

January 2012

MEDICARE

Lack of Price Transparency May Hamper Hospitals' Ability to Be Prudent Purchasers of Implantable Medical Devices



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Highlights of [GAO-12-126](#), a report to the Chairman, Committee on Finance, U.S. Senate

Why GAO Did This Study

Implantable medical devices (IMD)—including a variety of cardiac and orthopedic devices provided to Medicare beneficiaries in inpatient or outpatient hospital settings—represent a significant share of hospitals' supply costs. Hospitals purchase IMDs directly from manufacturers or through group purchasing organizations (GPO) and their purchasing agreements often contain confidentiality clauses restricting them from revealing to third parties the prices they pay for such devices. Policymakers are concerned that the lack of price transparency inhibits competition in the device market, leading to higher costs for hospitals, and ultimately higher Medicare spending. GAO was asked to examine (1) Medicare spending and utilization trends for procedures involving IMDs provided to beneficiaries, and (2) what available information shows about the prices hospitals pay for IMDs and any factors particular to the IMD market that influence those prices. GAO analyzed the most recently available Medicare inpatient and outpatient hospital claims from fiscal years 2004 through 2009. GAO requested price information on five devices from 60 hospitals, 6 GPOs, Department of Defense (DOD) medical centers, and the Department of Veterans Affairs (VA) health system. GAO interviewed officials from GPOs, device manufacturers, large hospital systems, and small hospitals about the factors that affect the prices hospitals pay for IMDs.

View [GAO-12-126](#). For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

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What GAO Found

From 2004 through 2009, expenditures for hospital IMD procedures increased from \$16.1 billion to \$19.8 billion, an increase of 4.3 percent per year—a rate equal to that of Medicare spending for other hospital procedures. While cardiac and orthopedic procedures accounted for nearly all IMD-related expenditures, orthopedic procedures accounted for most of the increase in such expenditures during this period. Utilization increased at a faster rate for orthopedic devices and accounted for the majority of changes in expenditures for IMD procedures during the period.

The information GAO obtained on the amounts hospitals paid for selected IMDs showed substantial variation. For a number of reasons, the detailed information needed to accurately compare prices across hospitals—both the specific model and sale price net of discounts and rebates—was not reported by all respondents for all IMDs in our study. However, data from 31 hospitals indicated substantial variation in reported prices for cardiac devices. For example, the difference between the lowest and highest price hospitals reported paying for a particular automated implantable cardioverter defibrillator (AICD) model was \$6,844. The difference between the highest and lowest price reported for another AICD model was \$8,723. The price differences for the remaining two AICD models in our study fell in between \$6,844 and \$8,723. The median prices across the four AICD models ranged from \$16,445 to \$19,007. A factor particular to the IMD market that affects prices hospitals pay is the influence of physicians on hospitals' IMD purchasing. Although physicians are not involved in price negotiations, they often express strong preferences for certain manufacturers and models of IMDs. To the extent that physicians in the same hospital have different preferences for IMDs, it may be difficult for the hospital to obtain volume discounts from particular manufacturers. Also, confidentiality clauses barring hospitals from sharing price information make it difficult to inform physicians about device costs and thereby influence their preferences. Other factors that influence IMD prices include the degree of seller competition and a hospital's market share.

These data suggest that some hospitals have substantially less bargaining power with the small group of companies that manufacture particular IMDs and consequently face challenges in obtaining more favorable prices. The lack of price transparency and the substantial variation in amounts hospitals pay for some IMDs raise questions about whether hospitals are achieving the best prices possible. Any excess or unnecessary costs that hospitals incur through IMD pricing may be passed onto the Medicare program.

The Department of Health and Human Services, VA, and DOD reviewed a draft of this report and had no general comments.

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Abbreviations

AICD	automated implantable cardioverter defibrillator
AHA	American Hospital Association
APC	ambulatory payment classification
CMS	Centers for Medicare & Medicaid Services
CRT-D	cardiac resynchronization therapy defibrillator
DOD	Department of Defense
FFS	fee-for-service
GPO	group purchasing organization
IMD	implantable medical device
MS-DRG	Medicare-severity diagnosis related group
PPS	prospective payment system
VA	Department of Veterans Affairs

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Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

January 13, 2012

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

Dear Mr. Chairman:

Implantable medical devices (IMD)—a broad range of items that include coronary stents, cardiac defibrillators, and hip and knee joint replacements—can prolong life and improve the quality of life for patients that receive them.¹ As the Medicare population grows and beneficiaries expect to live longer, the demand for IMDs is likely to increase steadily. Therefore, the Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—will continue to be a major payer for procedures involving IMDs provided in both inpatient and outpatient hospital settings.

For hospitals, IMDs represent a significant share of their supply costs; further, for some procedures, the cost of IMDs can be the most expensive part of an inpatient hospital stay or outpatient procedure. As with other medical supplies, hospitals buy IMDs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations (GPO). By pooling the purchasing power of multiple providers, GPOs may be strongly positioned to bargain for lower prices from manufacturers.² However, hospitals face challenges in obtaining information on IMD prices in the market because comparable price information across manufacturers generally is not publicly

¹For this report, we define implantable medical devices as artificial devices implanted entirely within the body that are intended to remain in the body permanently. However, some of these devices have a limit to their effective life span and will require replacement.

²See GAO, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices*, [GAO-10-738](#) (Washington, D.C.: Aug. 24, 2010).

available.^{3,4} Device manufacturers often require hospitals to sign purchasing agreements that contain confidentiality clauses restricting them from revealing to third parties the prices they paid for medical devices. To the extent that information on IMD prices in the market is not disclosed, the ability of hospitals to bring comparative price information to bear in IMD purchasing negotiations and decisions may be limited. Without such competitive pressure, the prices hospitals pay for IMDs may be higher than they otherwise would be.⁵

In an environment of increasing health care costs, the efficiency of the IMD market has implications for Medicare cost containment. Policymakers are concerned that the lack of price transparency inhibits competition in the device market, leading to higher costs for hospitals, and ultimately higher spending in Medicare.⁶ You asked us to examine various issues regarding Medicare spending and the prices of implantable medical devices. In this report, we examined: (1) how Medicare's hospital payment systems account for the prices hospitals pay for IMDs, (2) the spending and utilization trends for procedures involving IMDs provided to Medicare beneficiaries, and (3) what available information shows about the prices hospitals pay for IMDs and any factors particular to the IMD market that influence those prices.

To describe how Medicare's payment systems account for the prices hospitals pay for IMDs, we reviewed annual regulations for the inpatient prospective payment system and outpatient prospective payment system.

³Certain information on IMD prices may be publicly available through sources such as the Department of Veterans Affairs (VA) National Acquisition Center website. However, the database is not complete and represents price ceilings established under VA's national contracts with IMD manufacturers.

⁴GAO has reported on challenges consumers face in obtaining cost information for the health care services they obtain. See GAO, *Health Care Price Transparency: Meaningful Price Information Is Difficult for Consumers to Obtain Prior to Receiving Care*, [GAO-11-791](#) (Washington, D.C.: Sept. 23, 2011).

⁵See D. Andrew Austin and Jane G. Gravelle, *Does Price Transparency Improve Market Efficiency: Implications of Empirical Evidence in Other Markets for the Health Sector*, RL34101 (Washington, D.C.: Congressional Research Service, Apr. 29, 2008.)

⁶During the 110th Congress, Senators Grassley and Specter sponsored legislation that would require device manufacturers to submit the average and median sales prices of covered devices to the Secretary of Health and Human Services on a quarterly basis. S. 2221, 110th Cong. § 2 (as introduced and referred to the S. Comm. on Finance, Oct. 23, 2007). This legislation did not become law.

We also interviewed officials from CMS and the Medicare Payment Advisory Commission.

To identify the Medicare spending and utilization trends for IMD procedures provided to Medicare FFS beneficiaries, we analyzed the most recently available Medicare inpatient and outpatient hospital claims for a 6-year period, from fiscal years 2004 through 2009.⁷ Using procedure and payment codes obtained from CMS and industry sources, we identified 364 inpatient and 85 outpatient procedure codes that were generally associated with an IMD.⁸ We matched these procedure codes with 115 inpatient and 30 outpatient “device dependent” payment codes in each claim. Because our list of IMD-dependent codes represented procedures performed almost exclusively in a hospital setting, we excluded procedures performed in other facilities (e.g., ambulatory surgical centers). We only included services and expenditures when the IMD-dependent procedure code was the primary procedure associated with the payment for the claim submitted to Medicare.^{9,10} We examined the extent to which changes in expenditures were explained by changes in utilization or average cost.¹¹ We determined that the claims data we used were sufficiently reliable for the purposes of our analysis by performing appropriate electronic data checks.

