

The Impact of Payment Reform on Industry Strategy

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The following essay examines implications of new Centers for Medicare and Medicaid Services payment regulations, especially those stemming from the Medicare Access and CHIP Reauthorization Act (MACRA), which the medical technology industry faces in the health care market. Providers determine the coverage of medical devices within the constraints of Medicare's payment systems and therefore are affected by new payment regulations. MACRA aims to improve the quality of care, advance care information distribution, and reduce health care costs, which can only be achieved together through enhanced care coordination and collaboration between different stakeholders. For the medical technology industry, success means that the paradigm shift from volume to value needs to be accepted at all levels. Medical device creators must better recognize consumer needs and establish systems to measure, monitor, and improve patient-centered outcomes. Moreover, companies need to understand their contribution to the full cycle of care through expanded collaboration between different stakeholders and participation in risk-sharing. Collaboration is also needed regarding electronic health records to make patient documentation simple and standardized. The medical technology industry is not directly integrated in Medicare's payment reforms. As a result, it is their responsibility to demonstrate their value to patients, providers, and payers. In the long run, these different stakeholder needs must be integrated in the research and development of novel technologies.

Contents

1	Push Towards Value-Based Payment Systems	136
2	Definition of Value in Health Care	137
3	Current Payment Situation	137
4	Payment Reforms	138
4.1	Overview of Reforms in Medicare	138
4.2	Medicare Access and CHIP Reauthorization Act.....	139
5	Implications for the Medical Technology Industry	142
5.1	Paradigm Shift: from Volume to Value	142
5.2	Demonstrating Value	143
5.3	Creating a Holistic Perspective of Treating a Condition	143
5.4	Increasing Collaboration Between Different Stakeholders	144
5.5	Ensuring Easy Implementation	144
6	Conclusion.....	145
	References	146

1 Push Towards Value-Based Payment Systems

Without a commensurate gain in health outcomes, the United States spends more per capita on healthcare technology and care than European nations. Higher technology costs, larger volumes of certain procedures (e. g. hip and knee replacements), and a greater supply of doctors and hospitals contribute to higher US spending (Sorenson et al., 2013, p. 788). As a result, US payment regulations are undergoing considerable reform to lower spending.

In general, there is a push towards value-based payment schemes. The Patient Protection and Affordable Care Act of 2010 and the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 have played a leading role in this shift for Medicare. As the single largest healthcare payer in the US (MedPAC, 2016 c), p. 3), Medicare influences the payment schemes of private insurers. Using Medicare as a role model, these companies adjust their reimbursement rates and structures accordingly (Clemens, Gottlieb, 2013, p. 1).

Through its prospective payment system, Medicare regulates the cost and coverage of most medical devices. This means that within the constraints of fixed prospective payment, the provider determines the coverage. In this way, the coverage and payment decisions made on an individual basis determine revenues. Explicit coverage decisions are made locally (Sorenson et al., 2013, pp. 789, 790).

Consequently, the payment the Medical Technology Industry (MTI) receives is dependent on the providers who care for Medicare beneficiaries. This suggests that the MTI may also be affected when payment regulations for provider's change, but the effect on the MTI remains uncertain.

This essay analyses possible implications of recent Medicare payment regulations, especially MACRA, for the MTI and focuses on the inpatient sector through implantable medical devices, using hip and knee replacements as examples.

Although the future of MACRA is unclear, currently available literature and journal articles from different stakeholder perspectives provide a window into possible change. In this essay, an illustration of the shift from volume to value in healthcare will first lay the groundwork for understanding the theory of new payment regulations in the US healthcare system. Secondly, details surrounding the current situation of medical device payment will act as a starting point for the implications of Medicare policy changes. Thirdly, an exploration of political developments that influence Medicare payment, with a focus on MACRA, will provide an image of the present leading into the future. Lastly, the implications of new payment regulations on the MTI will demonstrate where the industry is headed in the coming years.

2 Definition of Value in Health Care

When discussing value in health care, the question “What is value in health care?” arises. This question will be addressed in the following section.

As a whole, value in healthcare is both largely misunderstood and unmeasured, as all stakeholders tend to have diverging goals (here and the following Porter, 2010, pp. 2,477-2,478). As a result, the first goal should be unifying healthcare stakeholders under one common goal: creating high value for patients. The following illustrates value in healthcare.

Figure 1: Value in Health Care

$$\text{Value in Health Care} = \frac{\text{Health Outcomes}}{\text{Dollar spent}}$$

Source: Author according to Porter, 2010, p. 2477.

