients receive from hospitals rarely identify the costs of each device (Lerner et al. 2008).²¹ Further, patient cost sharing is typically based on the procedure’s total payment. For example, a Medicare beneficiary who receives a stent is responsible for the same amount of cost sharing (e.g., roughly 20 percent of the payment rate in a hospital outpatient department) regardless of how much the hospital paid for the stent. While beneficiaries have limited information on device costs and their marginal costs for any given surgery are not affected by how much a hospital paid for a device, beneficiaries bear the burden of higher device costs through higher premiums and higher total cost sharing (because higher device costs ultimately get built into payment rates).

Physicians have also been shown to have a limited knowledge of device prices, despite their substantial influence over the choice of device. One study asked

orthopedic surgeons to estimate the price of several commonly used devices and found that about 80 percent of the responses were incorrect, which was defined as being more than 20 percent different from the actual purchase price (Okike et al. 2014). There are several reasons why physicians might be unaware of device prices. First, many physicians are not financially responsible for the cost of devices, so there may not be an incentive for them to seek pricing information. Second, to the extent physicians do seek device prices, hospitals can be limited in the type of information they can share with physicians because IMD manufacturers often put confidentiality clauses in their contracts. For example, GAO has reported that some hospitals restricted by confidentiality clauses have resorted to using colored stickers to indicate to physicians which devices are the high-, medium-, and low-cost options (Government Accountability Office 2012).

Hospitals, which are predominantly responsible for purchasing IMDs, have more knowledge about the prices paid for IMDs but still face limitations. Hospitals know the prices they themselves paid for devices and the prices competing manufacturers submitted to their institutions. However, hospitals often do not know what other buyers (e.g., hospitals and ambulatory surgical centers) paid for the same or similar devices. This inability to discern the price at which manufacturers are willing to sell IMDs could contribute to large variations in transaction prices. Because IMD costs often constitute a large majority of the cost associated with a given procedure, opaque prices can contribute to large variations in the profitability of the same procedures across hospitals.

Hospitals have responded to opaque device prices by working with GPOs and consulting firms to gain insight into the prices paid by other hospitals (Robinson 2008). For example, one firm sells hospitals access to a database that allows them to benchmark the price they paid for devices relative to the lowest, 25th percentile, median, 75th percentile, and highest price that other hospitals paid for the same device (ECRI Institute 2017). However, while such services provide hospitals with additional information, not all hospitals share such information (so a given database might not represent the full market); also, hospitals might be limited by manufacturer nondisclosure clauses from sharing certain information, and off-invoice or other discounts might not be captured.

The Medicare program has only aggregate information on device costs. Through Medicare claims data and cost reports, the approximate total device costs for a

procedure and total hospital spending on devices are documented. However, Medicare cannot determine from this information the exact devices used in a procedure or the price that hospitals paid for a specific device.²² Also, because ambulatory surgical centers do not submit cost reports, Medicare knows even less about how much those entities spend on devices.

Finally, manufacturers know the actual transaction prices, net of all rebates and discounts, at which their own firms sell devices to their customers. Arraying this information in certain ways could help manufacturers gain a better understanding about the device market. For example, the data could be arrayed longitudinally to understand trends in pricing and by hospital characteristics to better understand the willingness of certain types of hospitals to pay higher or lower prices. In addition, manufacturers may know the pricing behavior of the limited number of competitors in the IMD market. Some have suggested that manufacturers gain insight into their competitors' pricing behaviors by commissioning studies by third parties and by their sales representatives routinely getting information about their competitors' bids from hospital staff (Lerner et al. 2008).

Proponents of greater IMD price transparency suggest that the asymmetrical availability of pricing data has allowed IMD prices to remain high and that increasing transparency can counteract that historical imbalance. Arguments in favor of increased IMD price transparency include:

- **Decreased prices.** Proponents believe increasing IMD price transparency could assist hospitals in making better informed decisions about the value of devices and negotiate lower prices for them accordingly.
- **Reduced price variation.** Even if increased price transparency does not reduce IMD prices on average, some believe an attenuation of the variation could be beneficial. Because IMDs can represent a substantial majority of the costs associated with a procedure and the prices hospitals pay for IMDs can vary greatly, some hospitals might find device-intensive procedures extremely profitable while others may not. Narrowing the variation in IMD prices (and therefore the profitability of device-intensive procedures) could help ensure continued access to these services without a need for higher payment rates. One example of transparency leading to a narrower price distribution is what occurred in the German electricity market a year after the government mandated publication

of transmission charges—the average price was little changed but the distribution of rates narrowed (Congressional Budget Office 2008).

- **Increased value.** Some contend increasing physicians' understanding of IMD prices could serve as a mechanism for hospitals to engage physicians in jointly negotiating with device manufacturers (Pauly and Burns 2008). Improved pricing information could also enhance the ability of technology assessment committees to properly judge the value of a device.

Opponents of IMD price transparency argue that the current system has worked well to keep the growth in device costs low and that mandatory price transparency would increase costs. In concentrated markets (as IMD markets often are), increased transparency could lead to higher prices since such markets are more likely to be conducive to firms coordinating to keep prices high (Congressional Budget Office 2008). For example, if prices were made completely transparent, IMD manufacturers might have few incentives to offer lower prices to hospitals because if their competitors could see and match their prices, their price discounts would be unlikely to win them business. In addition, in a concentrated market with transparent prices, a manufacturer can be assured that none of its competitors is undercutting their price because they can see all their competitors' prices. The Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) have said that even aggregated data that contain less than five providers would not fall in their "safety zone" for antitrust concerns (Department of Justice and the Federal Trade Commission 1996). This threshold could be an issue for price transparency in the IMD market since there are often few manufacturers for specific devices. Empirical research is limited regarding whether price transparency in concentrated health care markets increases prices, but three studies from industries outside health care are commonly cited to demonstrate the point: a study that showed mandatory price transparency increased prices in the Danish concrete industry and two studies that showed companies took advantage of a U.S. law requiring railroads to disclose some of their contract terms with grain shippers by raising their prices when they could observe what their competitors in concentrated markets were charging (Congressional Budget Office 2008).