⁷These data only include payments to hospitals for procedures performed in the 50 states and the District of Columbia. Unless noted otherwise, we report all years on a fiscal year (Oct. 1 through Sept. 30) basis.

⁸Because codes used by hospitals to submit claims to Medicare are broadly defined to cover a set of related services and may or may not include the implantation of a medical device, we relied on several sources to develop a list of procedure codes for services that generally involve an IMD—what we refer to as “device-dependent.” To ensure that these codes met our definition of an IMD, we developed a content analysis using key word criteria to identify exclusions—procedures involving devices that did not meet our definition of an IMD—and inclusions—procedures generally involving devices that did meet our definition. We completed our compilation of inpatient procedure and payment codes by reviewing CMS payment system final rules.

⁹We use the term “case” to indicate claims where an IMD procedure largely determined the Medicare payment.

¹⁰All expenditures are reported in nominal terms and are not adjusted for inflation.

¹¹Because inpatient and outpatient services are paid for differently, we examine these separately.

To determine what information is available on the prices hospitals pay for IMDs, we selected five specific devices used in the five IMD-related procedures that ranked highest in terms of Medicare spending in 2009. The five devices were primary total knee implants, primary total hip implants, coronary drug-eluting stents, automated implantable cardioverter defibrillators (AICD), and cardiac resynchronization therapy defibrillators (CRT-D).¹² We asked 60 randomly selected hospitals,¹³ 6 GPOs,¹⁴ Department of Defense (DOD) medical centers and hospitals, and the Department of Veterans Affairs (VA)¹⁵ to report fiscal year 2010 pricing information for each of these five IMDs. Of the 60 hospitals, 39 hospitals—or 65 percent—provided IMD pricing data; in some cases, the information reflected purchases made by the health system with which the hospital is affiliated or for a point in time during fiscal year 2010. In addition, 5 of the 6 GPOs, 8 DOD medical centers or hospitals, and the VA health care system provided IMD pricing data.¹⁶ To compare the prices that hospitals paid for cardiac IMDs, we limited our analysis to those hospitals that provided detailed information on both the specific model and the sale price net of discounts and rebates. Not all hospitals provided pricing information for each device model in our study.¹⁷ To

¹²In a total joint replacement, “primary” denotes the original implant and differentiates it from a revision total joint replacement which replaces the original implant.

¹³These hospitals performed at least one implantation procedure for each of the five IMDs based on Medicare claims data for 2009.

¹⁴The six GPOs were selected based on their reported 2007 purchasing volume in Health Industry Distributors Association, *Group Purchasing Organization & Integrated Delivery Network: Market Brief* (Alexandria, Va.: July 2009).

¹⁵We obtained device price data from the VA National Prosthetic Patient Database, which contains all IMD price information reported by VA medical centers. We did not use data from the National Acquisition Center because certain IMDs, such as coronary stents, are not purchased through national contracts. In addition, VA medical centers may obtain waivers to purchase IMDs outside of national contracts for medical reasons only. Therefore, the data on the National Acquisition Center website do not reflect the full range of prices that VA medical centers actually pay for IMDs.

¹⁶DOD data include IMD pricing information from two of three Navy medical centers, two Navy hospitals, and four of five Air Force medical centers. Data obtained from the Army were not representative of the full range of prices hospitals paid and were not used in this analysis.

¹⁷The number of hospitals providing sale price net of discounts and rebates for a particular device model ranged from 3 to 19. In addition, to ensure comparability of prices for device model types that may or may not be purchased with leads, we removed cases where the price reported included leads. A lead is the connection between the heart and the power source for an AICD or CRT-D.

compare the prices that hospitals paid for orthopedic IMDs, we used examples from the information provided by hospitals and GPOs on behalf of their member hospitals. The data we obtained on cardiac and orthopedic IMD prices are not generalizable. To identify the factors that affect the prices hospitals pay for IMDs, we reviewed relevant literature and interviewed officials from the 6 GPOs from which we requested pricing data, 3 nongovernment hospital systems with the highest revenues for 2009 and 2010,¹⁸ 5 large IMD manufacturers that volunteered to participate through a trade association, 2 small hospitals that performed a low volume of procedures involving orthopedic IMDs commonly used among Medicare beneficiaries in 2009, and professional associations representing orthopedic surgeons and cardiologists.

We conducted this performance audit from June 2010 to December 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Device Features and Industry Characteristics

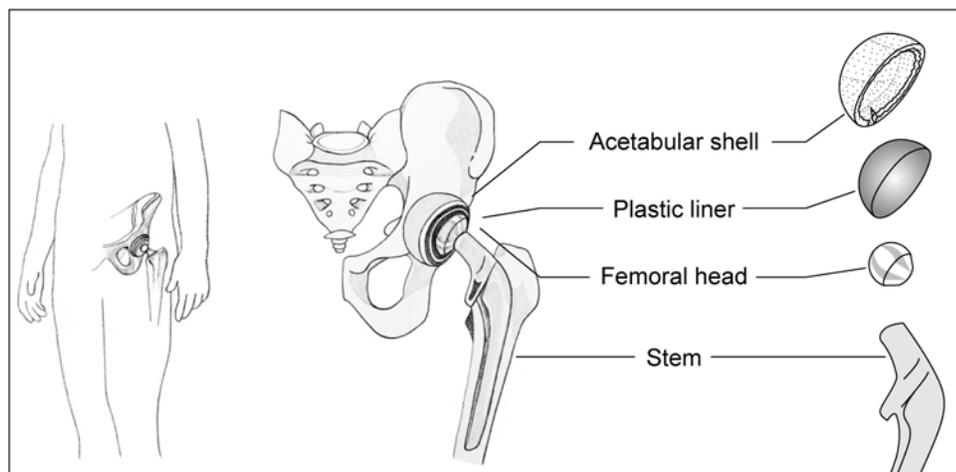
Cardiac IMDs include cardiac rhythm management devices (such as pacemakers, AICDs, CRT-Ds) and coronary stents. A pacemaker monitors the patient's underlying heart rhythm and delivers an electrical pulse to cause the heart to beat at the desired rate. An AICD is similar to the pacemaker in design, but is capable of delivering a higher energy electrical pulse—called defibrillation shocks—to correct more serious rapid and sustained heart rhythm irregularities. A CRT-D is a combination of a pacemaker and defibrillator. A coronary stent (either bare metal or

¹⁸The three hospital systems were selected based on the reported 2009 revenues in Modern Healthcare, *Big dividends: annual survey of hospital systems shows a strong financial comeback thanks in large part to resurgent investment portfolios* (Chicago, Ill.: June 2010) and 2010 revenues in Modern Healthcare, *A solid year: annual survey shows health systems posted strong revenue and earnings, but expenses are also rising* (Chicago, Ill.: June 2011).

drug-eluting) is a wire mesh tube used to prop open a blocked coronary artery.¹⁹

Orthopedic devices include joint implants—mostly commonly hips and knees—as well as spinal devices used for spinal fusion. Typically, hip and knee implants have a variety of components and are made up of different materials, which may be combined into different configurations to make the total device. The components and configurations of orthopedic devices can vary by manufacturer. For example, for a hip replacement with four different components there are different configurations and different types of materials (metal, plastic, ceramic) that can be used as well as different ways to secure the implant (cemented or fitted into the bone with new bone growth to hold the implant in place). See figure 1.

Figure 1: Components of a Total Hip Replacement



Source: National Institute of Arthritis and Musculoskeletal and Skin Diseases Image Gallery (musculoskeletal illustration), GAO (technical illustration).

The markets for specific cardiac and orthopedic IMDs are generally dominated by a few large manufacturers. In the cardiac rhythm management segment, the market is dominated by three U.S. manufacturers. Also, four manufacturers share the drug-eluting stent

¹⁹Some stents are coated with drugs that slowly release and help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

market.²⁰ In the hip and knee replacement orthopedic segment, sales by four manufacturers accounted for about 83 percent of the market share in 2009.

IMD Purchasing Agreements

Typically, hospitals negotiate IMD prices with manufacturers directly or through GPOs. Contract negotiations between hospitals or GPOs and manufacturers can occur at the national or local level. A custom or local contract establishes a price for products that were not part of the GPO's overall contract portfolio or achieves a better price for a specific product than what the national GPO contract offered. Contracts can include an agreed-upon price for one or more devices and reflect rebates—an agreement by the manufacturer to return a portion of the payment, which may depend on a hospital's commitment to purchase a certain volume.