Value can be defined as health outcomes achieved per dollar spent. However, outcomes are multidimensional and, therefore, difficult to measure. Outcomes depend on the condition and no single outcome encompasses the total body of delivered care. Consequently, costs in the equation refer not to individual services but to the total costs of the full cycle of care. Altogether, to improve outcomes and reduce costs, there must be a push towards expanding measuring and reporting metrics combined with a robust method of comparison (Porter, 2010, pp. 2,477-2,478).

3 Current Payment Situation

Medicare uses a prospective payment system in the outpatient and inpatient hospital sectors. The base rate for each prospective payment system is modified to consider geographic differences in input prices and type of case or service. Payment rates are updated annually (MedPAC, 2016 a), p. 67). As mentioned in Section 1, coverage for and purchase of medical devices is made by providers considering the constraints of Medicare’s payment system.

The decision to use a device is usually determined by the desires of the physician and the added value for the patient. Costs for medical devices like hip and knee implants account for approximately 30% to 80% of a hospital’s reimbursement for the procedure. Similarly, physician preferences account for a large amount of hospitals’ variable costs as they choose the devices while the hospital faces the financial burden. Along those same lines, a physician can reduce the total cost of care by choosing devices from a discounted contracted vendor, but they still have the option to prefer more expensive

options, thereby forcing hospitals to pay higher prices (Obremskey et al., 2012, pp. 1,054-1,055).

Additionally, setting prices for medical devices does not need to follow requirements. Depending on negotiations with group purchasing organizations, device costs for high volume items can both be discounted and set individually for each hospital. Consequently, to stay competitive, health systems are increasingly using the services of consulting firms to get insight into the prices paid by similar hospitals. However, even this avenue is flawed as hospitals only post prices listed rather than those negotiated with various payers, thereby creating a lack of price transparency (Robinson, 2008, p. 1,526). Through a fixed, less flexible prospective payment system, hospitals face higher costs associated with changes in technology and devices (Clyde et al., 2008, p. 1,632).

As a result, fragmentation and misalignment of information, incentives, and organizational capabilities between the hospital and physician are the main obstacles for value-based purchasing of medical devices (Robinson, 2008, p. 1,524).

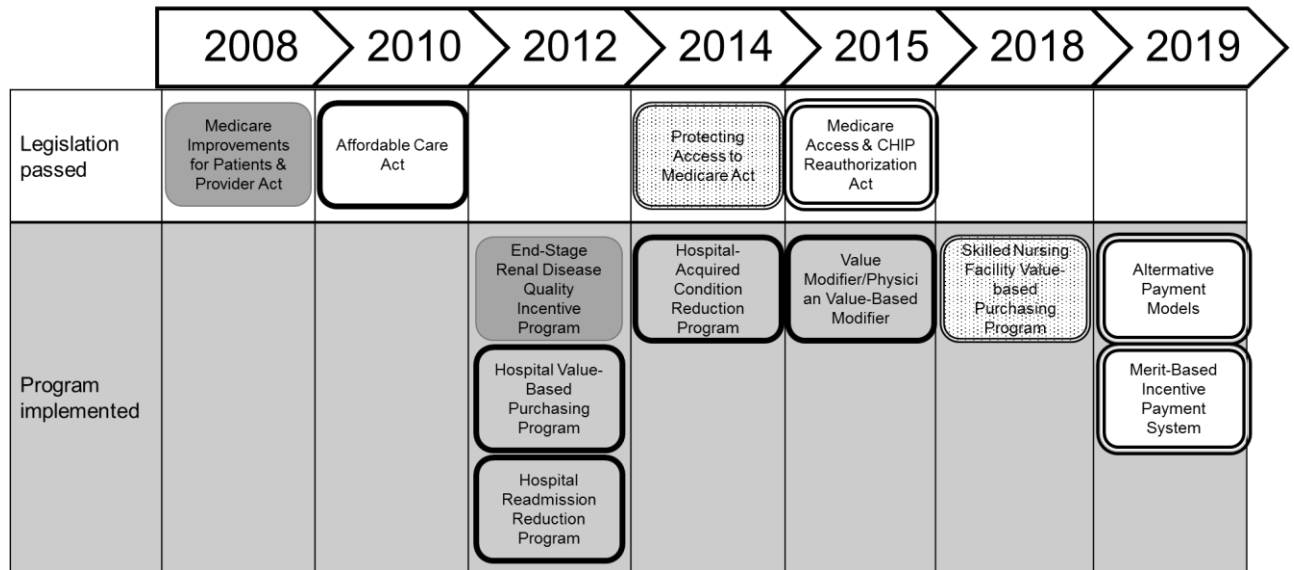
4 Payment Reforms

In this section, an overview of reforms within the past nine years is given first. Then the latest developments in value-based payment will be described. The most common inpatient surgery for Medicare beneficiaries is hip and knee replacement (CMS, 2017 b)). For this reason, hip and knee replacement play a key role for the Center for Medicare & Medicaid Services (CMS) and therefore will be used as example.