The ramifications of any policy designed to increase IMD price transparency vary greatly depending on the details of the program. Some of the key design choices for

policymakers to consider when designing a program to increase IMD price transparency include:

- **Transparent to whom.** Physicians and hospitals have the largest influence over IMD purchases, so transparency efforts could be aimed at improving their understanding of prices. Allowing payers to access pricing data could allow them to improve payment accuracy and potentially advance value-based insurance designs. In contrast, increasing beneficiary awareness of IMD prices is unlikely to lower device costs, at least in part because beneficiaries pay only a fraction of the cost of the procedure and their costs often do not vary with device selection. In addition, sharing pricing data with IMD manufacturers, which is tantamount to what happens when the data are publicly reported, could result in collusive behavior and higher prices.
- **Timing of pricing data.** Data that are more current are likely more beneficial to providers seeking to negotiate with IMD manufacturers. However, data that are more current could be used in an anticompetitive manner. The FTC and DOJ have suggested that, to avoid antitrust scrutiny, pricing data should be more than three months old to help ensure that competitors cannot use the information for coordination of prices (Department of Justice and the Federal Trade Commission 1996).
- **Type of pricing data reported.** The prices collected need to represent actual transaction prices, net of any rebates or discounts. Beyond this, one question is how granular the data should be. Legislation that was introduced in the Congress in 2007 but never enacted had sought public disclosure of the average and median device prices for certain devices (U.S. Senate 2007). Others have suggested that more granular data, including information on the range of prices offered, could be more helpful (Pauly and Burns 2008). In general, the more granular the data, the more useful the data become to providers in their negotiations with manufacturers; however, more granular data could potentially allow manufacturers to “back out” their competitors’ prices. Another consideration is whether pricing information should represent the price at which manufacturers sell IMDs or the price at which hospitals buy them. These prices could be different if devices are first sold through a physician-owned distributor or other intermediary, which could also have implications for who would be responsible

for reporting the data—providers (hospitals and ambulatory surgical centers) or manufacturers.

- **Administrative costs.** Collecting sales data from manufacturers or providers would increase administrative costs for the reporting entity and CMS. Other proposals to increase transparency that do not involve data reporting (e.g., prohibiting manufacturers from limiting price disclosures between hospitals and physicians) would involve lower administrative costs.

Relationships between device manufacturers and physicians

The medical device industry is particularly notable for the substantial relationships that often exist between medical device manufacturers and physicians. These ties are often deeper and more extensive than those between physicians and drug makers (Robinson 2008). These relationships can take many different forms, such as:

- royalty payments to physicians who help develop medical devices;
- consulting fees to physicians for providing feedback about the performance and design of a company’s devices;
- funding for physicians to conduct research;
- funding for medical education activities; and,
- for physicians who use IMDs, regular interactions with the manufacturer’s sales representatives, who are often present at the physician’s invitation in the operating room during procedures and may help the physician make a final decision about which devices to use (Robinson 2015).

In many instances, these relationships can benefit the public by fostering the development and improvement of new medical devices and educating physicians about how medical devices can be used safely and effectively (Demske 2008). However, physicians have substantial influence over the purchase and use of many medical devices, and device manufacturers have a strong incentive to cultivate close relationships with physicians and encourage the use of their products. Manufacturers can also use their relationships with physicians to implicitly reward physicians for using their products, which has led to persistent concerns that these relationships may affect physicians’ judgment about the best way to treat their patients (Robinson 2015).²³

Device companies were generally not required to disclose information about their financial relationships with physicians until 2010, when the Patient Protection and Affordable Care Act required drug manufacturers, device manufacturers, and GPOs to submit information to CMS about their payments to physicians and teaching hospitals. The Commission had previously recommended the reporting and disclosure of this information in a 2009 report to the Congress (Medicare Payment Advisory Commission 2009). CMS refers to this initiative as the Open Payments program and has released information for part of 2013 and all of 2014 and 2015.

We analyzed Open Payments data for 2015—the most recent year of data available—to identify non-research payments made by medical device manufacturers to physicians. We found that device manufacturers accounted for \$1.7 billion of the \$2.8 billion in non-research payments to physicians in 2015, or 59 percent of the total. By comparison, drug manufacturers made \$1.0 billion in payments (35 percent of the total). The remaining \$0.2 billion in payments (7 percent of the total) were made by companies that produce both devices and drugs or by other entities. The non-research payments made by device manufacturers to physicians comprised ownership or investment interests in companies (42 percent) and “general payments” (58 percent), a category that includes promotional speaking fees, royalty and license payments, consulting fees, food and beverage, travel and lodging expenses, education, and other transfers of value.

Physician-owned distributors

Physician-owned distributors (PODs) are entities that derive revenue from selling, or arranging for the sale of, IMDs ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (Office of Inspector General 2013a). While IMD manufacturers traditionally sell and distribute their products directly to hospitals, PODs can operate as intermediaries between device manufacturers and hospitals that purchase devices—that is, a device manufacturer sells a device to a POD and the POD resells the device to a hospital at a higher price. Also, some PODs purport to design or manufacture their own devices (Office of Inspector General 2013a). In such cases, a POD might seek a 510(k) clearance to market a relatively simple device, such as a surgical screw, and then outsource the production of the device to a contract manufacturer.²⁴ A third model

PODs often use is the “GPO model.” Under this type of arrangement, physicians form a POD to aggregate their purchasing power and get bulk discounts from manufacturers (U.S. Senate Committee on Finance 2011).

PODs commonly supply devices used in spinal surgery. In the most comprehensive report on the prevalence of PODs, OIG surveyed 596 hospitals in which spinal fusion was performed in 2011 and determined whether each hospital purchased spinal devices from PODs.²⁵ OIG found that PODs supplied at least some of the spinal devices for nearly one in five spinal fusion surgeries billed to Medicare in 2011 and that roughly a third of hospitals purchased these devices from PODs (Office of Inspector General 2013b). In addition, the use of PODs grew dramatically in the years immediately preceding the survey. For instance, 88 percent of hospitals that purchased spinal devices from a POD said that they began doing so only after 2005 (Office of Inspector General 2013b).