In addition, hospitals may engage consulting firms that may act as data intermediaries by gathering price information from clients and sharing benchmarks for IMD costs with them. However, to the extent that such information is derived from purchasing agreements containing confidentiality clauses, these data intermediaries may be potential targets of litigation by device manufacturers.²¹

Medicare's Payment Systems for Hospital Services

Medicare has separate inpatient and outpatient prospective payment systems (PPS) for paying hospitals for services provided to beneficiaries enrolled in FFS Medicare. Under the inpatient PPS, a hospital generally receives a fixed, predetermined payment amount for a bundle of services provided during a beneficiary's hospital stay.²² Inpatient payment rates are based on Medicare-severity diagnosis-related groups (MS-DRG), a system that classifies inpatient stays according to both patients' clinical conditions (the primary diagnosis along with any secondary illnesses and

²⁰One of the four manufacturers of drug-eluting stents plans to exit the market by the end of 2011, leaving only three manufacturers in that market segment.

²¹Researchers examining this issue have noted lawsuits alleging violations of confidentiality clauses by data intermediaries providing price information to hospitals. See Jeffrey C. Lerner, Daniel M. Fox, Todd Nelson, and John B. Reiss, "The Consequence of Secret Prices: The Politics of Physician Preference Items" *Health Affairs*, vol. 27, no. 6 (2008).

²²Throughout this report, we use the term "stay" to represent a patient's hospitalization, which CMS and hospitals refer to as a discharge for data-reporting purposes.

complications developed during the stay) and the procedures patients receive.²³ In general, an inpatient MS-DRG payment is calculated using a base payment amount—a per hospital-stay rate for operating costs that efficient hospitals would be expected to incur in furnishing covered inpatient services—multiplied by a MS-DRG relative weight. The MS-DRG relative weight signifies the average costliness of stays assigned to that MS-DRG relative to the average costliness of other inpatient stays. CMS updates MS-DRG weights annually to incorporate any changes in the cost of inpatient care.

Under the outpatient PPS, generally, the unit of payment is the individual service. Outpatient PPS rates are based on ambulatory payment classifications (APC), a system that classifies services based on their similarity in terms of clinical characteristics and cost. For each APC, Medicare makes a single bundled payment for the primary service and any ancillary or supportive services. For example, the APC payment for a pacemaker implantation procedure represents a bundled payment for the pacemaker device, routine supplies, and the operating or procedure room. An APC payment is calculated by multiplying an APC relative weight by the conversion factor, a dollar amount that translates the relative weight into dollar amounts.²⁴ The APC relative weight measures the resource requirements of the service and is based on the median cost of services in the APC.²⁵ CMS updates APC weights annually to account for any changes in the cost of outpatient care.

CMS calculates inpatient and outpatient payments based on data from Medicare cost reports and charges from Medicare claims. Each year, hospitals submit Medicare cost reports to CMS identifying hospitals' actual costs for services rendered to all patients, not just Medicare beneficiaries. Upon a Medicare beneficiary's discharge, hospitals submit

²³Prior to 2008, CMS assigned inpatient stays to diagnosis-related groups (DRG) which classified inpatient stays by patient diagnosis and the procedures they received; CMS replaced DRGs with MS-DRGs to better account for severity of illness.

²⁴CMS initially set the conversion factor so that projected total payments would equal the estimated amount that would have been spent under the old cost-based outpatient payment system, after correcting for some anomalies in statutory formulas.

²⁵CMS scaled all of the APC relative payment weights to APC 601, a midlevel clinic visit, because it is one of the most frequently performed services.

Medicare claims to CMS identifying charges for services delivered to the beneficiary—such as procedures involving IMDs.

Medicare's Payment Systems Indirectly Account for Prices Hospitals Pay for IMDs; Efforts Are Under Way to Better Account for These Prices

Medicare does not directly purchase IMDs but accounts for hospitals' IMD prices indirectly. To help set prospective payment rates for inpatient and outpatient hospital procedures, Medicare's payment systems use data from cost reports and claims. CMS collects data on hospitals' costs for all services and supplies from Medicare cost reports. The cost reports capture data on hospitals' costs for all services and supplies, including IMDs, but do not separately identify specific IMD costs. Rather, hospitals report costs for all medical supplies in one category, aggregating the costs of low-cost items, such as surgical gloves, with the costs of high-cost items, such as cardiac defibrillators and total knee replacements. On hospitals' claims submitted for inpatient services, charges are billed by categories of service. For example, an inpatient hospital claim for the implantation of an AICD could include charges for an AICD and surgical dressings in the supplies category. Using these aggregated cost data, Medicare's inpatient and outpatient payments indirectly account for prices hospitals reportedly paid for IMDs.

Compared to hospital cost reports and charges on inpatient claims, the data on hospitals' charges on outpatient claims provide more specific information about hospitals' charges for individual IMDs. This occurs because of the way Medicare classifies outpatient procedures for claims and payment purposes. Specifically, CMS requires hospitals to include device codes on claims where an appropriate code exists to describe a device utilized in the procedure. Further charges reported on the outpatient claims generally reflect what the hospital reports as the full cost of the IMD.

Due to a lag in data, the cost of the newest IMD technology may not be reflected in data used to set payment rates. Although CMS uses the most recently available hospital claims data in order to help set inpatient MS-DRG and outpatient APC payments, the claims reflect data that predate the year for which rates are being set by 2 years. For example, 2009 inpatient payments are based on Medicare claims from 2007.

To better reflect costs of new technology, Medicare makes additional payments under the inpatient and outpatient payment systems. These additional payments are generally made for 2 to 3 years, until sufficient data on hospitals' new technology costs can be collected and used in payment rate setting. For inpatient procedures, CMS makes add-on

payments—made in addition to the MS-DRG payment—for procedures involving new IMDs that meet certain criteria for newness, clinical benefit, and cost.²⁶ For outpatient procedures involving new IMD technology, CMS makes pass-through payments for eligible new IMDs that can be used in an existing service, and new technology APC payments for a new procedure involving an IMD that cannot be adequately described by an existing APC. Pass-through payments are made in addition to the APC payment for the procedure involving the new IMD.²⁷ CMS assigns services to new technology APCs based on cost information collected on applications for new technology status.²⁸

CMS is taking further steps to better account for hospitals' reported IMD prices in the data it uses to set inpatient and outpatient prospective payment rates. Specifically, CMS has modified the way hospitals report costs of IMDs on Medicare cost reports. CMS created a new cost category called "Implantable Devices Charged to Patients," which requires hospitals to report separately their high-cost IMDs and their other lower-cost medical supplies. The new cost category is intended to provide CMS with more accurate information about hospitals' reported costs specific to IMDs for use in setting inpatient and outpatient payment rates. The revised cost report with the new cost category for "Implantable Devices Charged to Patients" was made available for use for cost reporting periods beginning on or after May 1, 2009. According to CMS, data collected with the revised cost reports will likely be available for setting payment rates for 2013.

²⁶CMS determines the add-on payment on a claim-by-claim basis; payment is limited to 50 percent of the hospital's costs above the standard MS-DRG payment, up to a maximum of 50 percent of the estimated cost of the new device. For fiscal year 2012, there is one brand-specific new technology eligible to receive an add-on payment.

²⁷Pass-through payments are based on each hospital's actual reported cost of the new IMD minus the device offset amount—the portion of each APC payment rate CMS could reasonably attribute to the cost of the device that the new IMD replaces. As of October 2011, there are three device categories eligible for pass-through payment.

²⁸New technology APC payment levels are set at the midpoint range of the cost category; for example, payment made for New Technology APC 1507 (\$500 to \$600) is made at \$550. In calendar year 2011, there are three procedures receiving payment through a new technology APC.

In addition to more accurately accounting for IMD costs, CMS intends to link payment to the quality and efficiency of care provided—a move toward value-based purchasing in Medicare. One of the principles of value-based purchasing is having good data on performance; currently such data generally are lacking for specific brands of implantable medical devices. Most IMDs are introduced as incremental modifications to existing devices without studies of performance relative to alternative devices and for specific patient populations.²⁹ There are registries of postoperative outcomes for some cardiac devices, such as AICDs, but none for orthopedic or spinal devices outside of specific organizations such as Kaiser Permanente.^{30,31} Furthermore, because hospital data currently are embedded in multiple data systems—such as medical records, operating room logs, purchasing department records, and billing systems—it can be difficult to match which device brand was used with a particular patient.³²

²⁹James C. Robinson, “Value-Based Purchasing for Medical Devices,” *Health Affairs*, vol. 27 no. 6 (2008).

³⁰In 2005, CMS issued a Medicare national coverage policy for AICDs that requires providers implanting these devices for certain clinical conditions to enter implant data into a clinical registry.

³¹There is a joint registry under development. The American Joint Replacement Registry is a nonprofit organization for data collection and research on total hip and knee replacements. This registry is a collaborative effort supported by orthopedic medical professional societies, hospitals, health insurers, government agencies, and medical device manufacturers.

