

System Partnerships between Medical Device Companies and Health Care Providers

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The American health care system has some of the worst quality outcomes and highest costs internationally. In order to address these issues, the Medicare Access and CHIP Reauthorization Act (MACRA) was passed in 2015 by Congress. MACRA is a new value- and quality-based payment model which rewards providers for high quality care and penalizes providers with low quality outcomes. Under the law, two health care payment models, the Merit-based Incentive Payment System and Alternative Payment Models, put patients as the focus to promote patient-centered health care. Providers have difficulties adapting to these new models, but through system partnerships they can be supported. System partnerships are relationships between medical device companies and providers which are more than common customer-vendor relationships. In fact, system partnerships aim to develop complex treatment solutions together. This paper reviews whether system partnerships can effectively lower costs and improve the quality of health care systems. In addition, the advantages of the system partnerships, such as digitalization, are compared to the risks they pose to patients and providers, such as information asymmetries. At present, analysis of these factors shows that the advantages outweigh the risks. Therefore, the use of system partnerships as a means to lower costs and improve quality is recommended.

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1 Introduction

The American health care market is one of the largest in the world and acts as a role model for other countries. Every legislative change is observed and discussed because its size can illustrate problems and advantages more explicitly than other, smaller markets can.

This paper will discuss whether system partnerships between medical device companies and providers save costs and improve the quality of care. To accomplish this, MACRA is briefly explained (section 2) and its impact on providers is detailed in section 3. Section 4 presents how the providers deal with the new regulation and what problems might occur. A description follows of possible solutions that could be implemented to support the providers with adapting to this legislation, emphasizing system partnerships as a possible solution (section 5). Thereafter, the advantages and opportunities a system partnership provides, the risks presented by these partnerships under MACRA, as well as cost savings and quality improvement will be discussed (section 6). At the end, a conclusion will be drawn which considers the presented results of the previous sections.

2 MACRA

The American health care system has some of the world's highest expenses for health care, but also some of the worst quality outcomes when compared to different countries (Squires, Anderson, 2015, w.s.). In order to tackle this imbalance, the government introduced the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015 (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). With MACRA in place, CMS strives to achieve better, more patient-focused care. The system is intended to be understandable and flexible for each participating physician. It rewards high-quality patient care through two options: The Merit-based Incentive Payment System (MIPS) or the Alternative Payment Model (APM). Both payment systems and their rewards are described in the following section.

2.1 Merit-based Incentive Payment System

The Merit-based Incentive Payment System (MIPS) will affect almost every physician because any physician which earns at least \$10,000 from Medicare payments is involved in this payment reform (Shinkman, 2016, w.s.). The new system combines and unites multiple quality and value programs which were formerly separate into one.

MIPS mainly lays focus on three aspects: quality, resource use, and use of certified electronic health record (EHR) technology. Performance will be measured and reported in four performance categories. The first, quality, will compose 50% of the measurement taken in the first years of MACRA and is therefore the most important part of the meas-

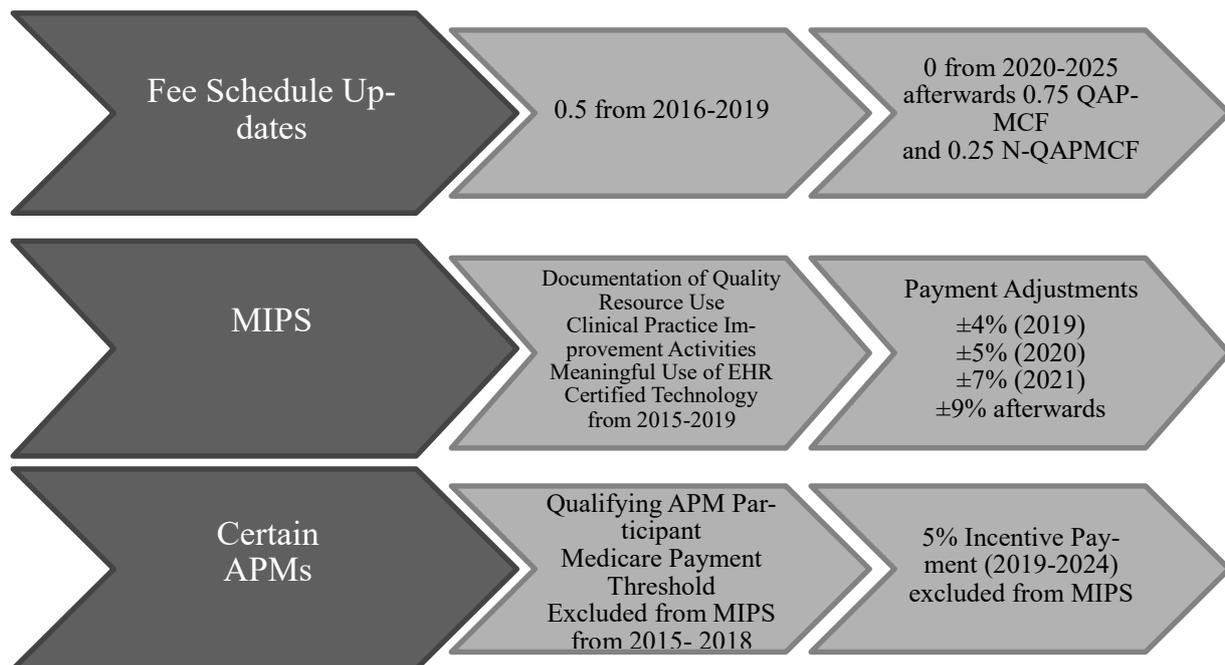
uring. The second one is resource use, which is the only category that is directly measured by CMS and will compose 10%. The third one clinical practice improvement activities has rather lower importance at the beginning of the reporting period because it was not included in former laws and needs to be introduced to the physicians. The last one is the meaningful use of EHR certified technology (Yaraghi, 2016, w.s.).