While the OIG report established the historical use of devices purchased from PODs in spinal surgeries, less is known about the current prevalence of such use and the extent to which PODs are involved in other clinical areas, at least partially because of their lack of reporting under the Open Payments program. PODs have historically been limited to supplying devices for spinal surgery, but some are concerned that PODs may now be appearing in other areas such as joint replacements, prosthetics, and orthotics (U.S. Senate Committee on Finance 2016). Under the Open Payments program, drug and device manufacturers and GPOs report information to CMS about payments to physicians and teaching hospitals. While PODs that fall within the definition of an applicable manufacturer or GPO must report under the Open Payments program, few PODs have actually reported under the program (Centers for Medicare & Medicaid Services 2013). (See Chapter 6 of this report.)

Critics have charged that PODs present an inherent conflict of interest because their physician-owners can determine which devices to use in their procedures and benefit financially when they use devices supplied by their POD. The conflict of interest can lead to increased Medicare expenditures, increased costs for hospitals, and potentially inappropriate care for beneficiaries. Specific concerns raised by POD critics include:

- **Increased volume.** Opponents of PODs contend that physicians have a financial interest in referring more patients for surgery because physicians profit from the

devices used in surgery. Referring a larger number of patients for surgery increases costs for Medicare and beneficiaries.

- **Increased intensity.** POD critics suggest that physicians using devices from their POD have a financial incentive to use more devices in patients referred for surgery. Physicians can use more devices during surgery or refer beneficiaries for more intense procedures that require more devices. For example, physicians can refer a patient for spinal fusion rather than decompression, a less intense procedure. For patients with a common spinal condition that has several treatment options, researchers have found that “more complex procedures were associated with greater complications, mortality, hospital charges, and other measures of health care use, even after adjustment for patient demographic and clinical characteristics” (Deyo et al. 2010).
- **Inappropriate care.** Opponents of PODs contend that physicians who have a financial interest in a POD may have an incentive to refer patients for surgery inappropriately. In addition, some have suggested that surgeons have an incentive to use devices of inferior quality or that are not best suited for the procedure simply because they have a financial interest in choosing the devices that their PODs sell (U.S. Senate Committee on Finance 2011).
- **Higher device costs.** Because the physician-owners of PODs can profit from the difference between the price at which a POD buys a device from a manufacturer and the price at which it then sells it to a hospital, critics suggest that PODs have an incentive to seek the highest price possible from their hospital clients. Some hospitals might have a limited ability to negotiate lower prices because IMDs are typically physician preference items, and hospitals could risk losing patients if they refuse to purchase devices from PODs.²⁶ Higher IMD prices put pressure on hospital margins and can contribute to calls for higher reimbursements from Medicare.

Proponents of PODs argue that PODs can save money if properly structured. Specifically, proponents suggest that PODs can lower device costs by aggregating the buying power of multiple physicians, eliminating the cost of sales representatives that is part of the traditional model for selling and distributing IMDs, and increasing competition.

One group that advocates on behalf of PODs—the American Association of Surgeon Distributors (AASD)—has developed standards that PODs should adhere to in order to mitigate the conflict of interest many believe is inherent in PODs. For example, AASD standards include adhering to an appropriate-use monitoring policy and keeping device price increases below a certain level (American Association of Surgeon Distributors 2017). A case study authored by individuals with financial interests in PODs found that devices acquired through five PODs that were members of AASD were, on average, 36 percent less expensive compared with similar devices not acquired through PODs (Steinmann et al. 2015). However, the results of this case study contradict the results of OIG’s study that examined a broader universe of PODs.

Specifically, OIG found that none of the six types of spinal devices they examined was less costly per unit when purchased through a POD, and one—spinal plates—cost \$845 more on average when supplied by a POD (\$2,475 vs. \$1,630) (Office of Inspector General 2013b). Further, OIG found that the rate of spinal surgery grew faster among hospitals that began purchasing devices from PODs compared with all hospitals (16 percent vs. 5 percent, respectively). The rate of spinal fusions—surgeries that are more likely to use devices—grew more than twice as fast among hospitals that acquired devices from PODs compared with all hospitals (21 percent vs. 9 percent, respectively). However, OIG found that surgeries in which the devices were acquired through PODs involved fewer devices on average (12.3 vs. 14.2 when not acquired through PODs), and the findings were mixed with regard to the complexity of surgeries at hospitals that acquired devices through PODs and those that did not.

OIG also issued a Special Fraud Alert about the use of PODs in 2013, calling them “inherently suspect under the anti-kickback statute” (Office of Inspector General 2013a). While the legality of any particular POD depends on the intent of the parties, OIG highlighted specific characteristics of concern. For example, PODs are particularly concerning when the size of the investment offered to each physician varies with the volume or value of devices used by the physician. Because a violation of the anti-kickback statute applies to both parties in an illegal kickback scheme (e.g., the hospital and the POD), some hospitals began enacting policies forbidding or strictly curtailing business with PODs after OIG issued the Special Fraud Alert (Office of Inspector General 2013b, U.S. Senate Committee on Finance 2016). For example,

The excise tax on medical devices

The Congress enacted an excise tax on medical devices in 2010 as part of the Health Care Education and Reconciliation Act, the companion piece of legislation that modified the Patient Protection and Affordable Care Act. The excise tax equals 2.3 percent of the manufacturer's price for certain medical devices, which makes it akin to a sales tax. The tax applies to all medical devices sold in the United States except those that are "generally purchased by the general public at retail for individual use" or exported. Medical device companies can deduct the excise tax as a business expense on their corporate income tax returns, which reduces the impact of the excise tax on profitable firms by about 35 percent. The tax went into effect on January 1, 2013, and was expected to generate \$29 billion in additional tax revenue over 10 years (Gravelle and Lowry 2015).

The medical device industry has been strongly opposed to the excise tax. The industry has argued that the tax

reduces incentives to invest in the development of new medical devices and thus harms the industry's ability to develop innovative new products. In particular, the tax is seen as a hardship for small medical device companies that are heavily engaged in research and development since they must pay the tax even if they are not profitable. (The tax is based on medical device sales, so the tax liability for a medical device company is effectively a function of its gross revenues rather than its profits.) The industry has also argued that the tax will lead to higher prices for medical devices, which would reduce the demand for them. The industry has estimated that the combination of lower investment, higher prices, and lower demand will result in significant job losses and encourage U.S. device companies to relocate abroad (Advanced Medical Technology Association 2015b, Furchtgott-Roth and Furchtgott-Roth 2011).

