

Insight on the Issues

UNDERSTANDING THE MARKET FOR IMPLANTABLE MEDICAL DEVICES

Keith D. Lind, JD, MS
AARP Public Policy Institute

The market for implantable devices, such as hip replacements and heart valves, is an important and growing part of the health care industry. This *Insight on the Issues* delves into the market for implantable devices; financial incentives faced by manufacturers, hospitals, physicians, and payers; the impact of the current market structure on competition; and the lack of price transparency. Finally, without endorsing them, this paper discusses the strengths and weaknesses of a range of policy options that could increase price transparency and strengthen competition in the marketplace for implantable devices. A second *Insight on the Issues* explores the FDA's process for approval and oversight of these devices and policy options that could both strengthen and streamline the process to better protect public health and safety while also encouraging the development and marketing of devices that will benefit patients.

BACKGROUND

Millions of Americans have implantable devices, such as artificial hips or cardiac pacemakers, in their bodies. During recent years, advances in technology and medical innovation have expanded the types and sophistication of implantable devices to include such things as artificial hearts and deep-brain stimulators to control epilepsy. Due to an aging population and the increasing presence of chronic conditions, the number of people who can benefit from implantable devices continues to grow.

What Are Implantable Devices?

Implantable devices make up a category of medical devices¹ that are inserted into the human body to replace a missing body part, support a damaged body part, or modify an important body function. Examples of implantable devices include orthopedic rods, pins, and screws used to repair fractured bones; artificial hip joints used to replace hip bones worn by

arthritis; and cardiac pacemakers used to restore an irregular heart rhythm.

Why Focus on the Market for Implantable Devices?

Implantable devices often provide substantial benefits. Cardiac pacemakers save lives and artificial hips help people recover function and relieve pain. Millions of Americans have undergone surgery to implant some type of medical device. Americans receive about 370,000 cardiac pacemakers and about 1 million total hip and knee replacements per year.² Experts estimate that 7.2 million Americans are living with joint implants.³

On the other hand, the cost of implantable devices is significant. The price hospitals must pay for implantable devices accounts for 30–80 percent of the payment they receive from insurers, such as Medicare, for related procedures. For example, in 2008, Medicare paid about \$33,000 for the entire surgical procedure

to implant a cardiac defibrillator, while a hospital paid about 75 percent of that amount for the device.

In the United States, medical devices expenditures amounted to over \$170 billion and accounted for about 6 percent of total national health expenditures of \$2.9 trillion in 2013.⁴ Industry reports suggest that implantable device sales totaled about \$43 billion in 2011 and are expected to grow to \$74 billion by 2018.⁵

Few data are publicly available on the average price paid by US hospitals for implantable devices. The Government Accountability Office (GAO) was able to obtain limited data regarding implantable device prices in a small 2012 survey of 60 hospitals, about half of which responded with price data. The survey found a range of several thousand dollars between the lowest and highest prices paid for similar devices. For example, a particular implantable cardiac defibrillator with a median price of about \$19,000 had a price range of almost \$9,000.⁶

Anecdotally, the device industry has a reputation for generating high profits with high prices.⁷ In 2013, a *Time* magazine article highlighted the case of a neurostimulator with a list price of about \$19,000, which was about four times the manufacturing cost.⁸ Another article, in the *New York Times*, reported that hospitals routinely pay about \$8,000 for hip implants that cost about \$350 to manufacture.⁹ Studies suggest that the high price for these implantable devices may be due to lack of price transparency and other factors peculiar to the market for implantable devices.^{10,11}

Industry sources have reported that average prices for several major categories of implantable devices declined from 2007 to 2011.¹² However, these reports have not included data about actual price levels.

To the extent price data are available, the cost of medical devices sold in the United States—especially implantable devices—is often greater than in other countries. In 2007, American hospitals reportedly paid an average of about \$8,000 for an artificial hip. In Belgium, the government-approved list price for the same hip implant was about \$4,000 and could be marked up by only \$180.¹³

Although over 5,000 medical device manufacturers operate in the United States, only a small number of them sell the vast majority of implantable device products.¹⁴ The three largest device manufacturers

each had a market capitalization (i.e., total stock value) exceeding \$10 billion in 2014.¹⁵ While device manufacturers' profits may go up and down from year to year, some large medical device companies have been highly profitable with earnings of 20–30 percent before interest, taxes, depreciation, and amortization.¹⁶ Some large publicly traded medical device manufacturers have achieved substantial profits, even after taxes:

- Zimmer Holding, which makes orthopedic implants, had a net profit of more than 15 percent on revenue of \$4.6 billion in 2014.¹⁷
- St. Jude Medical, which makes cardiovascular devices such as pacemakers, had a net profit of 18 percent on revenue of \$5.6 billion in 2014.¹⁸
- Johnson & Johnson, which makes implantable devices among other things, had net profits of 23 percent on revenue of \$72 billion.¹⁹

Who Buys Implantable Devices?