The four performance categories will be pooled together into a MIPS composite performance score (CPS). This CPS will be used to decide whether a physician receives an upward, downward, or even no payment adjustment to either reward or penalize the provider. Quality, resource use, and meaningful use of certified EHR technology were present in former laws and have now been modified, extended, and transformed into one. The report for quality performance must include at least six measures, one trans-sectoral measure, and, if possible, one outcome measure (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). In lieu of an outcome measure, there is the option to add a high priority measure such as patient safety. The required clinical practice improvement activity, the only new regulation, addresses population management and care coordination. CMS will annually establish a new performance list with additional detailed information about changes to MIPS and the metrics of the CPS after the collected data is submitted.

2.2 Alternative Payment Model

The second payment system reform option is the Alternative Payment Model (APM). To be part of the program, a physician must meet a higher Medicaid revenue or patient threshold than under MIPS. It will only affect 5% of health care systems and is used to establish some kind of better and newer accountable care organizations (ACO). Most ACOs are APMs, but not all APMs are ACOs because there are a variety of possible models for APMs. The requirements for an advanced APM are the following: having a quality measure component, using EHR certified technology, and either bearing more than a nominal financial risk or being part of a Medical Home Model (an expansion under the authority of the Medicare and Medicaid Innovation Center) (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). Those who participate in the most advanced APMs will be upgraded to Qualifying APM Participants (QP). QPs are physicians and practitioners who have a certain percentage of their patients or payments through an eligible APM. Those who qualify to be a QP gain a 5% bonus payment from 2019 – 2024 and after 2026 receive higher fee schedule updates than under MIPS as detailed in figure 9.1 (Hussey, Liu, White, 2017, pp. 697-705).

Figure 1: MACRA fee schedule timeline comparing Fee Schedule Updates, MIPS, and APMs



Source: own illustration

MIPS will include all eligible clinicians except those who participate in an APM. Whereas APMs are designed for larger practices, MIPS is designed for smaller and solo practices. APMs have a greater risk, however, and this is rewarded with higher bonuses than in MIPS.

Both models are applicable to payment for Medicare and Medicaid patients. Those two forms of public insurance originate from the federal government and cover about 34% of the American population (Kaiser Family Foundation, 2015, w.s.). These models often align with CMS regulations closely as they consider them important guidelines for health care payment system success.

3 Providers' challenges with MACRA

MACRA mainly affects providers, meaning they must now adjust to the new payment models, which often implies a difficult process.

According to MACRA, there are four main domains to which the providers must adjust. The first domain is quality, where providers have to measure the quality of their performance in six different ways. Within this process, providers can choose their own means of measurement (Pullen, 2017, pp. 591-592). This is a difficulty because it might invite providers to exploit the system (Yaraghi, 2016, w.s.). Consequently, providers can easily manipulate the measurements and present themselves as better than they actually are. In general, quality measurement is complicated because the patient as well as the physician should ideally describe results of care episodes. Quality is often a personal perception and therefore it is challenging to design a conclusive survey which depicts the situation

in an objective way. In addition, health care providers do not have the ability to access all data being submitted to CMS (Deloitte Report, 2017, p. 5).

The second domain is resource use, with its performance being calculated by using administrative data. Therefore, physicians and providers do not have to submit any additional data (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). However, obtaining this data is very complex because it cannot be extracted from one source (Deloitte Report, 2017, p. 6). Usually, CMS also does not communicate the results to providers more than once a year, which can lead to invalid responses to the system, which means that changes cannot be made without the data. However, this issue has already been detected and addressed by simplifying the reporting requirements for the first year of MACRA.