³²Efforts to improve information known about patient safety and medical devices would be supported by the implementation of unique device identifiers. The Food and Drug Administration Amendments Act of 2007 requires the promulgation of regulations establishing a unique device identification system, which will require the devices to bear a unique identifier. Pub. L. No. 110-85, § 226, 121 Stat. 823, 854 (codified at 21 U.S.C. § 360i(f)) (the provision allows for the exemption of particular devices or types of devices).

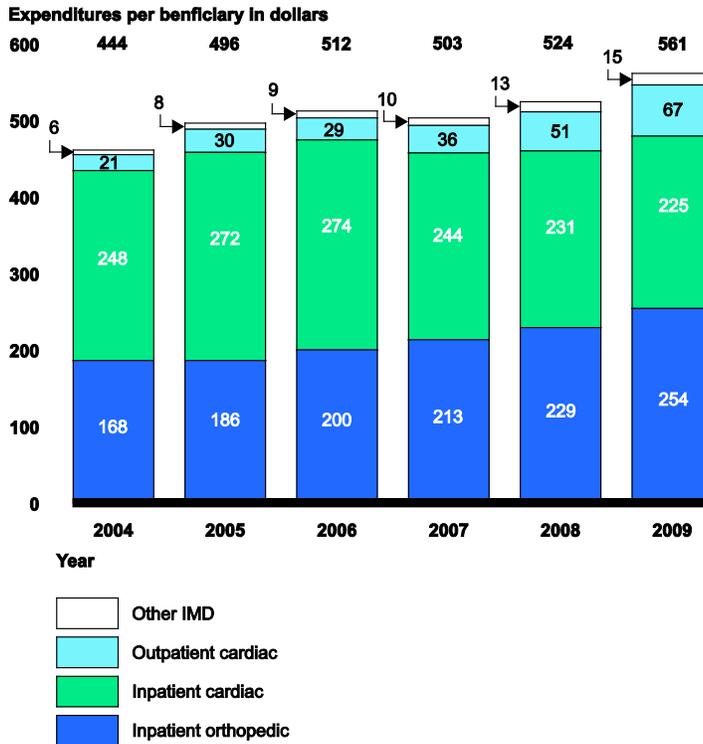
Medicare Expenditures for IMD Procedures Increased from About \$16 Billion to \$20 Billion from 2004 through 2009—Driven Largely by Increased Utilization of Orthopedic Devices

From 2004 through 2009, Medicare expenditures for IMD hospital procedures increased from about \$16 billion to \$20 billion. While cardiac and orthopedic procedures accounted for nearly all IMD-related expenditures, orthopedic procedures accounted for most of the increase in such expenditures during our period of study. Utilization increased at a faster rate for orthopedic devices and explained the majority of changes in expenditures for IMD procedures during the period.

Medicare Expenditures for IMD Procedures Increased from About \$16 Billion to \$20 Billion between 2004 and 2009, with Orthopedic IMD Procedures Driving Most of That Growth

From 2004 through 2009, expenditures for hospital IMD procedures increased from \$16.1 billion to \$19.8 billion, an increase of 4.3 percent per year—a rate equal to that of Medicare spending for other hospital procedures. Expressed in terms of expenditures per beneficiary—a measure which accounts for changes in the size of Medicare’s FFS population—IMD expenditures increased from \$444 to \$561, an increase of 4.8 percent per year (see fig. 2). Inpatient expenditures for IMD procedures increased from \$15.1 billion to \$17.0 billion, an increase of 2.4 percent per year. Outpatient expenditures for IMD procedures increased from \$1.0 billion to \$2.9 billion, an increase of 24.1 percent per year. In comparison, Medicare expenditures for all non-IMD procedures increased by 4.3 percent per year, 4.8 percent when measured per beneficiary. Inpatient and outpatient expenditures for these procedures increased by 2.9 and 10.8 percent per year, respectively.

Figure 2: IMD Expenditures per Medicare FFS Beneficiary, 2004 through 2009



Source: GAO analysis of Medicare Inpatient and outpatient hospital claims data.

Note: Reported expenditures include Medicare's payment to the hospital for the set of services associated with the procedure performed. The other IMD category includes neurological and outpatient orthopedic IMD procedures.

As figure 2 indicates, orthopedic and cardiac procedures accounted for nearly all IMD-related Medicare expenditures from 2004 through 2009. Furthermore, during this period, the share of inpatient orthopedic expenditures relative to all IMD-related Medicare expenditures increased from 38 percent to 45 percent. In addition, an increasing share of cardiac procedures shifted to the outpatient setting. Generally, Medicare pays hospitals a relatively lower rate for the same procedures delivered in the outpatient setting than in the inpatient setting. Specifically, as a share of Medicare's total IMD expenditures, inpatient cardiac IMD procedures decreased from 56 percent to 40 percent while outpatient cardiac IMD procedures increased from 5 to 12 percent.

From 2004 through 2009, orthopedic procedures accounted for most of the growth in Medicare IMD-related expenditures. Medicare expenditures for orthopedic IMD procedures increased from \$6.1 billion to \$9.0 billion, an increase of 8.1 percent per year.^{33,34} Procedures related to knees, hips, shoulders, and the spine accounted for nearly all of Medicare's orthopedic IMD expenditures in 2009.³⁵ The average growth rate of expenditures related to each of these procedure types exceeded that of non-IMD hospital procedures.³⁶ Spinal fusion procedures had the highest growth in per beneficiary expenditures—more than doubling during the period (see fig. 3).

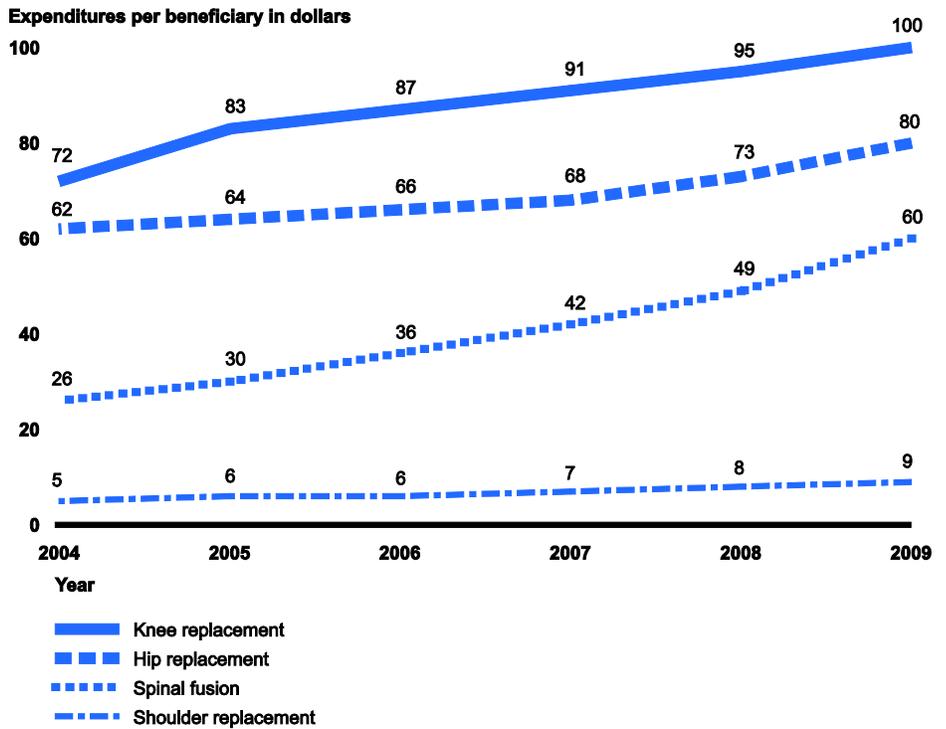
³³Medicare expenditure growth rates for orthopedic IMD procedures exceeded that of non-IMD hospital procedures throughout our period of study.

³⁴Revisions, procedures that replace part or all of an IMD, accounted for 8.9 percent of these expenditures in 2004 and 11.0 percent in 2009, increasing from \$0.5 billion to \$0.9 billion.

³⁵For example, in 2009, these procedures accounted for 98 percent of the program's orthopedic IMD expenditures.

³⁶On a per beneficiary basis, expenditures related to hips, shoulders, and the spine grew the most between 2007 and 2009.

Figure 3: Orthopedic IMD Expenditures per Medicare FFS Beneficiary, 2004 through 2009



Source: GAO analysis of Medicare inpatient and outpatient hospital claims data.

Note: Reported expenditures include Medicare's payment to the hospital for the set of services associated with the procedure performed.

