Medicare provides federal health insurance for persons older than 65 years, disabled persons, and individuals with end-stage renal disease or amyotrophic lateral sclerosis. Established in 1965 by former President Lyndon Johnson, the program is administered by the Centers for Medicare and Medicaid Services (CMS), part of the Department of Health and Human Services (HHS). Medicare currently provides health insurance for more than 50 million Americans, and currently costs the federal government an estimated $500 billion each year.

Medicare is the primary payer for both physicians and medical device manufacturers (MDMs) who participate in the program. While increases or decreases in Medicare payments to physicians generate significant controversy, the fees for implantable medical devices (IMDs) garner less attention. During the past decade, Medicare physician payment fees have increased at less than the rate of inflation. However, Medicare payments for medical devices have seen robust growth, particularly in the area of IMDs such as joint replacements and spinal implants, both relevant to orthopedic and neurological surgeons.

Physician Reimbursements

Medicare has 4 parts: Part A is hospital insurance; Part B is medical insurance; Part D covers prescription drugs; and Part C is a combination of the 3 parts known as Medicare Advantage. Physician payments fall under Part B, and in 2012 Medicare allotted $69.6 billion (13%) of its $536 billion budget for this purpose.

Payment to physicians is based on a fee schedule that sets a fixed maximum price for more than 9,000 defined services, including office visits and surgical procedures, and assigns each service a Current Procedural Terminology (CPT) code. The Medicare Fee Schedule (MFS) determines that each service be priced within a resource-based relative value scale (RBRVS), which is based on 3 relative value units (RVUs): physician work, physician expense, and malpractice expense. Relative value units are mostly decided by the American Medical Association’s Specialty Society Relative Value Scale Update Committee. This monetary value is then adjusted to geographical area and multiplied by a conversion factor, which ultimately leads to a price in US dollars.

Federal statute requires that CMS update these prices each year, using a formula that in theory safeguards that total per capita spending for physician services does not exceed the increase in gross domestic product (GDP). This formula is known as the sustainable growth rate (SGR) formula and was first implemented in 1998. The SGR is applied to the RBRVS to attempt to control Medicare costs. During the past decade, the SGR targets have been exceeded, which, according to law, should have been followed by a cut in physician pay of more than 25%. Nonetheless, Congress has annually deferred pay cuts with a so-called “doc fix,” postponing this estimated decrease of 25% to 35% in physician payment.
Paradoxically, physician payments have increased slightly in the past 10 years, albeit at a lower rate than inflation (Figure 1). In 2004 and 2005, Congress delayed expected cuts and permitted an increase in payment by 1.5% each year, thanks to the Medicare Modernization Act (P.L. 108-173). In 2006, physician payments increased 0.2%, followed by stagnation in 2007 and an increase of 0.5% in 2008. In 2009 and 2010, payment rates increased 1.1% and 2.2%, respectively. Between November 2010 and January 2014, there were no increases in physician payment rates. Cumulatively, payments to physicians have increased only 4.1% since 2002. For comparative purposes, the inflation rate has cumulatively increased approximately 28% since 2002.

**Implantable Medical Device Reimbursements**

Implantable medical devices are part of hospital inpatient services, which are covered by Medicare Part A. A medical device must first undergo Food and Drug Administration (FDA) approval before CMS makes a decision on paying for the product. The FDA determines the safety and effectiveness of a product and CMS determines whether it is “reasonable and necessary” for its enrollees. However, FDA approval does not guarantee CMS coverage, and CMS may further cover the device in a local region rather than nationwide.

Medical device manufacturers obtain FDA approval for their products mainly via the premarket approval or premarket notification (510k) pathways. On the one hand, the premarket approval pathway involves a rigorous evaluation of the device by the FDA that usually involves clinical trials, which translates into a higher investment by the MDM. On the other hand, the 510k pathway allows MDMs to gain clearance if they can demonstrate that their new device is as safe and effective as an existing, similar medical device. Fast tracking of the approval process has led to patient safety concerns related to device failures, and it has been recommended that postmarket surveillance be mandatory for all devices to identify harmful devices.

Today, Medicare covers approximately 80% of devices that are FDA-approved. Coverage is based on how reasonable and necessary the devices are, and MDMs must show evidence that the device improves health outcomes. Medicare does not currently cover experimental devices that are used in clinical trials when their absolute risk has not been established (Category A Trial). However, Medicare may cover an experimental device when it is determined to be reasonable and necessary and has passed other coverage requirements established by individual Medicare contractors (Category B Trial). This coverage is currently jurisdiction-based, but CMS has recently proposed a more uniform and centralized review to facilitate the process.

Currently, Medicare is spending more than $20 billion per year on IMDs as part of its Part A budget, and payments in-
creased 4.3% each year from 2004 to 2009 according to the US Government Accountability Office (Figure 1). Cumulatively, this represents a more than 52% increase since 2002. Medicare does not purchase IMDs directly and instead relies on the prices obtained by individual hospitals. While the cost of a particular device may influence a hospital’s buying decision, hospitals also sign confidentiality agreements with MDMs. These issues raise the question of whether both Medicare and hospitals are overpaying for IMDs.

**Reimbursements to Physicians vs Implantable Medical Devices**

Over the long term, Medicare faces financial challenges due to an increasing number of enrollees, decreasing ratio of labor force to enrollees, and increasing health care costs. Total spending on Medicare is expected to increase from $523 billion in 2010 to $932 billion by 2020. Despite this, physician payment fees have essentially increased at much slower rates when compared with inflation, while payments to IMDs continue to increase exponentially. In fact, if current trends continue, by the year 2043 payments to IMDs will have surpassed payments to physicians (Figure 2).

As mentioned previously, Medicare states that freezing (as opposed to lowering) physician fees would cost an estimated $145 billion in the next 10 years. However, if the current increase rate for IMDs is maintained, these payments will cost Medicare an estimated $323 billion in the next 10 years. The US IMD market, valued at $43.1 billion in 2011, is expected to increase to $73.9 billion by 2018. The MDMs face significant pressure to obtain Medicare coverage of their devices, a trend that will certainly continue.

When comparing payments to physicians, hospital inpatient services (including IMDs), durable medical equipment, and prescription drugs, the greatest increase in the past 6 years has been for IMDs. Payments for Medicare Part A have increased 23.9% since 2006, including a 32.6% increase in payments for IMDs alone in the same period. From the categories studied in this editorial, payments for hospital inpatient services are the greatest area of expenditure (Figure 3), followed by payments to physicians.

**Conclusion**

Overall, CMS payments to physicians have increased cumulatively by 4.1% since 2002, compared to an increase of 52.4% in reimbursements for IMDs. If these trends continue, reimbursements for IMDs will surpass payments to physicians by the year 2043. As Medicare’s budget continues to face downward pressure, payments to MDMs are likely to receive increasing scrutiny.

**References**

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