4.1 Overview of Reforms in Medicare

Figure 8.2 shows the legislation timeline between the years 2008 and 2019 along with associated value-based programs. Providers for Medicare recipients receive incentive payments through these value-based programs (CMS a), 2017).

Figure 2: Timeline for Value-Based Programs



Source: Author according to CMS a), 2017.

As shown, a variety of programs that introduce value into payment systems are being implemented or are intended to be established. However, since it takes several years to implement a program after the passage of legislation, considerable time and resources are required to ensure that the program is successfully carried out and evaluated. Under consideration and review for years before its recent passage, MACRA is the latest significant regulation that impacts payment reform.

4.2 Medicare Access and CHIP Reauthorization Act

Final regulations for MACRA were released in 2016 by CMS to repeal the sustainable growth rate formula and update the physician fee schedule. The act rewards the delivery of high-quality care with quality measurements incorporated into provider payments and the development of new policies to incentivize provider participation in alternative payment methods (APMs), including innovative episode payment models for joint care and shared savings program. The Quality Payment Program was created (Department of Health and Human Services, 2016, pp. 1-4) to reform Medicare Part B payments for more than 600,000 clinicians (specifically for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetics) (CMS, 2016).

The Quality Payment Program consists of the Merit-based Incentive Payment System (MIPS) which combines three existing Medicare incentive programs: Physician Quality Reporting, Electronic Health Record Meaningful Use, and the Value-Based Payment Modifier (Quality Payment Program Service Center, 2017 a)). It also includes Advanced

APMs. These programs can apply to a specific clinical condition, an individual care episode, or a population (Quality Payment Program Service Center, 2017 b)).

In aggregate, the budget will stay neutral, but the bonuses and penalties of individual physicians will have a significant impact on payments at the individual level. Hence, there will be effects on the attractiveness of the APM and MIPS path (MedPAC, 2016 b), p. 30). If clinicians do not participate in the Quality Payment Program in the Transition year 2017, it will result in a negative 4% payment adjustment. Eligible clinicians are free on what and how they report. They can choose between submitting a minimum amount of data, reporting for 90-day period or full participation to avoid the negative payment adjustment (CMS, 2016).

Merit-based Incentive Payment System

The Merit-based Incentive Payment System (MIPS) determines whether physicians receive a bonus or penalty on their fee-for-service payments through the quality of their performance (MedPAC, 2016 b), 29-30). To begin, physician performance in 2017 will adjust the payments for 2019, with the anticipated amount of data submitted for the transition year of 2017 resulting in neutral to modest positive changes with regards to performance (CMS, 2016). The law determines the measurement of performance on four components, outlined in Figure 8.3.

Figure 3: Performance Categories in 2017 for payment in 2019



Source: Author according to Quality Payment Program Service Center a) (2017); CMS (2016).

The four categories are weighed differently and different measures can be chosen by providers. Each of the categories is weighed differently, with quality making up 60%, improvement activities 15%, advancing care information 25%, and cost initially making

up 0% but increasing over time. Quality of performance is measured with six measures of the provider's choice out of a possible 300 and compared against benchmarks. For improvement activities, clinicians can choose from over 90 activities categorized in nine different areas, including care coordination and participation in an Advanced APM. Advancing care information provides more flexibility with two different sets of measurements for reporting based on Electronic Health Record Meaningful Use. Costs are not weighed in 2017 (CMS, 2016).

Existing measurements do not capture many important aspects of quality. Furthermore, differences in patient severity influence and conflict measurements as well. Using similar measures in the 2016 Value-based Payment Modifier, 96% of physician practices were scored "average costs." Since these measurements are used by smaller practices that often do not capture their discretionary service through well-developed episode definitions, average scores do little to promote change. This high percentage suggests that there is a risk of the same phenomena for MIPS measures, which could limit the usefulness of measurements to drive change toward a value-based care system (Clough, McClellan, 2016, p. 2,397).