Supporters of the tax have argued that the health reform law will ultimately benefit the medical device industry

(continued next page)

Intermountain Healthcare implemented restrictions on contracting with PODs after the 2013 Special Fraud Alert (U.S. Senate 2015).

While the 2013 Special Fraud Alert made clear that PODs are inherently suspect, federal prosecutions have been limited. Some have suggested that government enforcement actions against PODs have been rare at least partly because the anti-kickback statute requires proof of intent. The most prominent POD prosecution involves a series of cases brought by the Department of Justice against Dr. Aria Sabit, a POD in which Sabit was an investor (Apex Medical Technologies), and others. In one case, Sabit pled guilty and was sentenced in 2017 (Department of Justice 2017). In connection with his guilty plea, Sabit admitted that:

- the financial incentives provided to him by his POD caused him to use more spinal implant devices than were medically necessary to treat his patients to

generate more sales revenue for his POD, which resulted in serious bodily injury to his patients; and

- the money he made from using his POD's spinal implant devices motivated him either to refer patients for unnecessary spine surgeries or for more complex procedures that they did not need (Department of Justice 2017).

Despite these actions, PODs continue to operate throughout the country. For example, a 2016 report from the Senate Finance Committee majority staff states that PODs were believed to be operating in 43 states (U.S. Senate Committee on Finance 2016). In addition, PODs may be changing their operations to avoid hospital-level POD policies and to avoid reporting under the Open Payments program. For example, PODs may be shifting to smaller and more rural hospitals, which may have not yet developed POD-specific policies. In addition, PODs may be changing their structures—such as physicians becoming employees of PODs instead of investors—to

The excise tax on medical devices (cont.)

by increasing the number of people in the United States with health insurance, which should increase the use of health care services. They also note that the health reform law raises revenues from several other health care sectors (for example, by imposing industry-wide fees on health insurers and brand-name pharmaceutical manufacturers) and argue that the medical device industry is being treated in a similar manner. Further, they assert that the tax will not lead medical device companies to relocate abroad because medical devices that are imported for sale in the United States are also subject to the tax (Van de Water 2015).

The Congressional Research Service (CRS) found that the impact of the tax on the medical device industry will be relatively small. CRS based its conclusion on the fact that the tax rate is relatively low and that about half of domestic U.S. production will not be subject to

the tax because of the exemptions for retail sales and exports. CRS also argued that the demand for health care services is not very sensitive to price changes, which will enable medical device manufacturers to pass along the impact of the tax in the form of higher prices. Overall, CRS estimated that the tax would reduce employment and output in the medical device industry by no more than 0.2 percent. CRS also noted that initial tax collections were lower than expected, suggesting that some manufacturers may not be aware that they are required to pay the tax (Gravelle and Lowry 2015).

The Congress enacted a two-year moratorium on the tax at the end of 2015, so medical device companies do not have to pay it in 2016 or 2017. However, if the Congress takes no additional action, the tax will go back into effect in 2018. ■

avoid reporting under the Open Payments program (U.S. Senate Committee on Finance 2016).

Financial performance

Most financial assessments of the medical device industry focus on the roughly 20 to 30 largest companies. These firms are publicly traded, so data on their financial performance are readily available, and the firms account for most of the industry's overall revenues. In contrast, most small medical device companies are privately held and do not release their financial information to the public.

Large medical device companies have consistently been highly profitable, with annual operating margins that are often between 20 percent and 30 percent (A. T. Kearney 2014, Seligman 2013).²⁷ The investment bank J. P. Morgan recently examined nine major U.S. device companies—including six of the eight U.S. companies listed in Table 7-1 (p. 210)—and found that their profit margins in 2014 ranged from 19 percent to 39 percent, with a median profit margin of 30 percent.²⁸ These nine companies were projected to have similar profit margins over the 2015 to 2017 period (Weinstein et al. 2016).

Annual revenue growth for large device companies slowed noticeably after the 2007 to 2009 recession, dropping between 2008 and 2013 from about 7 percent to about 2 percent or 3 percent (Weinstein et al. 2016). However, many companies reduced their costs in response, and overall profit margins remained stable (PricewaterhouseCoopers 2012). Annual revenue growth has since improved and is projected to range between 4 percent and 6 percent for most companies over the next few years (Weinstein et al. 2016). These companies have also been able to maintain their profit margins despite the enactment of a controversial excise tax on medical devices (see text box).

Large medical device companies are highly profitable for a number of reasons already discussed. These companies receive a significant portion of their revenues and profits from the sale of IMDs and other advanced medical devices, and the markets for those products typically have significant barriers to entry (high research and development costs, FDA regulatory oversight, patents) and limited competition. Similar to brand-name prescription drugs, medical devices can require significant research and

development before entering the market but, after that, the cost of producing them is relatively low (Seligman 2013). Some hospitals have difficulty negotiating lower prices for devices because of the influence of physician preferences, and the methods that some private health insurers use to pay for IMDs encourage hospitals to purchase higher cost devices.

In contrast, the profit margins for smaller, publicly traded device companies are generally much lower. GAO's analysis of net profits between 2005 and 2014 for 102 device companies of varying sizes found that the small- and medium-sized companies, in aggregate, experienced net losses each year (Government Accountability Office 2015). These companies are typically less diversified than the large device companies, and their success or failure may depend heavily on a particular device. These companies may lose money for several years because of a combination of high research and development costs and the time needed to persuade physicians and hospitals to use their products.

How Medicare pays for medical devices

Although Medicare uses a wide variety of methods to pay for health care services, its payment rules for medical devices have two common elements. First, Medicare does not pay medical device companies directly for their products. Instead, the program reimburses health care providers—such as hospitals and physicians—when they use medical devices to deliver care. Second, Medicare rarely makes payments for individual medical devices. Instead, reimbursement for a medical device is typically part of a bundled payment that covers many of the items needed to deliver the associated service or procedure. For example, Medicare's payment to a hospital for knee replacement surgery covers the cost of the operating room, routine surgical supplies, and the knee implant itself (Robinson 2015). To do otherwise—that is, pay separately for each individual medical device—would be administratively burdensome and give providers little incentive to use devices in a cost-effective manner.

Accounting for the cost of medical devices in payment rates

CMS uses several methods to account for the cost of medical devices, depending on the type of associated service. Examples of three methods for calculating cost include those associated with inpatient and outpatient

hospital services, clinician services, and durable medical equipment (DME).