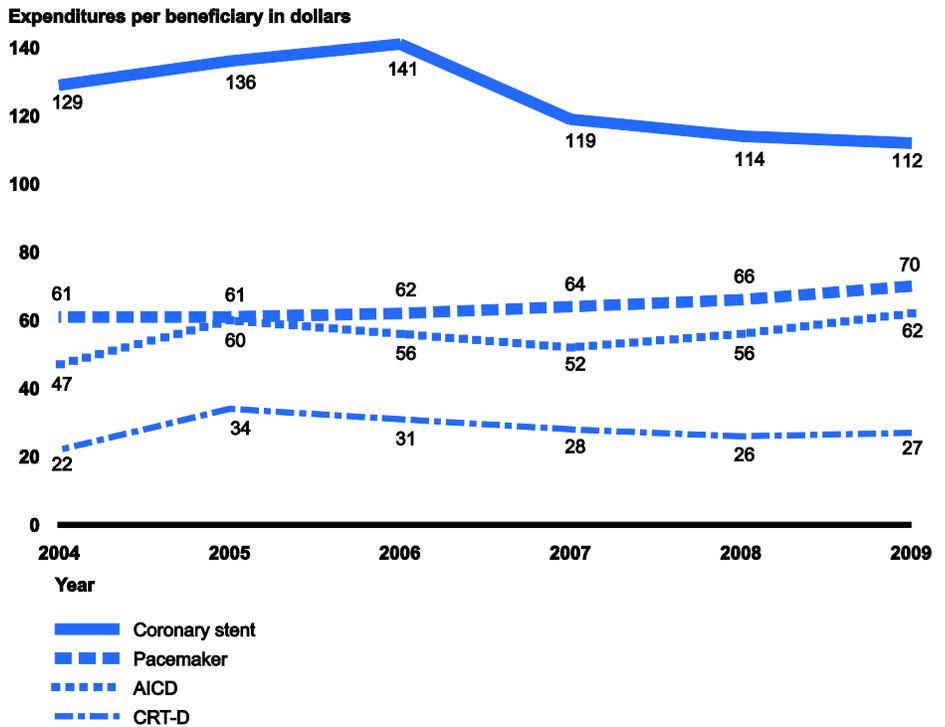
Cardiac procedures accounted for relatively little of the growth in Medicare IMD-related expenditures from 2004 through 2009. Medicare expenditures for cardiac IMD procedures increased from \$9.8 billion in 2004 to \$10.3 billion in 2009, an increase of 1.2 percent per year. In 2009, procedures involving stents, pacemakers, AICDs, and CRT-Ds accounted for 93 percent of expenditures for cardiac IMD procedures.³⁷ Over the entire 2004 through 2009 period, only cardiac expenditures related to AICD procedures increased at a higher annual rate than that of non-IMD procedures. On a per beneficiary basis, expenditures peaked in 2006 but reached their second lowest point of the period in 2007, largely resulting from expenditures for coronary stent procedures, which

³⁷Other cardiac IMDs included vascular grafts and vena cava filters.

decreased by 15 percent that year (see fig. 4). Furthermore, inpatient expenditures for cardiac IMD procedures generally decreased over the 2004 through 2009 period, while those expenditures in the lower payment outpatient setting generally increased. Inpatient expenditures for cardiac IMD procedures reached their peak of \$10.0 billion in 2005 but dropped to \$7.9 billion in 2009, decreasing 5.5 percent per year over that period. In contrast, outpatient expenditures for cardiac IMD procedures increased from \$0.8 billion in 2004 to \$2.4 billion in 2009, an increase of 25.5 percent per year. During that period, expenditures for coronary stent, AICD, and pacemaker procedures decreased in the inpatient setting but increased in the outpatient setting.³⁸

³⁸ Medicare's Recovery Audit Contractor program may be associated with both the shift of cardiac IMD procedures from the inpatient to the outpatient setting and the higher outpatient expenditure growth rates for IMD procedures compared with non-IMD procedures. From 2005 to 2008, these audits collected overpayments for inpatient defibrillator and pacemaker procedures that could have been performed in the outpatient setting, possibly prompting other hospitals to change their admissions patterns.

Figure 4: Cardiac IMD Expenditures per Medicare FFS Beneficiary, 2004 through 2009



Source: GAO analysis of Medicare inpatient and outpatient hospital claims data.

Note: Reported expenditures include Medicare's payment to the hospital for the set of services associated with the procedure performed.

Utilization Increased at a Faster Rate for Orthopedic Devices Compared with Cardiac Devices and Explained Most of the Changes in IMD-related Medicare Expenditures from 2004 through 2009

From 2004 through 2009, utilization of IMD procedures increased from about 1.3 million cases to about 1.6 million cases, an increase of 3.8 percent per year.³⁹ Per 10,000 beneficiaries, the utilization of IMD cases increased from 357 to 440, or an increase of 4.3 percent per year. During our period of study, inpatient IMD utilization increased from 1.1 million cases to 1.2 million cases, an increase of 1.4 percent per year. In contrast, outpatient IMD utilization increased from about 180,000 cases to about 363,000 cases, an increase of 15.0 percent per year.

³⁹We use the term "case" to indicate a claim where an IMD procedure drove the Medicare payment.

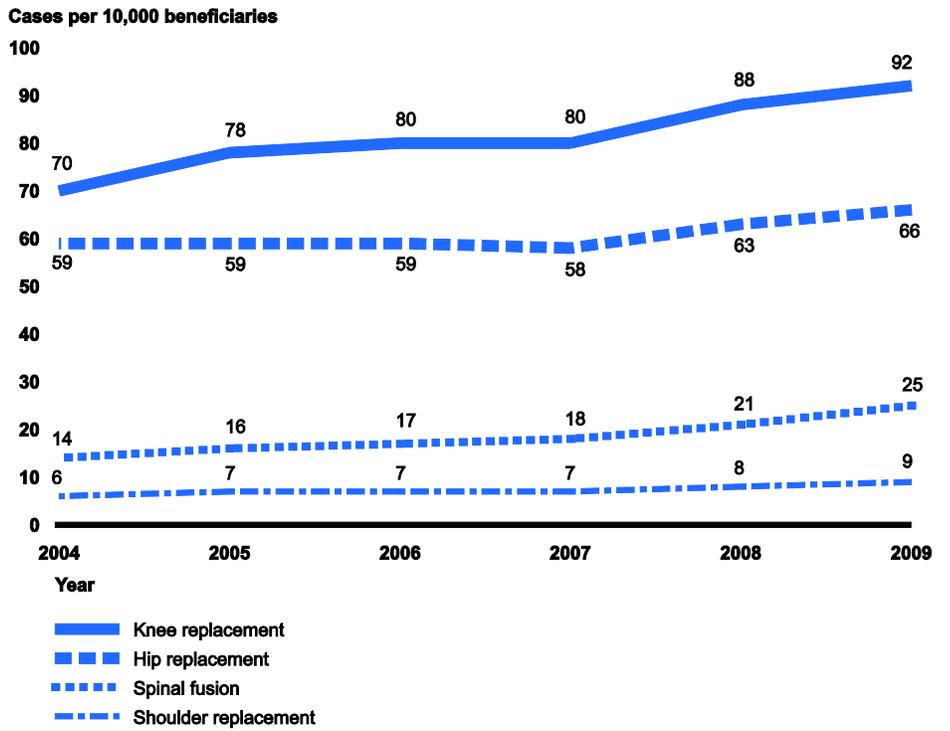
Utilization increased at a faster rate for orthopedic devices compared with cardiac devices. From 2004 through 2009, orthopedic IMD procedure utilization increased from about 556,000 cases to about 697,000 cases, yielding an annual growth rate of 4.6 percent per year or 5.1 percent when measured per beneficiary. While utilization per beneficiary of orthopedic IMD procedures related to knees and hips were highest,⁴⁰ the fastest increase in utilization of orthopedic IMD procedures came from those related to spinal fusions, increasing at a rate of 12.1 percent per year (see fig. 5).⁴¹ In contrast, utilization of cardiac IMD procedures increased from about 705,000 cases to about 797,000 cases, yielding an annual growth rate of 2.5 percent per year, 3.0 percent when measured per beneficiary. Not all cardiac procedures followed a steady increase in utilization. For example, between 2006 and 2007, utilization associated with stent procedures decreased by 9.3 percent and increased thereafter (see fig. 6).⁴² Inpatient utilization of cardiac IMD procedures decreased from 154 to 140 cases per 10,000 beneficiaries, while such utilization in the outpatient setting increased from 41 to 85 cases per 10,000 beneficiaries during the period. Per-beneficiary utilization related to cardiac stents, AICDs, and pacemakers all decreased in the inpatient setting and increased in the outpatient setting.

⁴⁰During our period of study, utilization of knee and hip replacements grew at annual rates of 5.5 and 2.2 percent, respectively.