Advanced Alternative Payment Models

Advanced APMs are APMs that hold the chance to earn a 5% incentive payment in 2019 for participation in 2017. Comprehensive ESRD Care, Comprehensive Primary Care Plus, Next Generation ACO Model, Shared Savings Program (Track 2), Shared Savings Program (Track 3), Oncology Care Model or Comprehensive Care for Joint Replacement Payment Model (CJR) are the seven Advanced APMs in 2017 (Quality Payment Service Center, 2017 b)). The concept these programs are based on is that bearing some financial risk for spending might contribute to limit spending growth (MedPAC, 2016 b), p. 33). In Advanced APM the participants share risk, not only for gains, but also for losses. However, CMS set the standard higher than many hoped for (Clough, McClellan, p. 2,397). In the following section information on the CJR are given.

Comprehensive Care for Joint Replacement Model

The CJR Model is classified as an Advanced APM (Quality Payment Service Center, 2017 b)).

The most common inpatient surgeries for Medicare beneficiaries are hip and knee replacements (here and for the following CMS, 2017 b)). Advanced APMs support better and more efficient patient care by using bundled payments and quality measurement systems for each episode of care. This improves the quality and coordination of care along the extended, post-acute care continuum.

In the program, participating hospitals are financially accountable for the quality and cost of a CJR care episode, including all related items and services paid under Medicare

A and B. The system aims to increase coordination among different stakeholders, including physicians and hospitals, while raising patient awareness of quality of care. The admission of a patient with certain Diagnosis Related Groups (DRGs) to a participant hospital is the beginning of the care episode and ends 90 days post-discharge. Actual spending for the episode is compared to target episode prices at the end of the performance year. Through DRG analysis and CMS' use of simple risk stratification methodology different target prices are set for patients with a hip fracture. Well-performing hospitals may receive additional payment whereas poor performers must repay Medicare for a certain share (CMS, 2017 b)).

5 Implications for the Medical Technology Industry

Medicare reforms are likely to change the entire health care system. Therefore, physicians and other providers need to understand the opportunities represented by MACRA to shape the future of payment and medical practice (Clough, McClellan, 2016, p. 2,397). The MTI needs to both to understand its significance and also their role in improving the outlook of healthcare.

5.1 Paradigm Shift: from Volume to Value

Marketing and sales activities of the MTI involve seeking preferred positions through discounts, rebates, and volume incentives. Meanwhile, suppliers behave as if their technologies are interchangeable and demonstrate little effort in justifying their value to certain patient groups. Competition happens through offering lower prices or incentives offered to physicians for using their technologies instead of demonstrating effective results (Porter, Teisenberg, 2006, p. 285). As a result, a major challenge is the shift from volume to value, which depends on results rather than inputs. Value is not measured by volume, but rather the outcomes achieved (Porter, 2010, p. 2,477).

Fortunately, physician medical education programs are beginning to place importance on the concept of value in healthcare. Topics including patient safety, quality improvement, team work, and health policy are becoming the third pillar of medical education after the basic and clinical sciences (Prina, 2017, p. 191). This goes along with the need for a strategy for health care organizations to thrive in a competitive marketplace (Porter, Lee, 2015, p. 1,684).

For the MTI, this means that all activities must be focused on value, requiring a paradigm shift from volume to value at all levels of a company. Furthermore, developments in the customer environment, like education programs and strategies for organizations, must be monitored and tackled with appropriate reactions. For example, creating a purchaser strategy together with a provider to solidify a market, establish a price, and create a performance feedback loop would better incorporate a member of the MTI into the strategy of a healthcare organization.

5.2 Demonstrating Value

A major challenge in determining the value of care is collecting effective data that objectively influences coverage and reimbursement decisions. Such data are generally not required for market approval (Sorenson et al., 2013, p. 792). More obtainable details on process measurement and improvement are poor substitutes for outcome and cost measurements. Similarly, providers tend to measure what is in their direct control and what is easily obtainable, e. g. providers measure what is billed (Porter, 2010, pp. 2,477-2,478). It is crucial to track patient-centered outcome measures and make results transparent to the organization and patients to demonstrate delivery of high-value health care (Shaikh, U; Roth, A., 2017, p. 1). With that, new kinds of data and analyses are required to better measure value and abundant, novel relationships must be formed with providers. The MTI must work alongside groups of providers to collect and analyze care cycle information, since such data has been shown to be difficult to obtain and interpret alone (Porter, Teisenberg, 2006, p. 291). Similarly, the training and skills of health professionals, especially surgeons using medical devices, have an enormous impact on the accuracy and effective use of these devices (Sorenson et al., 2013, p. 793). Surgeons must begin to work in networks and communicate to better coordinate care, guiding investigations of patient-centered outcomes and healthcare delivery systems that give the organization a competitive advantage (Rudnicki et al., 2015, p. 355).