For inpatient and outpatient hospital services, CMS accounts for the cost of medical devices using data that hospitals submit each year in their cost reports. The cost reports have information on both costs and charges, which CMS uses to calculate cost-to-charge ratios for major categories of hospital activity known as cost centers. The cost of medical devices is reported in several different cost centers, such as one for medical supplies and another for implantable devices. CMS uses the cost-to-charge ratios to convert charges that hospitals submit on claims to an estimated cost of providing services. CMS calculates the average cost for each service across all hospitals and uses that as the basis for its payment rates under both the inpatient prospective payment system (IPPS) and the outpatient prospective payment system (OPPS). As a result, Medicare's payment rates for an inpatient or outpatient service include an amount that approximates the average amount that hospitals pay for the medical devices used in that service.²⁹

For clinician services, CMS accounts for the cost of medical devices using information collected from surveys fielded by specialty societies. These surveys ask about the time and intensity involved in providing a service and the associated practice costs, such as nonphysician clinical staff and the specific medical devices used in each procedure.³⁰ A group of health care professionals known as the AMA/Specialty Society Relative Value Scale Update Committee then recommends clinician payment rates to CMS based on the survey information and their professional judgment. CMS converts information on the types of devices used for a given service into an overall cost estimate using price data that it collects. CMS then calculates weights that measure the relative costliness of each physician service. However, the amount included for medical devices can often be inaccurate because the information on the number and type of medical devices used in a procedure is based on a small number of surveys, and CMS has not thoroughly updated the information on prices since 2004. In some cases, the price of a device is based on only one or two invoices.

Unlike hospital and physician services, DME (as well as prosthetics and orthotics) is an area where medical devices such as wheelchairs and home oxygen equipment are considered services in their own right. CMS traditionally used a fee schedule to pay for these products, but the Congress required the agency to begin using competitive

bidding in 2009 to determine the payment rate for many DME products and has expanded its use since then. Under competitive bidding, DME suppliers submit bids to provide certain products in selected metropolitan areas and indicate how much of each product they can supply. CMS selects suppliers who offer the best price and meet applicable quality and financial standards and then uses the median bid from the winning suppliers as its payment rate. The DME competitive bidding program has substantially reduced DME payment rates, thereby saving Medicare and beneficiaries billions of dollars since its inception (Centers for Medicare & Medicaid Services 2016, Government Accountability Office 2014a). CMS has also reported that the implementation of the DME competitive bidding program has not resulted in widespread beneficiary access issues (Government Accountability Office 2016).

Ramifications of bundling medical devices with other inputs

Medicare's general strategy of bundling its payment for medical devices with its payment for all of the other "inputs" used to provide a service is beneficial because it gives providers an incentive to limit their spending on medical devices (as well as the other inputs that are bundled into the payment rate). Providers do not receive any additional payment when they use a more expensive device, and they lose money if their costs exceed the Medicare payment rate. This incentive is particularly strong for IMDs, which can make up a significant share of the overall costs of an inpatient stay or outpatient procedure. Conversely, providers that can keep their costs below the Medicare payment rate benefit financially.

The experience of private health insurers illustrates how bundling medical devices into payment rates can help control spending. In contrast to Medicare, private insurers are often forced to carve IMDs out of their payment rates and pay for them separately, instead of bundling them with other inputs. Some hospitals can also add a significant markup to their purchase price when they negotiate IMD payment rates with private insurers. This arrangement allows some hospitals to turn IMDs into a significant source of profit and (since the markups are usually calculated on a percentage basis) gives them an incentive to use more expensive devices (Robinson 2015).

Bundling medical devices with other inputs also has some drawbacks, although they are outweighed by the benefits. One drawback to bundling is that claims data cannot be used to determine how much Medicare spends on medical devices or monitor how that spending—in aggregate or

for specific procedures—changes over time. This lack of information may not matter much for inputs like common medical supplies, but it may be more significant for high-cost items such as IMDs. Given the limitations of claims data, Medicare cost reports for hospitals can be used as an alternate source of information. Hospitals are the largest purchasers of medical devices, and they must submit information on the overall costs and charges for both medical supplies and implantable devices on their cost reports. However, this information is highly aggregated and better suited for analyzing major areas of hospital costs than the underlying costs of individual services.

Using cost report data, we estimate that medical supplies and implantable devices in 2014 represented about 15 percent of total hospital costs for Medicare-covered services (Table 7-4, p. 232). That year, hospitals spent about \$14 billion on implantable devices and almost \$10 billion on medical supplies. Between 2011 and 2014, spending on implantable devices grew at an average annual rate of 4.7 percent, compared with 2.0 percent for total hospital costs. During this period, implantable devices also grew as a share of total hospital costs, rising from 8.0 percent to 8.7 percent, while spending on medical supplies increased slightly faster than total hospital costs. The higher growth in spending on implantable devices relative to total hospital spending could be due to higher prices for IMDs, higher utilization rates for procedures that use IMDs, and sluggish growth in inpatient stays that do not involve IMDs.

Another concern about bundling medical devices with other inputs is that CMS's IPPS and OPDS rates are ultimately based on historical data from cost reports. There is a two-year delay before cost reports for a given year are available, and this lag discourages hospitals from using new devices that benefit patients but are more expensive than existing technology (Robinson 2015). CMS mitigates this incentive during the period between the introduction of a new device and the availability of suitable cost report data by increasing payment rates for devices that satisfy three criteria: (1) they have received FDA approval or clearance within the past three years; (2) they are sufficiently expensive that existing payment rates are inadequate; and (3) they have a clear clinical benefit.³¹ These new-technology payments remain in effect for no more than three years; by that time, hospitals have submitted cost reports that include the costs of the new technology, and CMS can use its regular methodology to set payment rates. For inpatient services, the new-technology payment equals 50 percent of the difference

**TABLE
7-4****Hospital spending on implantable devices and medical supplies for Medicare-covered services in 2011 and 2014**

	Reported costs (billions of dollars)		Average annual growth 2011-2014	Share of total hospital costs	
	2011	2014		2011	2014
Implantable devices	\$12.1	\$13.8	4.7%	8.0%	8.7%
Medical supplies	\$9.1	\$9.8	2.4	6.1	6.2
Total	\$21.2	\$23.6	3.7	14.1	14.8
Total hospital costs	\$150.2	\$159.1	2.0	100.0	100.0

Note: The figures in this table are based on Medicare cost report data for 3,002 hospitals that submitted cost reports for each year between 2011 and 2014, used the same cost reporting period during those years, were paid under the inpatient prospective payment system, and did not use all-inclusive rates. Figures include costs for both inpatient and outpatient services. Actual costs for implantable devices may be somewhat higher than these figures indicate because some hospitals may report the cost of some implantable devices in other sections of the cost report (for example, by including coronary stents in the cost of a cardiac catheterization laboratory). Components may not sum to totals because of rounding.