The third domain involves clinical practice improvement activities. These are difficult to identify because there is no data infrastructure yet to measure performance in this domain (Deloitte Report, 2017, p. 11).

The meaningful use of EHR certified technology is the last domain. EHR certified technology is expensive, hence it is easier for larger providers to equip themselves with than it is for solo practitioners. More than 600 EHR manufacturers sell the technology to providers across the US health system (Deloitte Report, 2017, p. 5). Even though 60% of the provider market is supplied through 5 EHR companies, the large variety of systems and vendors make it complicated to synthesize and compare data by setting or provider. Consequently, there are many different and incompatible EHR systems in the American health care market.

Many physicians reported that the MACRA performance documentation may distract them from actual patient care due to the excessive bureaucratic burden (Shinkman, 2016, w.s. and Shyrock, 2016, p. 2). CMS reacted to these objections by loosening the restrictions. Currently, providers can select between three options in order to avoid a negative payment adjustment. All these options introduce the participant to the new value-based payment system to encourage conformity with the requirements of the system over time (Medicare Access and CHIP Reauthorization Act, 2015, w.s.).

It is expected that MACRA will drive physicians to join larger organizations and networks to be part of APMs and their payment advantages, thus increasing participation in value based-payment agreements (Survey of US Health Care Executives, 2016, p. 7). However, the law might disrupt the relationships between health care systems, physicians, and life science companies like medical device companies and pharmaceuticals, creating barriers. Nevertheless, these parties need to work together to overcome obstacles in providing quality care. Therefore, alliances between health care systems and life science companies will be significant in order to evaluate which products work best on which type of patient to achieve better treatment outcomes and improve cost efficiency (Lohmann, Rippmann, 2014, pp. 127-131).

4 System partnerships

Providers need to optimize and digitalize medical processes in order to secure quality and efficiency in the health care sector, an endeavor that is complicated and expensive. Often providers cannot afford these expensive innovations, so they simply try to save costs by dismissing staff. This in turn leads to poor quality care and eventually leads to negative payment adjustments (Lohmann/Rippmann, 2014, p. 122). Add something here about how system partnerships can avoid that scenario and how you will discuss the positive and negative aspects of these partnerships in this section.

4.1 Positive aspects of a system partnership

To be successful under MACRA, providers need to completely change the way they have been working (Deloitte Report, 2017, p. 1). One way to become successful is to establish a system partnership with a medical device company. Such a partnership means that the two entities have more than a common customer-vendor relationship; this implies a full partnership where they develop and establish treatment solutions together (Siemens Healthineers, 2015, w.s.). A variety of partnerships exist, creating tailored solutions for every possible cooperation between medical device companies and providers. On one hand, providers often need to invest in their digital infrastructure or innovate in general (Lohmann, Rippmann, 2014, pp. 122-131), but they often do not have the financial reserves to do so. On the other hand, Medical device companies are able to support these changes financially through multiple payment models which ease the payment for providers. Additionally, they can provide them with medical devices to clear the way for further innovation processes, given that they are in a system partnership. As a result, the provider can participate in the progress of medical technology without worrying about financial resources.

The provider can further benefit from cooperation with a medical device company by using the company as a positive role model for modernization of health care (Lohmann, Rippmann, 2014, p. 126). Currently, medical device companies are global players who have to align to the market. Providers are protected by law and thus never had to adjust to the global market in the same way. However, now that the market is changing through MACRA, providers are forced to compete on a higher level. Medical device companies can encourage providers to take steps in the direction of digitalization. They can assist providers in terms of restructuring and reorganizing while also relieving the company financially and motivating the staff through quick wins in digitalization.

Medical device companies can also teach staff how to optimally operate devices and technology, generating an efficiency gain (Lohmann, Rippmann, 2014, p. 128). Also, the companies have the expertise to analyze weak points in a process and subsequently

help to optimize those. Together, the two partners have the opportunity to use the development work of the medical device company to create change more swiftly than previously possible.

If the providers and medical device company cooperate closely together, they are also able to establish clinical pathways together. Clinical pathways are the unitary way, agreed upon by all concerned parties, a provider treats patients with steady, proficient quality (Lohmann, Rippmann, 2014, pp. 122-131). It is determined to be the most efficient way to treat a patient and is complex to develop. When the provider and all relevant employees along with the medical device company agree to devise a clinical pathway, it will be especially efficient.