Implantable devices can be sold only to health care providers, such as hospitals or physicians, and are available to patients only by physician prescription. Hospitals are the primary purchasers of most high-cost implantable devices in the United States.

How Are Implantable Devices Regulated?

The approval and marketing of implantable devices in the United States is regulated by the Food and Drug Administration (FDA). FDA categorizes implantable devices according to their complexity and the degree of risk posed to patients. Greater risk means more stringent regulatory requirements.

The vast majority of implantable devices are considered intermediate risk (Class II). Devices in this category can be cleared for market through a simple administrative review, referred to as the “510(k) process,” if a company assures FDA that the device is “substantially equivalent” to devices already available.²⁰ Although FDA may rely on a paper application, in some cases, FDA may request nonclinical bench performance testing or analytical studies using clinical samples.²¹ However, this process does not require clinical testing to demonstrate safety or effectiveness of the device.²² As a result, many implantable devices arrive on the market without the benefit of studies that demonstrate their safety and effectiveness.²³

How Are Implantable Devices Paid For?

In many cases, health plans and insurers, such as Medicare, do not pay directly for a specific device. Instead, they agree to pay a fixed rate set in advance for hospital services related to the surgical procedure, including the implantable device, supplies, drugs, nursing care, and—in the case of inpatient procedures—hospital room and board. For instance, for a hip replacement, Medicare will pay for all costs related to the surgery needed to implant an artificial hip, including the device—Medicare does not pay the hospital separately for the specific implanted device. Devices implanted in both inpatient and outpatient settings are reimbursed under this “bundled payment” model. However, some private insurers pay the hospital a per diem amount plus a supplement for the device. Typically, surgeons are paid separately for the procedure to implant the device.

Under Medicare’s payment system, hospitals pay for implantable devices as part of the cost of doing business. Occasionally, Medicare creates a new category and payment rate when an entirely new procedure is introduced that includes an expensive new device. In the case of particularly high-cost devices, such as an implantable cardiac defibrillator, Medicare will temporarily make a separate additional payment for the new device to ensure that beneficiaries have access to this new technology.

Medicare’s payment systems, which are based on hospitals’ reported costs, tend to squeeze hospital margins and encourage hospitals to negotiate for lower device prices.²⁴ Unfortunately, these payment systems are slow to capture price reductions that arise from improvements in hospital efficiency and competitive price reductions for devices.²⁵ Also, because Medicare makes payment adjustments in a budget-neutral manner, allocating hospital payments to an expensive new device results in cutting payment for other services, such as nursing and other routine costs. On the other hand, Medicare’s annual payment updates tend to lag device price increases by at least two years. This two-year lag puts downward pressure on device prices. In addition, delays in the process of creating new payment categories result in “stickiness” of prices—reducing upward price adjustments and slowing the diffusion of expensive new devices.²⁶

To the extent that other payers, such as Medicaid and some private insurers, base provider reimbursement on Medicare’s methodology, hospitals face similar pressure to cut the price they pay for implantable devices.

When private insurers pay hospitals separately for implantable devices, hospitals may feel less pressure to contain the cost of devices they purchase.²⁷ In an effort to control these costs, some large private insurers contract with Device Benefit Managers, which act as intermediaries by negotiating with manufacturers and buying implantable devices in bulk at lower cost and selling them to hospitals at a markup.²⁸

WHAT ARE THE PROBLEMS WITH THE MARKET FOR IMPLANTABLE DEVICES?