⁴¹The percentage of spinal fusions performed with either a cage or bone morphogenetic protein increased throughout the period, going from 42 percent in 2004 to 60 percent in 2009. The percentage of spinal fusions that used both a cage and bone morphogenetic protein increased from 7 percent in 2004 to 17 percent in 2009.

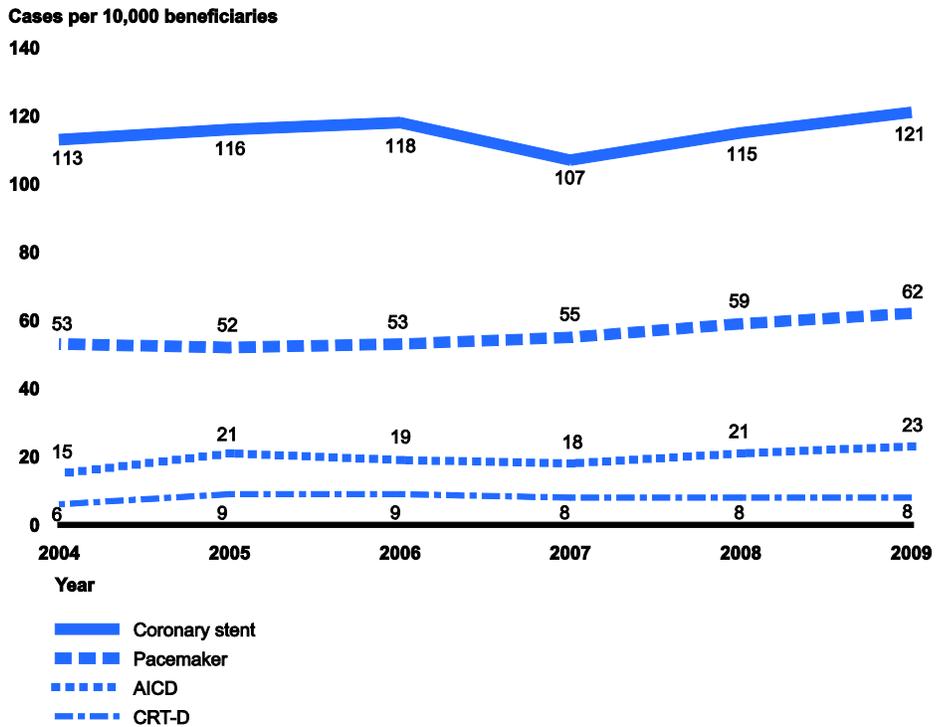
⁴²A 2007 *New England Journal of Medicine* study that found treating Stable Coronary Disease with stent-related procedures did not produce improvements compared to other types of treatment may be a factor in the decrease in stent utilization. See William Boden, et al., "Optimal Medical Therapy With or Without PCI for Stable Coronary Disease," *The New England Journal of Medicine*, vol. 356, no. 15 (2007).

Figure 5: Orthopedic IMD Utilization per 10,000 Medicare FFS Beneficiaries, 2004 through 2009



Source: GAO analysis of Medicare inpatient and outpatient hospital claims data.

Figure 6: Cardiac IMD Utilization per 10,000 Medicare FFS Beneficiaries, 2004 through 2009



Source: GAO analysis of Medicare inpatient and outpatient hospital claims data.

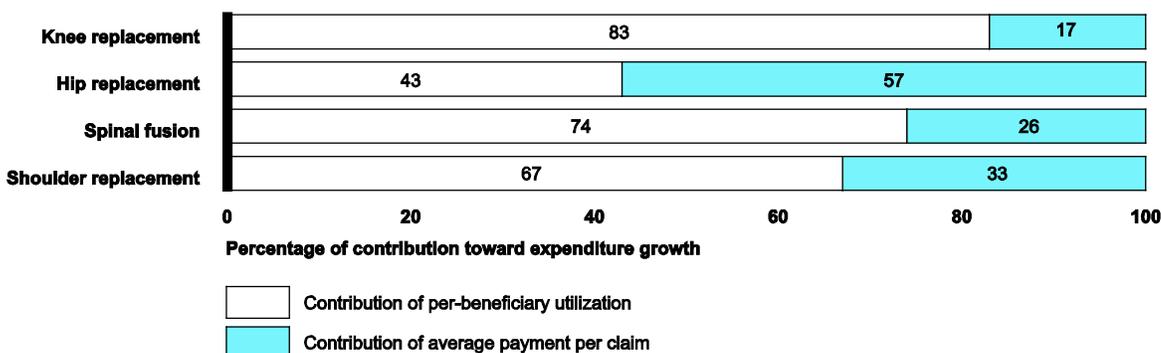
Between 2004 and 2009, the overall increase in per-beneficiary Medicare expenditures for IMD procedures resulted more from increased utilization than from an increased average payment per claim. Specifically, our analysis shows that utilization contributed to 67 percent of the increase in such inpatient expenditures. Utilization and average payment growth rates varied by year during the study period. The largest rate of increase in inpatient per-beneficiary utilization occurred from 2007 to 2008. During this time period, CMS adjusted inpatient discharge payment rates to better distinguish beneficiaries with comorbidities and complications,⁴³ which was followed by the only decrease of average inpatient expenditures. The average IMD-related inpatient payment decreased by

⁴³CMS transitioned to MS-DRGs, replacing DRGs as the method for grouping patient stays in determining payments. MS-DRGs better capture severity of illness differences among patients.

5.4 percent while per-beneficiary utilization of those same procedures increased by 6.5 percent. Similarly, utilization contributed to 69 percent of the increase in per-beneficiary Medicare expenditures for outpatient IMD procedures.

Among orthopedic IMD procedures, utilization contributed to the majority—62 percent—of the overall growth in per-beneficiary Medicare expenditures between 2004 and 2009. Utilization contributed to most of the increased expenditures for three of the four main types of orthopedic IMD procedures (see fig. 7). Four of the five orthopedic IMD procedures with the largest expenditures in 2009 had growth that resulted more from increased utilization than an increased average payment.⁴⁴

Figure 7: Contribution toward Per-Beneficiary Expenditure Growth between 2004 and 2009, by Orthopedic IMD Procedures



Source: GAO analysis of Medicare Inpatient and outpatient hospital claims data.
 Note: Reported expenditures include Medicare’s payment to the hospital for the device as well as the set of services associated with the procedure performed.

The extent to which utilization drove changes in per-beneficiary Medicare expenditures for cardiac IMD procedures varied by hospital setting. Decreased utilization contributed to 94 percent of the decrease of such inpatient expenditures between 2004 and 2009. The decrease in utilization accounted for all of the decrease in per-beneficiary inpatient

⁴⁴These five procedures were total knee replacement, total hip replacement, lumbar and lumbosacral (spinal) fusion with a posterior technique, partial hip replacement, and total shoulder replacement. They represent 77 percent of the Medicare expenditures for orthopedic IMD procedures in that year. Per-beneficiary utilization of the partial hip replacement procedure decreased during our period of study, and therefore, all of its increase in per-beneficiary expenditures resulted from an increased average payment per claim.

expenditures related to pacemakers. Decreased utilization contributed to 61 percent and 52 percent of the decrease in per-beneficiary inpatient expenditures related to AICDs and coronary stents, respectively. In comparison, increased utilization contributed to 67 percent of the increase in per-beneficiary outpatient expenditures for cardiac IMD procedures. Increased utilization contributed to 79 percent and 93 percent of the increase in such expenditures related to pacemakers and AICDs, respectively. Furthermore, increased utilization explained 59 percent of the increase in per-beneficiary outpatient expenditures related to coronary stents.

Information Available on the Prices Hospitals Paid for Selected IMDs Shows Substantial Variation; Hospital-Physician Relationships Are a Particular Influence on Prices Paid

Complete and comparable information on the prices hospitals paid for the various models of IMDs was limited, as reflected in responses to our data request. The price information that was provided showed substantial variation in the prices hospitals paid for the same type of device. A particular factor that influences the prices hospitals pay for IMDs is hospitals' ability to manage relationships with physicians and manufacturers.

Various Factors Limit the Availability of Detailed Information on the Prices Hospitals Paid for Selected IMDs

Detailed information on both the specific model purchased and the sale price net of discounts and rebates is needed to accurately compare the amount hospitals paid for various types of IMDs.⁴⁵ However, not all 39 hospitals, 5 GPOs, the VA health care system, and 8 DOD medical centers or hospitals responding to our request provided us with such detailed information for three types of cardiac IMDs and two types of orthopedic IMDs purchased during fiscal year 2010. Only 31 hospitals, 1 GPO, and 1 DOD medical center provided detailed information on cardiac device prices, and only 14 hospitals, 1 DOD medical center, and 1 DOD hospital provided detailed information on orthopedic device prices

⁴⁵The size of rebates and discounts may differ based on the volume of devices purchased and the extent to which a hospital purchases a predetermined number of a certain device from a particular manufacturer.