Source: MedPAC analysis of Medicare hospital cost reports.

between the estimated cost of the inpatient stay and the regular Medicare payment rate, or 50 percent of the cost of the new device, whichever is less. For outpatient services, the new-technology payment equals the estimated cost of the device, which CMS calculates using the hospital's cost-to-charge ratio. Hospitals identify the services that qualify for new-technology payments by including specific procedure or service codes on their claims.

Relatively few devices have qualified for these new-technology payments. Between 2001 and 2015, CMS approved only 19 of 53 applications (from both device and drug manufacturers) for new-technology payments under the IPPS. Medicare spending for new-technology payments has also been relatively low; between fiscal years 2002 and 2013, the program spent about \$200 million on new-technology payments under the IPPS (Hernandez et al. 2015). The medical device industry has argued that CMS should make it easier to qualify for new-technology payments and that the IPPS should pay 80 percent of the cost of a new device or drug instead of 50 percent to more strongly encourage the use of new technology (Advanced Medical Technology Association 2016). However, the existing criteria encourage hospitals to negotiate discounts on new devices, which limits the ability of device companies to introduce new devices at higher prices and helps to contain program spending (Robinson 2015).

Gainsharing in Medicare

While bundled payments give hospitals an incentive to keep their costs low, physicians significantly influence device selection, and physicians may be indifferent or antagonistic to hospitals' efforts to lower costs (Robinson 2008). One way to align hospital and physician incentives is to engage in gainsharing. Our work provides a brief overview of what constitutes gainsharing, gainsharing in Medicare, and arguments for and against allowing broader participation in gainsharing arrangements in Medicare.

While gainsharing arrangements take many forms, the term generally refers to programs that allow hospitals to share savings with physicians if costs are reduced below a historical or other benchmark. Gainsharing arrangements between hospitals and physicians can generate savings in several ways. Strategies traditionally used in gainsharing arrangements to lower costs include product standardization (which may allow hospitals to negotiate lower prices based on increased volume and to realize other efficiencies), product substitution (whereby physicians choose a lower priced device that is clinically appropriate), opening packaged items only as needed, and limiting the use of certain supplies or devices (Morris 2005). Gainsharing can also generate other savings by focusing on patient management, such as optimizing

bed management in intensive care units by transitioning patients to less intense settings in the hospital (e.g., “step-down” units) when appropriate (Hopkins et al. 2015).

Gainsharing arrangements between hospitals and physicians can violate federal law. Three laws are of particular concern—the gainsharing civil monetary penalty (CMP) law, the anti-kickback statute, and the physician self-referral law (Centers for Medicare & Medicaid Services 2015b). The gainsharing CMP law prohibits a hospital from knowingly making a payment to a physician as an inducement to reduce or limit medically necessary services to Medicare beneficiaries under the physician’s care. Before the Medicare Access and CHIP Reauthorization Act of 2015, the gainsharing CMP law prohibited paying a physician to reduce or limit any care, regardless of whether the care was medically necessary (Centers for Medicare & Medicaid Services 2015b). The anti-kickback statute makes it a criminal offense to knowingly offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services payable by Medicare or other federal health care programs (Centers for Medicare & Medicaid Services 2015b). OIG has said that certain gainsharing arrangements could violate the anti-kickback statute, such as arrangements designed to attract physicians’ referrals to a particular hospital or those that reward physicians over an extended period for previously achieved savings (Morris 2005). Finally, the physician self-referral law, which generally prohibits physicians from making referrals for certain services to an entity with which they have a financial relationship, may not contain exceptions sufficiently flexible to encourage beneficial gainsharing arrangements (Centers for Medicare & Medicaid Services 2015b).

Because of these legal concerns, gainsharing arrangements involving Medicare FFS beneficiaries have been limited outside of programs approved through OIG’s advisory opinion process and demonstrations operating under waivers. OIG has issued a number of advisory opinions allowing specific gainsharing programs. Medicare has also tested gainsharing directly and allowed gainsharing as part of larger demonstrations. For example, the Bundled Payments for Care Improvement (BPCI) initiative, which is a demonstration testing whether giving providers larger payment bundles can lower costs and improve quality, gives participants many options for creating customized gainsharing arrangements after meeting certain requirements, such as specifying the methods for calculating and distributing gainsharing payments in

their implementation protocol (Lewin Group 2016).³² Most BPCI participants intend to engage in gainsharing; for instance, 80 percent, 83 percent, and 93 percent of BPCI participants in Models 2, 3, and 4 of the initiative, respectively, have indicated their intention to participate in gainsharing (Lewin Group 2016). While data regarding the implementation of these gainsharing programs are not yet available, interviews with BPCI participants indicate that gainsharing is a useful tool to redesign care (Lewin Group 2016). Outside of programs where fraud and abuse laws are waived by the government, industry stakeholders have suggested that providers are hesitant to enter into a gainsharing arrangement involving Medicare FFS beneficiaries because of the legal risk.