Limited Competition in the Marketplace for Implantable Devices

The United States relies on market forces rather than government regulation to control prices for implantable devices. Yet many of the key ingredients for a competitive market are not entirely satisfied, including the following:²⁹

- Large number of sellers
- Existence of similar products that are good substitutes for each other
- Low barriers to entry into the market
- Good information about prices, quality, and performance of products

Relatively few manufacturers supply the vast majority of implantable device products.³⁰ Five manufacturers control 90 percent of the market for artificial hip and knee implants.³¹ Even fewer manufacturers control the market for many sophisticated cardiovascular devices: three firms produce implantable cardiac defibrillators and only four firms produce coronary artery stents that are combined with an anticoagulant drug.³²

In consumer markets, such as the market for soft drinks, many buyers don’t mind paying more for products they perceive as different, even when they are basically substitutes. This type of product differentiation allows manufacturers to charge higher than competitive prices. Similarly, implant device manufacturers often go to great lengths to differentiate their products in the minds of physicians

and surgeons.³³ Some experts believe these efforts have resulted in an implantable device market controlled by a small number of manufacturers offering products that, while differentiated from those of their competitors for marketing purposes, are in fact similar and meet the same needs.^{34,35}

In the United States, the medical device industry is a highly regulated sector of the economy. According to at least one federal agency, device manufacturers must devote considerable resources toward product approval processes, clinical trials, user fees, and facility audits/inspections.³⁶ Studies suggest that US manufacturers of implantable devices are able to maintain high prices in part due to structural barriers to competition, such as the complex, costly regulatory approval process and patent protections.^{37,38,39}

Structural barriers discourage imported implantable devices that might compete with domestically manufactured devices and bring down prices. Manufacturers often find it faster and easier to launch new products in Europe than in the United States.⁴⁰ In any case, the majority of imported medical devices are lower-tech products, such as surgical gloves and instruments.⁴¹

In addition to structural barriers and product differentiation, device manufacturers have created further hurdles to price competition through lack of price transparency, brand loyalty, and financial ties, primarily to physicians who use the devices.⁴² While most of these strategies are entirely legal in the US market, in some cases manufacturers have crossed the line and been prosecuted for illegal activities, such as paying kickbacks to physicians for referrals.⁴³

Price Transparency: Gag Clauses Keep Device Prices Secret

Lack of price transparency significantly limits the ability of hospitals to be “prudent purchasers” of devices.^{44,45,46} Device manufacturers typically insist on a confidentiality agreement in the purchasing contract with hospitals.⁴⁷ According to reports, these clauses are sometimes slipped in surreptitiously as part of boilerplate language that appears on a receipt signed by a low-level employee to acknowledge delivery of the device.⁴⁸

Confidentiality or secrecy agreements act as “gag” clauses and are designed to make it difficult

for hospitals to negotiate better prices with manufacturers.⁴⁹ These secrecy agreements prevent hospitals from disclosing prices to physicians who implant the devices, patients who use them, and insurers who indirectly pay for them. Some economists assert that the lack of price transparency created by gag clauses helps manufacturers disguise price differences for devices they sell and makes it easier to sell the same device at higher prices.^{50,51}

Studies suggest that pressure to increase price transparency has prompted device manufacturers to aggressively enforce these gag clauses through lawsuits.⁵² Often, the target of a manufacturer’s lawsuit is not the hospital, but a consultant who has collected price data from many hospitals in an effort to help negotiate lower prices.⁵³ Manufacturers have been known to make implicit threats to rescind hospital contracts for violation of secrecy agreements.⁵⁴

Hospitals: Limited Ability to Negotiate Prices

Hospitals are the primary purchasers of most high-cost implantable devices in the United States, but they have limited bargaining power to negotiate lower prices. In addition to lack of price transparency, they also face

- A fragmented hospital industry,
- Limited device data, and
- Lack of control over buying decisions.

Fragmented Hospitals Industry

With many different hospitals as buyers, the industry is fragmented. In the United States, about 5,000 acute care hospitals represent potential buyers of implantable devices.⁵⁵ Many of them are competitors in overlapping geographic markets.

Hospitals have, to some extent, strengthened their bargaining position with manufacturers by acquiring and merging with other hospitals.⁵⁶ Because these health systems account for a larger share of a manufacturer’s business for any single device, they are often successful in obtaining discounts and lower prices.⁵⁷

Antitrust laws prevent hospitals from cooperating directly with one another to negotiate prices. However, hospitals are permitted to join forces through group purchasing organizations (GPOs) that are allowed to negotiate discounts and pass them on

to participating hospitals. In its basic form, a GPO is a cooperative of buyers. Virtually every hospital in the United States belongs to at least one GPO. In 2012, an industry study estimated that GPOs purchased over \$300 billion in medical supplies including over \$30 billion for implantable devices.⁵⁸ Although industry sources claim that GPOs provide hospitals with substantial savings on the cost of implantable devices, others have raised questions about the extent of savings.⁵⁹

Historically, most implantable devices are not purchased through GPOs because many large manufacturers do not contract with GPOs.⁶⁰ Instead, manufacturers market their devices to physicians who influence hospital purchases, as described below.