For the MTI, the impact of a device on patient-centered outcomes must be measurable at both the individual and aggregate level to determine the efficacy of both devices and providers. This requires communication with providers and stakeholders, particularly surgeons using the devices and technology.

5.3 Creating a Holistic Perspective of Treating a Condition

When determining the total cost of an episode of care, costs must be evaluated for the cycle of care in its entirety rather than for individual steps or parts of treatment along the way. Concentrating too narrowly on the technology rather than on the entire cycle of care is a common mistake. In making this change, shared resources must be added to the costs for individual patients to align with actual use as opposed to equally distributing costs among all patients. This process would allow for cost comparisons between patients with the same medical condition (Porter, 2010, p. 2,481). When determining the value of care, there is a tendency to focus on selective indicators for patient benefit than overall measures of long-term value (Porter, Teisenberg, 2006, p. 286). The Medicare Payment Advisory Commission reported that measuring quality is challenging when the number of cases per provider are low, thereby hampering the ability to properly evaluate care. Furthermore, the Commission is concerned that quality measurements of Medicare

rely too heavily on clinical process measures than on outcomes of interest, such as mortality and readmissions (MedPAC, 2016 a), pp. 54-55).

For the MTI, this means that their contribution to the full cycle of care through their device and applicable add-on services must be communicated to providers and payers to negotiate value-based prices.

5.4 Increasing Collaboration Between Different Stakeholders

Value encompasses efficiency as outcomes are relative to costs. A potential limit for effective care is the consideration of cost-reduction alone without regards to outcomes achieved. Value measurements should encompass all services or activities that jointly define success in meeting patient needs. For realized savings to have a systemic impact on the continuum of care, they must be shared among all involved stakeholders. Value is created through combined efforts over the full cycle of care, with effectiveness depending on not one but several interventions. However, joint responsibility for outcomes is not widely accepted by physicians (Porter, 2010, pp. 2,477-2,478). Additionally, other factors may influence physician choice, such as personal relationships with sales representatives and provision of technical support during the procedure from the device company. In an attempt to align the diverging interests of physicians and hospitals, gainsharing might be an appropriate approach, meaning that both groups share financial savings from the collaboration (Obremesky et al, 2012, p. 1,055).

For the MTI, collaboration with physicians and hospitals must increase in order for the industry to contribute to improving the value of healthcare. One possibility would be to prove to physicians the cost-effectiveness of one device compared to others while also enabling risk-sharing between physicians and hospitals. The MTI can take a particularly active part in this effort by taking some risk and base pricing accordingly, a policy that fits with the intention of the CJR model.

5.5 Ensuring Easy Implementation

Reporting quality measures can be quite expensive due to the time spent by physicians and staff participating in direct reporting efforts. Physicians already spend more than 15 hours per week on average preparing challenging external quality measures while attempting to understand performance reports from their own from payers and other outside stakeholders (Casalino et al., 2016, p. 401). With regards to a health system, an efficient hospital purchasing strategy consists of a minimal number of relationships with medical device manufacturers while simultaneously covering the full range of device needs. Although such a model reduces a system's number of interactions, it also limits physician choices of medical devices (Robinson, 2008, p. 1,527).

For the MTI, these two issues present opportunities to develop strengths as competitive advantages. First, through acquisition and development of innovative technologies, a

firm's product offering can increase while the number of hospital vendors decrease through the elimination of competing inferior products. Second, a firm's research and development arm can focus on medical devices that target physicians' interests, thereby becoming a preferred company among doctors who impact purchasing decisions. Throughout the process, documentation must be standardized and simple. This is best realized with EHR-compatible software that not only manages the devices but complies with the Advancing Care Information component of the MIPS program.

6 Conclusion

The MTI has an opportunity to contribute tremendously to the aim of MACRA through quality improvement, care information advancement, and cost reduction while at the same time fostering collaboration between stakeholders. Although the MTI is not directly integrated into reforms of Medicare's payment systems, the industry must be aware of political developments in order to shape their value in and for the healthcare market. The industry must act outside of producing and selling devices by building relationships with providers to understand and integrate their needs in product research and development both now and in the long run. All payers use Medicare payment regulation as guidance while adjusting to their specific patient population, forcing the MTI to face many different approaches when entering the world of value-based payments. Therefore, companies should adapt their offers accordingly to meet needs and secure business. As a result, segmentation of customers and targeted approaches might be a good tactic. No matter which approach is taken, in the end firms must adapt to meet the needs of stakeholders to create value, remain competitive, and contribute to a more efficient US healthcare system.

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