Proponents of gainsharing argue that aligning the incentives of hospitals and physicians has proved effective at reining in high device costs and producing other efficiencies. The Commission has recommended that gainsharing arrangements between physicians and hospitals be permitted, with appropriate safeguards (Medicare Payment Advisory Commission 2008, Medicare Payment Advisory Commission 2005). Much of the research on gainsharing supports the utility of such arrangements. For example, a 2008 study of 13 OIG-approved gainsharing programs for coronary stent patients found several positive results: Gainsharing reduced costs by an average of 7.4 percent (with 91 percent of the savings from lower prices and 9 percent from lower utilization), surgical volume before and after implementing gainsharing remained steady, patient characteristics remained largely unchanged, and quality metrics either remained steady or showed significant improvement at gainsharing hospitals (Ketcham and Furukawa 2008). More recent studies substantiate these findings. For example, one hospital participating in CMS demonstrations that coupled bundled payments with the ability to institute gainsharing lowered its orthopedic implant costs by 29 percent from 2008 to 2015, while the three measured quality metrics either remained stable (emergency room visits and readmissions) or improved (the proportion of episodes with a prolonged length of stay) (Navathe et al. 2017).³³ The authors noted that this finding highlights the critical role gainsharing played in encouraging physicians to provide efficient care since the hospital in the study already had an incentive to keep its costs low under Medicare’s diagnosis related group payment before the demonstrations.³⁴

Critics of gainsharing include the medical device industry and those who are concerned that gainsharing

arrangements can become “potential vehicles for the unscrupulous to disguise payment for referrals or compromise the quality of care for patients in the interest of maximizing revenue” (Centers for Medicare & Medicaid Services 2008). The medical device industry has expressed concern that gainsharing in CMS’s bundled payment demonstrations could encourage hospitals and physicians to purchase lower cost and lower quality devices (Advanced Medical Technology Association 2015c).³⁵ OIG, CMS, and others have also raised concerns about gainsharing arrangements in which physicians are compensated for overall cost savings without knowing what specific actions generated those savings (Centers for Medicare & Medicaid Services 2008, Morris 2005). Such poorly structured arrangements may lack accountability (e.g., a transparent system that identifies what specific actions lead to savings), sufficient safeguards against improper referral payments, and objective quality measures (Morris 2005). In the process of trying to create an exception (that was ultimately not finalized) for gainsharing arrangements from the physician self-referral law, CMS noted that improperly structured gainsharing arrangements could lead to:

- **Payment for referrals.** Gainsharing payments from hospitals to physicians could be used to generate referrals to hospitals, which could lead to an increase in utilization.
- **Stinting.** Physicians could have a financial incentive to inappropriately reduce the amount or intensity of care received to achieve cost savings.
- **Cherry picking.** Physicians could have an incentive to treat only healthier patients.
- **Steering.** Physicians could have a financial incentive to avoid sicker patients or steer them to other facilities.
- **“Quicker and sicker” discharges.** Physicians could have a financial incentive to discharge beneficiaries too quickly in order to achieve cost savings (Centers for Medicare & Medicaid Services 2008).

In addition to the empirical research that supports the notion that gainsharing can lower costs and increase (or not affect) quality, several relatively recent changes to the manner in which Medicare pays for hospital care could mitigate some of these concerns. For example, the Hospital Readmissions Reduction Program, which began in fiscal year 2013, penalizes hospitals for excess

readmissions for certain conditions and procedures, such as heart failure, pneumonia, and elective total hip and/or total knee replacement (Centers for Medicare & Medicaid Services 2017a). The penalties associated with this program could help moderate any incentives to discharge patients inappropriately early because the hospital would be penalized if a high share of beneficiaries were subsequently readmitted. Other programs that could protect quality under gainsharing programs include the hospital value-based purchasing program (which began in fiscal year 2013) and the Hospital-Acquired Condition Reduction Program (which began in fiscal year 2015). Together with the Hospital Readmissions Reduction Program, these initiatives can increase a hospital’s inpatient payments by as much as 3.5 percent and lower payments by as much as 6.0 percent (Medicare Payment Advisory Commission 2017).

Gainsharing could also leverage increased price transparency for IMDs to lower device costs. Specifically, implementing a policy allowing all hospitals to share IMD prices with physicians who practice at their hospitals provides for the information necessary to make better judgments about value. Allowing hospitals and physicians to engage in gainsharing provides the impetus to use that data to lower device costs.

Conclusion

This chapter provides an overview of the medical device industry and how Medicare pays for devices. While the medical device industry produces valuable tools that improve the lives of beneficiaries, some challenges remain to ensure that Medicare and beneficiaries receive the best value for the substantial resources spent on devices.

Because Medicare does not pay directly for most medical devices, future changes designed to improve the quality of medical devices received by Medicare beneficiaries and reduce their associated costs could focus on improving the availability of device- and provider-specific information and aligning provider incentives. First, requiring device identifiers on administrative claims for certain devices could improve the information available to conduct postmarket surveillance, which is critical to ensure device quality. Second, information about the prevalence of PODs could be improved by requiring all PODs to report under the Open Payments program. Further, given the

adverse incentives that many believe are inherent in PODs, actions could also be taken to reduce the number of PODs; such actions could entail revisions to physician self-referral regulations. Finally, similar to the Commission's recommendations in 2005 and 2008, hospital-physician

gainsharing arrangements could be more broadly allowed in the Medicare program, potentially in combination with bundled payments. As past gainsharing efforts prove, well-structured programs provide an incentive for hospitals and physicians to collaborate to lower costs while maintaining or improving the quality of care. ■