Limited Device Data

Hospitals are often hampered by insufficient data, about not only implantable device prices, but also device performance and how it affects clinical outcomes. FDA's 510(k) clearance process does not require clinical testing of most devices, which gives cost and time advantages to implantable devices that can demonstrate that they are "substantially equivalent" to a similar device that is already on the market.^{61,62} As a result, most implantable devices arrive on the market without the benefit of studies that demonstrate their effectiveness. The absence of comparative performance data makes it difficult for hospitals to evaluate the relative effectiveness of implantable devices or to assess the cost-effectiveness of similar devices.

Lack of Control over Buying Decisions

Physicians typically select the devices they want to implant.⁶³ The hospital then pays for them, resulting in strong incentives to reduce the prices it pays for implantable devices. Often, physicians do not share these incentives and rarely face liability for the cost of devices they implant under siloed payment mechanisms in fee-for-service systems.

Although hospitals might want to encourage physicians to use lower-priced implantable devices, they rely on physicians to bring in patients. Hospitals do not want to risk alienating physicians and surgeons who generate most of a hospital's revenue, especially if the effect might be to encourage physicians to leave and move to a competing

hospital.^{64,65} The poor alignment of hospital and physician incentives is compounded by other factors, described below, that undermine the ability of hospitals to contain prices for implantable devices.

Physicians are often not aware of the cost of the devices they implant⁶⁶ despite their active role in the purchasing decision. According to a 2014 survey, just 21 percent of orthopedic physicians correctly estimated the cost of orthopedic devices within 20 percent of the actual cost.⁶⁷ The survey also found that the majority (about 70 percent) underestimated the price of high-cost devices (i.e., over \$5,000) but overestimated the price of low-cost devices (i.e., under \$500). However, over 80 percent of respondents said that cost should be "moderately," "very," or "extremely" important in the device selection process.

These findings suggest that increased access to relevant device pricing information might improve physician participation in cost containment efforts.

Manufacturers Influence Device Selection

Many device manufacturers make concerted efforts to build strong personal relationships with physicians who implant their devices. Manufacturers cultivate these relationships as they work with physicians through iterative collaborations during the product development cycle. These relationships often lead to strong physician loyalties to particular devices and manufacturers.

Large manufacturers employ many sales representatives, who promote implantable devices to the surgeons who use them. For example, Medtronic, a large medical device manufacturer, has created more than a dozen mobile applications to help a staff of more than 4,500 people promote device sales.⁶⁸

Sales representatives are frequently present in the operating room during procedures to train surgeons in the use of a device.⁶⁹ This support further influences physician preference and builds loyalty.

To a limited extent, patients who express personal preferences to their physicians for a specific implantable device may indirectly influence hospital purchasing decisions. Anecdotal evidence suggests that patients' expression of personal preferences has increased over time, largely in response to manufacturer marketing campaigns directed at consumers. However, patients are often not aware of

whether their physician has a financial relationship with the device's manufacturer.

Physician Conflicts of Interest Lead to Higher Spending

Manufacturers frequently provide physicians with financial incentives to use their products.^{70,71} A 2007 study revealed that 94 percent of US physicians had a financial relationship with the industry—83 percent received gifts and 28 percent received payments for consulting or research participation.⁷² In 2015, medical device companies paid at least \$2.3 billion to health care providers in the United States.⁷³

Financial relationships between manufacturers and physicians can create conflicts of interest. Studies have shown that physicians tend to use more of a manufacturer's products and incur higher health care costs when they have a financial relationship with manufacturers.^{74,75} High-volume surgeons may receive multiple payments from manufacturers for a variety of activities (e.g., research, consulting, and promotional speaking engagements). In 2007, implantable device manufacturers paid orthopedic surgeons about \$200 million for consulting, royalties, and other activities.⁷⁶ These payments can exceed physicians' professional fees for performing surgical procedures.⁷⁷ Firms may also provide physicians with free tickets to sporting events and pay for travel to conferences in exotic locations.

While some industry trade groups have adopted a code of ethics that prohibits manufacturers from paying physicians for expenses that are unrelated to scientific and educational purposes,⁷⁸ compliance with these guidelines is voluntary.