(see table 1).⁴⁶ Information from the remaining respondents did not adequately reference the IMD by model, provide the sale price net of discounts and rebates, or both.

Table 1: Type of Detailed Information Reported on Cardiac and Orthopedic IMDs, Fiscal Year 2010

IMD	Respondent	Number of respondents	Price data provided indicated			
			Both specific model and sale price net of discounts and rebates	Specific model only	Sale price net of discounts and rebates only	Other data ^d
Cardiac	Hospitals	39	31	8	0	0
	GPOs	5	1	4	0	0
	DOD Medical Centers or Hospitals ^a	3	2	1	0	0
	VA Health Care System	1	0	0	0	1
Orthopedic	Hospitals ^b	38	14	2	20	2
	GPOs ^c	2	0	2	0	0
	DOD Medical Centers or Hospitals	8	2	1	1	4
	VA Health Care System	1	0	0	0	1

Source: GAO.

Note: In some cases, hospitals and DOD medical centers or hospitals reported detailed pricing or model information for some devices, but not others. We considered an entity to have reported detailed information on specific model or sale price net of discounts and rebates if we could accurately identify the model or price—including all price discounts and rebates—for at least one of the devices reported by the entity.

^aThree of the eight DOD medical centers or hospitals that reported IMD pricing information included pricing information for cardiac devices. Some of these medical centers or hospitals indicated that cardiac procedures were consolidated in certain medical centers, while orthopedic procedures were performed more widely. In addition to the eight Air Force and Navy medical centers or hospitals that provided IMD pricing information, the Army also provided information for the highest volume purchaser of each type of implantable medical device. However, these data were excluded from our analysis because they may not represent the Army's range of prices—both high and low—that other hospitals were able to provide.

^bOne hospital did not report information on orthopedic device prices.

^cInformation provided by GPOs reflected the experience of their member hospitals. Although we did not request model numbers for orthopedic devices from GPOs, two GPOs provided this information.

⁴⁶Eight Air Force and Navy medical centers or hospitals provided IMD price information. The Army also provided information for the highest volume purchaser of each implantable medical device model. However, these data were excluded from our analysis because they may not represent the Army's range of prices—both high and low—that other hospitals were able to provide.

^dThe other data category includes respondents that provided information on cardiac or orthopedic IMD prices, but which did not include information on the specific model or sale price net of discounts and rebates for the device.

The respondents included in our study identified several reasons why detailed information on the model-specific sale price net of discounts and rebates is limited. First, many respondents indicated that the price information they provided for at least one device did not account for all discounts and rebates obtained. This issue was cited by 21 hospitals, 4 GPOs, and 1 DOD medical center. Officials from 1 hospital that reported receiving a rebate from a manufacturer for meeting certain volume targets stated that it would be difficult and time-consuming to determine the proportion of the rebate to attribute to each product. Officials from other hospitals and a DOD medical center noted that, because discounts were negotiated at the hospital system level, they lacked information on the discount amount. Similarly, 4 of the 5 GPOs told us the prices they provided from their member hospitals did not account for discount and rebate amounts because member hospitals did not necessarily report that information.⁴⁷

Second, a number of entities stated that the majority of contracts between hospitals and manufacturers include confidentiality clauses that generally limit hospitals from sharing price information with third parties. Specifically, all of the five manufacturers, five GPOs, three hospital systems, and one of the two small hospitals we interviewed reported that all or almost all of their contracts included language that restricted information disclosure to some extent. For example, some confidentiality clauses allow hospitals to share pricing information with other hospitals that are part of their system, and others do not. Among our respondents, four hospitals and one GPO stated that confidentiality clauses limited them from providing us with detailed pricing information for devices from certain manufacturers. Another GPO indicated that confidentiality clauses precluded some member hospitals from reporting pricing information to them. The extent to which confidentiality clauses may have affected responses to our request for pricing information is uncertain.

⁴⁷Officials from one GPO stated that even though their price data do not take rebates or other discounts into consideration, the data provide a valuable and reasonably accurate understanding of the range of prices being paid in the marketplace.

Finally, some respondents cited data retrieval or quality issues as limiting their ability to provide detailed price information. One hospital official reported that the components used for total knees and hips are recorded on paper invoices rather than in an electronic data system and that additional staff would be required to retrieve the hand-written component information. We also found data quality issues with the pricing information provided by VA and DOD. Specifically, in the VA database, product identifiers were entered in an inconsistent fashion or did not match, making it difficult to aggregate the data in a meaningful way. Among the issues identified with pricing information submitted by DOD, one hospital reported it could not calculate the price for primary total knees, and instead provided us with a range of prices per manufacturer. In addition, a DOD medical center only provided estimates rather than actual prices it paid for primary total knees.

Even when respondents report detailed information on the prices hospitals pay for IMDs, differences in how hospitals purchase the parts or components needed for certain procedures may limit the comparability of the information. Specifically, the parts or components needed for a certain cardiac and orthopedic procedure may be purchased together or separately. For example, some hospitals purchase AICDs and CRT-Ds with leads, while other hospitals purchase the leads separately from the device. Given these differences, prices for IMDs that include leads—which can cost up to several thousand dollars—cannot be meaningfully compared to prices that exclude leads. Similarly, some hospitals purchase the components used for a primary total knee or primary hip implant together, while other hospitals purchase each component separately. As a result, some hospitals reported one product number that reflects multiple components, while others reported separate product numbers for each component used, making it difficult to compare the prices for devices purchased as whole to devices purchased component by component.

Information from Study Respondents Indicates Substantial Price Variation for Some IMDs

Data from those respondents that provided detailed information on the specific model purchased and sale price net of discounts and rebates indicated substantial variation in the prices hospitals paid for the same device model. Among the 31 hospitals that provided detailed price information on cardiac IMDs, we found that for AICDs and CRT-Ds the difference between the reported lowest and highest model-specific prices

was several thousand dollars.⁴⁸ For example, the difference between the lowest and highest price hospitals reported paying for a particular AICD model was \$6,844. The difference between the highest and lowest price reported for another AICD model was \$8,723. The price differences for the remaining two AICD models in our study fell in between \$6,844 and \$8,723. (See table 2.) The median prices across the four AICD models ranged from \$16,445 to \$19,007.⁴⁹ The other models of cardiac devices for which we collected pricing data also showed substantial variation in prices.

Table 2: Median Prices and Differences between the Lowest and Highest Prices Hospitals Paid for Cardiac Devices, Fiscal Year 2010

Type of device	Number of models	Range of median prices	Range of differences between the lowest and highest model-specific price
Drug-eluting coronary stents	5	\$1,700 to \$1,800	\$309 to \$828
Automated implantable cardioverter defibrillator (AICD) ^a	4	\$16,445 to \$19,007	\$6,844 to \$8,723
Cardiac resynchronization therapy defibrillator (CRT-D) ^a	5	\$19,370 to \$22,603	\$3,035 to \$9,247

Source: GAO analysis of hospital-reported pricing data.

Notes: Results are based on implantable medical device pricing data submitted by 31 hospitals and include all discounts and rebates the hospital reported receiving. We limited our analysis to the most common devices for which these hospitals provided pricing data. Not all hospitals provided pricing information for each device model in our study; the number of hospitals providing sale price net of discounts and rebates for a particular device ranged from 3 to 19. Hospitals that contracted with GPOs may have obtained other financial benefits not reflected in the net sale price, such as a portion of the administrative fees GPOs received from manufacturers.

^aAICD or CRT-D prices that included leads were omitted from this analysis.

⁴⁸Two DOD medical centers reported prices for cardiac IMDs that were generally greater than the prices paid by the 31 hospitals that provided detailed price and model information. One DOD medical center reported detailed pricing information for all three types of cardiac devices, including four drug-eluting cardiac stent models, one AICD model, and one CRT-D model. For four of the six device models, the price paid by the medical center exceeded the highest price hospitals paid for the same device model by as much as \$3,530. For the other two device models, the prices paid by the medical center were less than \$100 below the highest price paid by those hospitals. The other DOD medical center reported a price for one drug-eluting cardiac stent model that was \$220 more than the highest price paid by any of the hospitals that provided detailed pricing information for the same device.

⁴⁹It is possible that hospitals that contract with GPOs receive other financial benefits not reflected in sales price, such as a portion of the administrative fees GPOs receive from manufacturers.

Further analysis of the pricing data shows that the variation in prices paid by hospitals for IMDs cannot be attributed exclusively to a few hospitals that were outliers in terms of the prices they paid. Among the nine IMD models included in our study for which at least 10 hospitals reported prices, the prices at the 90th percentile exceed those at the 10th percentile by about 14 percent to over 40 percent, depending on the specific IMD model. On average, the price paid by the hospitals at the 90th percentile for the nine IMD models was about 31 percent greater than the price paid by the hospitals at the 10th percentile. (See text box for a hypothetical example of how hospitals can be affected by price variation for IMDs.)