Endnotes

- 1 This definition of a medical device is in Section 201 of the Federal Food, Drug and Cosmetics Act. The exclusion of items that are absorbed or metabolized by the body distinguishes medical devices from prescription drugs.
- 2 A start-up company is often acquired when its medical device meets a key developmental milestone such as reaching the conclusion of promising clinical or preclinical tests or securing regulatory approval to market the device in the United States or the European Union.
- 3 Venture capital firms can also recoup their investments when start-up companies go public and sell stock to raise additional capital.
- 4 These figures overestimate the share of research and development conducted by large medical device companies to some degree because small device companies that engage in research and development but are not yet profitable cannot claim the credit.
- 5 The predicate device cannot be a device that requires premarket approval, discussed later in the chapter.
- 6 The FDA requires manufacturers of brand-name drugs to submit clinical data demonstrating that a drug is both safe and effective. Manufacturers of generic drugs do not have to submit data on safety and effectiveness, but they must demonstrate that the active ingredient in their product is identical to the active ingredient in the brand-name version of the drug. As long as the active ingredients are identical, the data on safety and effectiveness for the brand-name version of the drug are assumed to be equally valid for any generic versions of the drug.
- 7 The FDA uses distinct terminology to refer to its go-ahead for the marketing of medical devices through the 510(k) process versus the premarket approval process. In FDA parlance, the agency *clears* 510(k) notifications, and these actions are referred to as *clearances*. The terms *approves* and *approval* are reserved for devices that use the premarket approval process (Johnson 2016).
- 8 Before submitting a PMA application, a medical device manufacturer must first obtain an investigational device exemption (IDE) from the FDA. The IDE allows the manufacturer to use the device in the clinical trials that will support the eventual PMA application (Johnson 2016).
- 9 Conducting RCTs of medical devices can be difficult, especially for implantable devices. If the only individuals who undergo surgery are those in the treatment group, patients and providers can learn who is in the treatment group and who is in the control group, which can undermine the integrity of the trial. Some trials have addressed this issue by using sham surgeries on individuals in the control group, but this approach is controversial given the inherent risks of undergoing surgery. Participants in medical device trials may also be more likely to insist on being switched from the control group to the treatment group, or vice versa (Robinson 2015). However, the placebo effect may be stronger for implantable medical devices than for drugs, underscoring the potential value of using sham surgeries in RCTs (Redberg 2014).
- 10 Several exceptions from the UDI requirements exist. For example, Class I devices that bear a Universal Product Code on their labels and device packages are deemed to meet all UDI labeling requirements.
- 11 The Food and Drug Administration Safety and Innovation Act of 2012 established a deadline for the Secretary to issue UDI regulations (Johnson 2016).
- 12 For a full UDI implementation time line, see <https://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/compliancedatesforudirequirements/default.htm>.
- 13 The three FDA-accredited issuing agencies are GS1, the Health Industry Business Communications Council, and the International Council for Commonality in Blood Banking Automation.
- 14 The Global Unique Device Identification Database contains the device identifier, not the full UDI, associated with each device.
- 15 X12 is one of several organizations, referred to as Designated Standard Maintenance Organizations, that have been chosen by the Secretary to aid in updating and maintaining standards for health care transactions.
- 16 GPO contracts may include “commitment provisions” that provide additional rebates or discounts to customers that purchase a certain volume through the contract. But individual hospitals—especially large hospitals—may still be able to obtain more favorable prices for some products.
- 17 Many hospitals buy their IMDs directly from manufacturers because they can negotiate more favorable prices than the prices available on GPO contracts.
- 18 Medical device manufacturers bear most of the financial risk of maintaining inventory for IMDs. Hospitals usually do not stock IMDs and rely instead on the manufacturers’ sales

- representatives to bring devices with them when they visit hospitals (Robinson 2015).
- 19 A hospital might be able to negotiate lower prices by purchasing from only one manufacturer, but that strategy has some potential drawbacks. A hospital may have difficulty finding a manufacturer that can supply every kind of device that the hospital uses (even within a specific therapeutic area), and a hospital that uses a single vendor is more likely to have its supply of IMDs disrupted if the manufacturer has problems with production or distribution. A hospital that uses a single vendor may also have more difficulty switching to a new vendor later on because its physicians and staff have become accustomed to using the current vendor's products (Robinson 2015, Robinson 2008).
 - 20 Other actors could be involved in the IMD market, such as physician-owned distributors or GPOs.
 - 21 Patient summaries often include charges, which can vary substantially from costs, and itemized bills often group all devices used during surgery together, limiting patients' ability to identify the cost of any particular device.
 - 22 Cost-to-charge ratios are averages. Therefore, applying these ratios to hospital charges does not provide an exact price. In addition, more than one device is often used in a procedure, so the total device charges reported on a revenue center does not necessarily indicate the specific charge associated with an individual device.
 - 23 Numerous medical device companies have been the subject of lawsuits alleging that they provided illegal inducements or kickbacks to physicians to encourage them to use the company's products. Many of these lawsuits are "whistleblower" suits filed under the False Claims Act, which allows private citizens to file suit on behalf of the government against entities that have committed fraud against government programs and receive a share of any eventual settlement. In these cases, the whistleblower is usually a former employee of the company.
 - 24 In its 2013 Special Fraud Alert, OIG noted that it "did not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent."
 - 25 Of the 596 hospitals surveyed by OIG, 589 hospitals responded.
 - 26 A 2016 report from the Senate Finance Committee majority staff suggested that PODs have become so engrained in some markets that they have distorted competition and pricing for medical devices, forcing doctors and hospitals who refuse to purchase from PODs into an untenable financial position.
 - 27 Operating margins measure profits as a share of total sales revenue and include all costs except taxes, interest, and certain other expenses.
 - 28 J. P. Morgan measured profit margins using a measure known as earnings before interest, taxes, depreciation, and amortization (EBITDA). Many financial analysts prefer to measure profitability using EBITDA because it factors out the effects of a company's financing and accounting decisions (i.e., how much money it has borrowed and how it accounts for its capital investments), which makes it easier to compare the performance of different companies.
 - 29 This discussion does not apply to critical access hospitals and cancer hospitals that are not paid under the IPPS and OPSS. CMS pays those hospitals based on their reasonable costs, which means that each hospital is essentially reimbursed for the full cost of the medical devices that it uses. However, these facilities account for only a small share of Medicare spending for inpatient and outpatient services.
 - 30 The term *medical devices* has the same broad meaning here that is used throughout this chapter and encompasses everything from latex gloves to surgical instruments to imaging equipment. In the context of physician services, CMS classifies medical devices as either medical supplies (items that are used only once) or medical equipment (items that are used more than once).
 - 31 CMS also makes new-technology payments for prescription drugs. Drugs must meet the same eligibility criteria as devices under the IPPS, but are subject to somewhat different criteria under the OPSS.
 - 32 Other programs under which gainsharing has been tested include the Medicare Participating Heart Bypass Center Demonstration, Medicare Hospital Gainsharing Demonstration, Medicare Acute Care Episode Demonstration, and Comprehensive Care for Joint Replacement Model.
 - 33 The authors note that the proportion of episodes with a prolonged length of stay is a validated measure of complications for the studied procedures.
 - 34 Another recent study demonstrates an additional area where gainsharing could improve efficiency. Specifically, the study found approximately \$968 of surgical supplies per case was wasted for the 58 neurosurgical cases studied at one academic hospital (Zygourakis et al. 2017).
 - 35 The use of bundled payments for knee and hip replacements has prompted some device manufacturers to look for new ways to lower their costs, such as developing lower cost joint implants and eliminating the use of sales representatives for certain hospitals (Abrams and Phillips 2016).

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