Financial relationships between manufacturers and physicians sometimes cross the line to become illegal kickbacks. In 2007, several device manufacturers paid \$311 million to settle claims by the US Department of Justice that they had paid kickbacks to surgeons to use their artificial joint implants.⁷⁹ In 2014, Medtronic paid \$10 million to settle claims by the Department of Justice that it had paid kickbacks to doctors in the form of lucrative speaking engagements and tickets to sporting events in exchange for using its pacemakers and defibrillators.⁸⁰

Physician ownership of entities, such as physician-owned distributorships, can also lead to conflicts

of interest and higher spending. Under these arrangements, the physician-owners receive profits from the sale of devices they implant in their own patients. Although a Senate report and the US Department of Health and Human Services Office of the Inspector General have warned against the use of physician-owned distributorships as “inherently suspect” and a conflict of interest, the use of these arrangements has continued to expand.⁸¹ The growth of these entities is concerning because many fail to disclose their physician-ownership or comply with financial reporting requirements.

POLICY OPTIONS/SOLUTIONS

Without endorsing or ranking them, this paper discusses the strengths and weaknesses of a range of policy options that could increase price transparency and strengthen competition in the marketplace for implantable devices. These policy options fall into several categories:

- Increase device price transparency in the market by restricting gag clauses and disclosing prices.
- Improve availability of information on implantable device performance and clinical outcomes.
- Require disclosure or impose restrictions on abusive marketing practices.
- Encourage cost containment through payment and delivery reforms.
- Increase competition among device manufacturers.

Increase Price Transparency in the Market

Restrict Gag Clauses

Experts have recommended that policy makers enact legislation that would legally invalidate gag clauses, thus increasing price transparency. Such laws would allow hospitals to share price data with physicians and consultants without exposing themselves to legal liability for breach of contract.⁸² Some would argue that arming hospitals with comparative pricing data would strengthen their bargaining position and could allow them to negotiate lower prices with device manufacturers. However, this legislation would be controversial because a variety of stakeholders would likely oppose it.

Less-controversial approaches may include providing physicians with relative pricing information rather

than actual purchase price data. For example, the University of Maryland Division of Orthopedic Trauma posts color-coded categories for commonly used devices based on their relative prices in order to broadly educate physicians about the cost of the devices they use.⁸³ In this manner, hospitals can encourage physicians to cooperate in the selection of lower-cost devices without disclosing actual prices and violating gag clauses.

Allow or Require Price Disclosure

Mandatory public disclosure of sales prices for implantable devices has been proposed as a mechanism to improve price transparency. Advocates argue that price disclosure would strengthen hospitals' bargaining position with manufacturers and suppliers. For example, in 2007, proposed federal legislation would have required manufacturers to disclose prices for all implantable devices as a condition for receiving direct or indirect payments from Medicare or Medicaid.⁸⁴ Some states have imposed mandatory public disclosure of hospitals' prices for common surgical procedures.⁸⁵

Price disclosure could help hospitals and payers evaluate the value of similar implantable devices to the extent data on performance and clinical outcomes could be collected and combined with price data. In addition, concerns that price disclosure could facilitate collaboration among manufacturers might be addressed using new approaches, such as protected websites that are accessible only to hospital purchasers.

Critics, however, argue that mandatory public disclosure could result in higher, rather than lower, device prices.⁸⁶ Experts have observed that, without quality information, many consumers believe price acts as a proxy for quality and interpret a higher price as an indication of higher quality.⁸⁷ In addition, publicly available price data could be used by manufacturers to collaborate and raise prices, especially in highly concentrated markets for implantable devices. For instance, the Federal Trade Commission has found that public disclosure of prescription drug prices may increase prices.⁸⁸ While explicit price collusion would violate antitrust laws, tacit price collaboration among manufacturers and suppliers would not.

Furthermore, opponents argue that, because hospitals differ substantially in the volume and type of devices they purchase, many hospitals may not be able to use information about how much other hospitals pay for a device to negotiate a lower price for themselves. In addition, surgeons may be unwilling to accept standardized device purchasing by hospitals because manufacturers have effectively differentiated their devices in the minds of physicians and patients. According to some economists, such product differentiation contributes to the ability of manufacturers to charge some hospitals more than others for the same device and earn higher profits.⁸⁹

Finally, critics point out that even if mandatory disclosure allows hospitals to negotiate lower device prices, consumers and insurers may not benefit unless hospitals pass along the savings they realize.⁹⁰