Hypothetical Example of How Price Variation for IMDs Can Impact Hospitals

The variation in prices hospitals pay for the same device can have a substantial impact on the share of a hospital's Medicare payment that is available to cover other expenses and profit. For example, assume that one hospital pays about \$14,500 for a specific AICD model and another hospital pays about \$21,500 for the same device model—a difference of about \$7,000. In addition, assume that both hospitals pay an additional \$3,000 for leads. In 2010, the MS-DRG payment for the implantation of an AICD was approximately \$32,500.^a Therefore, the hospital that paid \$14,500 for the AICD model would have a little less than half of its MS-DRG payment to allocate to other costs associated with the IMD procedure, overhead, and profit. In contrast, the hospital that paid \$21,500 for the same device would have only about a quarter of its MS-DRG payment available for these items.

^aThe MS-DRG payment amount may vary depending on geography and other factors.

It was more difficult to compare prices for orthopedic IMDs because of the greater variation among device configurations. However, the data on orthopedic IMDs reported by hospitals and GPOs—which may not capture all discounts and rebates—provided some evidence of substantial price variation. For instance, one hospital reported spending about \$4,500 for a specific primary total hip construct in 2010. In comparison, a GPO provided information showing that one of its members paid about \$8,000 for the same device construct, or 78 percent more. Similarly, a GPO provided data on two of its member hospitals that purchased the same primary total knee construct. One hospital paid about \$5,200 for the

primary total knee construct, while the other hospital paid about \$9,500, or 83 percent more.⁵⁰

Hospitals' Ability to Manage Relationships with Physicians Is a Particular Factor That Influences Prices Paid for IMDs

The influence of physicians on hospitals' IMD purchasing decisions is a factor particular to the IMD market that affects prices hospitals pay. While physicians generally are not involved in price negotiations, they often express strong preferences for certain manufacturers and models of IMDs, known as physician preference items.⁵¹ Physicians may seek certain products in which they have high confidence in terms of their value to patient care and reliability, after promotion by device makers, or for other reasons noted below. To the extent that different physicians in the same hospital have preferences for IMDs made by different manufacturers, it may be difficult for the hospital to obtain volume discounts by consolidating its purchases from particular manufacturers. That is, individual hospitals or hospital systems may have less bargaining power relative to the few cardiac and orthopedic IMD manufacturers. In contrast, if the physician-hospital relationship is strong, the GPO can consider purchasing from multiple IMD suppliers and thus, gain leverage in negotiations. This could result in lower prices for hospitals.

Hospitals face a number of obstacles when it comes to working with physicians to consider cost when making IMD decisions. First, confidentiality clauses included in IMD contracts may bar hospitals from sharing price information with some physicians, making it difficult to get physicians the information they need to consider cost when making decisions about devices. According to one GPO, some hospitals restricted by confidentiality clauses have resorted to using colored

⁵⁰GPOs provided information on the sale prices its members reported paying for specific IMDs, but did not confirm that the reported price was net of all discounts and rebates. Two hospitals that provided information on the prices they paid for orthopedic devices also provided information on the discounts and rebates they received from specific manufacturers during our study period. The highest discount and rebate amount reported by these hospitals averaged about 5 percent for one device model. If we applied these discounts and rebates to the higher of the two prices in our orthopedic device examples, the difference between the prices would still be substantial—about 69 percent for the hip example and about 74 percent for the knee example.

⁵¹Physicians tend to use devices developed by one particular manufacturer, often due to having trained in a hospital that used that manufacturer's products or past experience with a manufacturer's products, and may be reluctant to switch manufacturers and learn how to implant another manufacturer's device using a new set of instruments.

stickers to indicate to physicians which devices are the high, medium, and low-cost options. Second, physician-hospital relationships regarding preference items frequently must contend with strong physician-manufacturer relationships. According to another GPO, physicians rely on manufacturer representatives to provide technical support during procedures involving IMDs, including setting up the operating room, consulting with the physician about the procedure, and programming devices, such as AICDs and CRT-Ds. In addition, some physicians might be loyal to certain manufacturers with whom they have consulting or professional relationships.

Some GPOs noted that, despite the financial impact of physician preference, hospitals are likely to accommodate physicians' IMD preferences in order to retain patient referrals to their facilities. One GPO commented that hospitals that ask physicians to be sensitive to IMD prices have encountered push back from some physicians. Another GPO cited a market where hospitals' attempts at cost-savings led some physicians to migrate away from their facilities. A third GPO said that because physicians are highly dependent on their relationship with manufacturer representatives who provide the physicians with technical support, they may not be willing to switch device models. An association representing orthopedic surgeons told us that if physicians are not involved in the negotiation process, it is difficult to encourage them to switch devices. If manufacturers determine that a physician is unwilling to switch device models, they can be more aggressive in negotiations, which could result in higher prices for hospitals.

In addition to hospitals' ability to manage relationships with physicians, device manufacturers we interviewed noted several other factors that influence the prices hospitals pay for IMDs. They pointed to marketplace dynamics—the degree of competition within a local market and the market power of hospitals purchasing the devices—as key influences. Additionally, they noted that the support offered by manufacturers, such as device servicing agreements and training, as well as the terms and length of the contract itself, play a role in price negotiations. Finally, the manufacturers told us that the extent to which changes in device technology improve patient care affects what hospitals pay for IMDs.

Concluding Observations

The lack of price transparency for the IMDs we examined makes it difficult to know whether hospitals are achieving the best device prices. This lack of price transparency may have implications for Medicare because excess or unnecessary IMD costs that hospitals incur may be passed on

to the Medicare program. In 2009, Medicare spent over \$19 billion for hospital procedures involving IMDs. A substantial portion of this amount may be attributable to the cost of the devices themselves, but exactly how much is unknown, in part, because hospitals purchase the IMDs and Medicare does not track IMD prices or how much individual hospitals pay for them.

Although Medicare's payment approach provides hospitals with an incentive to seek the best price on IMDs, hospitals may vary in their ability to achieve the best price because of limited price information and bargaining power. While we were able to obtain detailed IMD pricing data from 31 of the 60 hospitals we contacted, the effort revealed the challenges in compiling and analyzing meaningful price information even from this relatively small number of hospitals. Furthermore, we observed substantial variation in the prices that these 31 hospitals paid for cardiac devices. Some hospitals paid several thousand dollars more than other hospitals paid for the exact same device produced by the same manufacturer. These data suggest that some hospitals have substantially less bargaining power with the small group of companies that manufacture particular IMD devices and consequently face challenges in obtaining more favorable prices.

Physician preferences for particular manufacturer's devices and models may further complicate hospitals' bargaining power. Such preferences may shape hospitals' purchasing decisions and limit their ability to obtain volume discounts from device manufacturers. Moreover, many device manufacturers require confidentiality clauses that prohibit hospitals from disclosing their negotiated prices with third parties, which may include physicians. A hospital that is constrained in sharing price data with its physicians loses an opportunity to enlist their assistance in the hospital's efforts to be a prudent purchaser of IMDs.

Agency and Industry Comments

The Department of Health and Human Services and VA reviewed a draft of this report and provided technical comments, which we incorporated as appropriate. DOD also reviewed a draft of this report and had no comments.

Representatives from AdvaMed, the trade association representing device manufacturers, reviewed relevant portions of the draft and commented that there are many other factors—in addition to the hospital-physician relationship—that influence IMD prices. AdvaMed representatives noted that confidentiality clauses are not unique to the

IMD market. AdvaMed representatives also provided technical comments, which we incorporated as appropriate.

A representative from the American Hospital Association (AHA) also reviewed relevant portions of the draft and stated that confidentiality clauses that restrict hospitals from informing physicians about IMD prices inhibit hospitals from fully integrating care and making informed, cost-conscious decisions. Furthermore, the AHA representative noted that wide variation in IMD prices reported by hospitals shows that much of device price is driven by negotiations; therefore, lack of IMD price transparency puts hospitals at a disadvantage. The AHA representative also provided technical comments, which we incorporated as appropriate.

As we agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. We are sending copies of this report to the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of Veterans Affairs and other interested parties. The report will also be available at no charge on our website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix I.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'James C. Cosgrove', written in a cursive style.

James C. Cosgrove
Director, Health Care

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact

James C. Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Acknowledgments

In addition to the contact named above, individuals making key contributions to this report include Jessica Farb, Assistant Director; Gregory Giusto; Luis Serna III; and Ann Tynan. George Bogart and Krister P. Friday also provided valuable assistance.

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