Adopting mandatory price disclosure would require legislation at the state or federal level, which has proven controversial and difficult to enact. Efforts by Congress and the federal government to influence implantable device prices or costs have had limited success. In general, industry lobbying efforts have deflected such legislative efforts. In 2007, the device industry successfully opposed federal legislation (described above) that would have imposed mandatory price disclosure for all implantable devices as a condition for Medicare or Medicaid reimbursement.⁹¹ In a notable exception, in 2010, Congress imposed a 2.3 percent tax on medical device manufacturers. While this measure was primarily designed to raise federal revenue, it might also have had the effect of dampening the rise in implantable device prices. However, before it could take effect, Congress suspended this tax for two years (2016–2017).⁹²

Improve Information on Implantable Device Performance and Clinical Outcomes

Technology assessment committees can evaluate the performance of implantable devices to the extent appropriate data are available. These committees gather reliable data on quality, performance, and patient outcomes and integrate this information to objectively assess the comparative effectiveness and cost—sometimes referred to as the overall “value”—of similar devices. Many hospitals have established technology assessment committees of physicians and hospital executives as part of a broader cost

containment strategy.⁹³ As hospitals become larger, the use of such committees has become more widespread. As these committees have acquired more detailed data on devices, the sophistication and effectiveness of their assessments have increased.

Technology assessments have strengthened the bargaining position of hospitals as they negotiate with device manufacturers and put downward pressure on device prices. For example, Kaiser Permanente, a large, integrated managed care organization, has used this approach to gather and analyze large amounts of internal data on cost and use of key implantable devices, such as artificial joints.⁹⁴ This evidence-based approach has allowed Kaiser to identify safer and more effective devices. Based on its own analysis and experience, Kaiser has standardized its purchasing of many implantable devices and negotiated lower prices for them.

Some large payers have established technology assessment centers, such as the Blue Cross/Blue Shield Technology Evaluation Center.⁹⁵ Similarly, ECRI Institute, a nonprofit organization that represents multiple stakeholders, including payers, hospitals, and health systems, provides comparative effectiveness analysis and cost data on implantable devices to its members for a fee.⁹⁶

Currently, federal agencies do not perform technology assessments of specific implantable devices. However, with congressional approval, the mission of some federal agencies could be expanded to include assessments of implantable devices. For example, the Agency for Healthcare Research and Quality (AHRQ), an agency of the US Department of Health and Human Services, performs comparative effectiveness research based on reviews and synthesis of published studies.⁹⁷ While AHRQ's research is publicly available, it typically evaluates procedures, rather than specific implantable devices. In addition, Congress has prohibited AHRQ from including cost data in its analyses. Congress could expand the scope of comparative effectiveness research performed by AHRQ or other federal agencies doing similar work to include cost and price data.

Use Patient Data Registries and Unique Device Identifiers

Hospitals might be able to get better information on implantable devices through wider use of patient data

registries. A registry is a collection of information about individuals, usually focused on a specific diagnosis, condition, or device.⁹⁸ A number of professional societies, government agencies, private corporations, and independent researchers have established registries that collect standardized data for a limited number of implantable devices.⁹⁹ To some extent, analysis of device registry data could help provide information on safety, effectiveness, and performance.^{100,101}

Meanwhile, opportunities for data acquisition continue to emerge in other areas. Until recently, for example, defective implantable devices were difficult to identify and track on a patient-specific basis. In 2014, FDA started phasing in requirements that high-risk implantable devices carry a unique device identifier (UDI).¹⁰² These identifiers are intended to facilitate tracking and identification of medical devices by appearing on the device itself and on the label as plain text and in bar code form. UDIs are expected to increase implantable device safety by enabling FDA to more quickly identify and recall defective devices.

As more detailed data on implantable devices become available, hospitals and payers are expected to use data to better analyze and understand the safety, performance, and clinical outcomes related to specific devices. Hospitals and private insurers are expected to be able to use UDI data to identify the best-performing implantable devices and strengthen their bargaining position in price negotiations. However, it may take years before UDI data become available in sufficient quantity to be useful for evaluating the effectiveness of many implantable devices.

In the meantime, using currently available data from other sources, some hospitals and insurers have negotiated risk-sharing contracts that amount to performance guarantees or warranties with manufacturers for selected implantable devices. For instance, St. Jude Medical provides its hospital customers with a performance guarantee on its implantable cardiac resynchronization device, an advanced type of cardiac pacemaker. St. Jude will refund 45 percent of the device cost if a patient needs corrective surgery within one year.¹⁰³

Require Disclosure or Impose Restrictions on Abusive Marketing Practices

Greater transparency of financial relationships between manufacturers and physicians could discourage potential conflicts of interest. To some extent, increased disclosure and scrutiny of manufacturer–physician financial relationships could limit physician preference as a driver of hospital purchasing decisions, help increase competition in the market, and drive down prices of implantable devices.

The Physician Payments Sunshine Act¹⁰⁴ is designed to invite such public scrutiny of financial relationships that tend to drive higher health care costs.¹⁰⁵ This federal legislation requires medical device and pharmaceutical companies to publicly disclose payments to physicians and teaching hospitals, including free meals, free travel, speaking fees, and research participation grants, as well as ownership or investment interests held by physicians, family members, or teaching hospitals in manufacturers or group purchasing organizations. Starting in fall 2014, information on manufacturer–physician payments became publicly available.^{106,107} However, the Sunshine Act does not require physicians to disclose to their patients that they have a financial relationship with any particular manufacturer, even when prescribing or recommending the use of that manufacturer’s products.

Although many patients may have difficulty evaluating the information, more sophisticated stakeholders—such as hospitals, health insurers, and consumer watchdog organizations—are expected to use this information to exert pressure to reduce conflicts of interest and increase efficiency of the market for implantable devices.

The effects of the Sunshine Act on financial relationships have not been assessed and may take some time to achieve their full impact. Even before that, the Centers for Medicare & Medicaid Services (CMS) could undertake increased enforcement actions to ensure compliance with Sunshine Act reporting requirements by entities, such as physician-owned distributorships.

In the meantime, Congress could do more to discourage physician brand loyalty and conflicts of interest. For instance, measures could be adopted that would penalize or limit certain financial relationships between physicians and

device manufacturers. Policy makers could also place marketing restrictions on manufacturers to discourage conflicts of interest. For example, Nevada requires device manufacturers to adopt a marketing code of conduct, provide training to sales staff, and conduct compliance audits. Massachusetts and Vermont ban gifts from device manufacturers to health care professionals.¹⁰⁸ Policy makers could also require physicians to disclose to their patients that they have a financial relationship with a manufacturer when prescribing or recommending the use of that manufacturer’s products.

Encourage Cost Containment through Payment and Delivery Reforms

Recent “value-based purchasing” initiatives encourage providers to increase efficiency while maintaining and improving quality of care. These initiatives strengthen competition in health care markets and create strong incentives for purchasers and providers to negotiate lower prices for implantable devices.

Medicare’s bundled payment initiatives require participating providers to accept a predetermined package of payments for the average cost of a group of related services—that is, the same fixed fee for treatment of patients with the same diagnosis. Bundled payments cover all services related to the procedure, including devices and drugs.¹⁰⁹ Recent Medicare initiatives have increased the scope of bundles to include payments to multiple providers, such as hospitals and skilled nursing facilities, for both acute care and postacute care related to a hip or knee replacement.¹¹⁰ Under these large Medicare initiatives, participating providers share any profit (or loss)—referred to as *shared savings* or *gainsharing*—which creates strong incentives to reduce cost and increase efficiency.

Still, regulations could better align financial incentives by bundling physician payments together with those of hospitals. Most Medicare value-based purchasing initiatives continue to pay physicians on a fee-for-service basis separately from hospitals and other providers. As long as these payments are separate, physicians have weak incentives to save on device costs. Under a combined payment approach, physicians would be placed at risk for profits or losses along with hospitals.

In the private sector, large employers are using bundled payment approaches with providers designated as “Centers of Excellence” for certain cardiac and orthopedic procedures. This model encourages hospitals to negotiate more aggressively with device manufacturers. Employees are incentivized through lower cost sharing to receive care at a Center of Excellence that the employer has identified as a high-quality, low-cost provider. For example, PepsiCo pays for its employees and their dependents to have cardiac and complex joint replacement surgeries at Johns Hopkins Hospital in Baltimore, with no patient cost sharing, and will even pay for travel and lodging for patients and their companions who live outside the Baltimore area. PepsiCo pays the hospital an all-inclusive rate, which includes all related physician and hospital services, and preoperative testing.¹¹¹

Although shared savings and gainsharing arrangements provide clear incentives for providers to improve efficiency and cut the cost of such supplies as implantable devices, Medicare places important limitations on the use of these incentives. According to the Office of Inspector General, these arrangements, if not properly structured and monitored, can also be abused by providers.¹¹² As a result, under Medicare rules, shared savings arrangements are allowed only in the context of integrated provider networks (e.g., Medicare Advantage Plans and authorized demonstrations, such as Medicare’s Shared Savings Program for Accountable Care Organizations).^{113,114} Thus, gainsharing arrangements have limited application in the current Medicare fee-for-service environment.

Increase Competition among Device Manufacturers

Use Competitive Bidding

Competitive bidding has been suggested as a mechanism that could put downward pressure on prices for implantable devices. Medicare already uses competitive bidding as a cost control measure for such health care supplies as durable medical equipment (DME). CMS estimated that competitive bidding was responsible for the 45 percent decline in Medicare DME costs in 2013.¹¹⁵ Similarly, while Medicare does not pay separately for implantable devices, with congressional approval, Medicare

could employ competitive bidding to put downward pressure on device prices.

In theory, hospitals could request competitive bids from multiple manufacturers in cases for which more than one model of an implantable device is available. Some large health care organizations, such as Kaiser Permanente, have successfully employed competitive bidding to gain lower prices for implantable devices. But the potential effectiveness of this approach is limited by physician preference for particular devices and the fragmented structure of the hospital market, described previously, which makes it difficult for most hospitals to purchase sufficient volume to gain a price advantage through competitive bidding. In addition, many implantable devices lack clinically appropriate substitutes, reducing the potential for competitive bidding.

Use Reference Prices

That is not to say the market doesn’t offer options for certain devices. For implantable devices available from multiple sources, some payers have intervened in the marketplace to set a single reimbursement rate, or *reference price*, for the device and all related services. These reference prices are designed to establish a limit on the amount insurers will pay for a given procedure, such as a hip implant.¹¹⁶ Reference prices allow an insurer to negotiate lower prices for a bundle of services within a designated network of providers. A similar approach has been applied to pay the same low price for a brand name drug that is equivalent to a generic drug.¹¹⁷ Such limitation acts like a price cap reflecting the cost of a less-expensive class of implantable devices. Providers are expected to accept this fixed amount as payment in full. Patients, meanwhile, have the option of choosing procedures involving implantable devices that exceed the reference price and paying the excess cost.

Reference prices could drive down costs for implantable devices and procedures for which multiple alternatives are available. For example, using reference prices, a large California pension fund succeeded in pressuring hospitals to reduce prices by 34 percent for hip and knee replacements.¹¹⁸ In theory, the power of reference prices to control device prices could be increased further if all hospitals were required to use Medicare’s prospective payment systems. For many procedures involving

implantable devices, Medicare pays providers less than private plans and commercial insurers. For instance, Medicare pays hospitals about \$15,000 for a hip replacement procedure, including the hip implant¹¹⁹—less than the \$25,000 to \$35,000 paid by many insurers. Thus, using Medicare as the basis for reference prices would facilitate price comparisons and increase competition among hospitals.¹²⁰

The use of reference prices has important limitations. They may be ineffective when an implantable device is one of a kind or a related procedure is sufficiently complex that few surgeons are able to safely perform it (e.g., implanting an electrical brain stimulator to control epilepsy). Patients may find that access to needed implantable devices is limited and quality of care may be undermined.

These potential impacts suggest that, when reference prices are used, patient protections are necessary to ensure adequate access to providers. For instance, prior to surgery, patients need access to information about the reference prices for procedures they may be considering, such as a list of services and their prices, together with a list of providers who will accept the reference price and information about the quality of care they deliver. In addition, patients need time to consider their options, potentially making reference prices inappropriate for emergency services.¹²¹

Finally, reference pricing may offer limited potential for savings. One study estimated that using reference pricing for inpatient procedures involving most implantable devices might save a few tenths of a percent of total spending in the privately insured sector.¹²² This is because only a small proportion of inpatient procedures are “shoppable,” and reference prices directly affect only the high end of the price distribution. On the other hand, reference prices might have an important effect on prices for implantable devices.

CONCLUSION

Despite a large and growing market, not much information is publicly available about the prices of implantable devices. Lack of price transparency has made it difficult to gather substantial direct evidence of high device prices. This market lacks many of the attributes of competitive markets, suggesting

implantable device prices may be higher than they would be in a competitive environment.

The current dynamic results from many factors. Reimbursement mechanisms tend to hamper price transparency, while manufacturers impose gag clauses to keep prices secret for many implantable devices. Limited data on prices reduce the leverage of buyers, like hospitals, to negotiate lower prices. Incomplete data on the quality, performance, and comparative effectiveness of many implantable devices limit the ability of hospitals to assess the relative value of devices. Physician conflicts of interest can undermine competitive market pressures.

A range of policy options to increase price transparency and enhance competition in the market for implantable devices is available for policy makers to consider. Employing at least some of these measures would benefit patients and taxpayers alike.

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