Sometimes medical device companies collaborate to facilitate product improvements (Siemens Healthineers, 2015, w.s.). There are various products that can be innovated and upgraded, such as Magnetic Resonance Imaging (MRI) and Computerized Axial Tomography (CAT) scans. A partnership with a provider allows scrutiny of workflows and improvement of the device accordingly. For example, Siemens Healthineers and Northwell Health have been collaborating since December 2016 as a research partnership in order to improve the outcomes of Northwell's Imaging Clinical Effectiveness and Outcomes Research Program (Business Wire, 2016, w.s.). According to their first published paper, 'Value of Advanced Imaging in Improving Health Outcomes and Healthcare Spending in Acute Stroke', they already discovered that during a stroke the best choice for an imaging exam, whether to use an CT or MRI, depends on the personal characteristics of the patient. With this finding, Siemens Healthineers and Northwell Health hope to illuminate new pathways to treat patients more effectively and influence health policy rulings to improve population health.

4.2 Negative aspects of a system partnership

There are some factors, however, which providers and medical device companies should bear in mind when considering a partnership. Both parties need to be completely honest about their intentions when establishing a working relationship (Lohmann, Rippmann, 2014, p. 130). If there are any discrepancies it is highly likely that the cooperation will not work. Constant risk management is a necessity to detect possible inconsistencies early enough to rectify the situation. Also, credibility is an important matter. If the provider does not believe the intentions of the medical device company are genuine there is no basis to build on and thus it is likely that the partnership will not come about (KMU-, Krankenhausstudie 2000, 2000, pp. 94-100).

Furthermore, not every medical device company is able to establish a system partnership. There are special features needed for a partnership to occur. The structure of the company has to be more like a service company than a simple vendor (Lohmann, Rippmann, 2014, p. 127). These service qualities are essential to be successful in such a

partnership due to the thorough preparations which are needed to determine if the two partners fit well together before founding the partnership.

5 Discussion

In the following part, the focus lies on the central question: to what extent can a system partnership between a provider and a medical device company can save costs and simultaneously improve the quality?

First of all, it is apparent that there is a need for change in the health care market (Squires, Anderson, 2015, w.s.). MACRA expresses these needs and tries to take a step toward a better functioning health care market. To accomplish this, providers have to leave old pattern of fee-for-service logic. MACRA is a law propels providers into value-based payment reform and therefore makes changes inevitable.

The providers also have to digitalize. This might be expensive at first, however, as soon as the provider gets used to it expenses can be saved. In a partnership, the medical device company may help the provider to acclimate to new devices and new technology, allowing providers to benefit from the profound knowledge of the device company. The medical device company is then able to develop the products and sell them to the provider. Naturally, the company has more detailed insight into the product than the provider. This insight can be communicated to the provider and customized to the specific requirements the provider requests. Both can benefit from economies of scale and the medical device company can profit from economies of scope as well. A medical device company usually has more than one provider with whom it collaborates. After the new technology is incorporated, the provider is highly likely to receive higher revenues under MACRA, under the condition that the medical device company provides EHR certified technology and the provider reports the performance categories correctly.

Research partnerships, especially, can play an integral part in quality improvement. The medical device company and the provider work together to scrutinize topics which can contribute to excellent patient care provision. For example, imaging techniques can be enhanced and the evaluation of images can be simplified for physicians. Consequently, the rate of misinterpreted images might decrease and thus might lower the rate of incorrect diagnoses. There may then be more satisfied and correctly treated patients, which is an indicator for high quality as well as value in the health care market. If there are less wrong diagnoses, there are fewer follow-up treatments, which also would lead to decreasing costs. As a further result, quality would be improved as well by decreasing unnecessary care. Additionally, medical device companies can use collected data to improve all their devices and develop new devices. Older technologies will be replaced through this process in the near future. Consequently, providers will be provided with better technologies and the medical device companies can market more products.

When the medical device company tackles the burden of inefficient processes by optimizing them, both partners can focus on their core activities. It is particularly important for providers to focus on their core capacity to revise actual treatments. This is required to have a competitive edge against other providers (Lohmann, Rippmann, 2014, p. 129). If a provider has established clinical pathways together with a medical device company, both better concentrate on the maximal performance. The medical device company supports the provider to implement the provider's ideas, expectations, and suggestions. Together, they are able to achieve state-of-the-art medicine and improve the quality of treatments dramatically. Additionally, both can improve their images. Hence, the medical device company will gain more customers and the provider more patients. Both benefit from an excellent status and thus can save costs through economies of scale, leading to a positive effect on their revenue as well.

Physicians in a system partnership focus more on medical outcomes because their partner releases them of incidental economic, technical, and organizational issues to a great extent. Also, nursing staff is disburdened from supplementary documentation obligations and other administrative tasks so they can concentrate more on patients. Through such a system partnership, resources are efficiently used and will be reimbursed to a greater extent by MACRA.

Another notable point is that medical device companies can support providers by building up a good data infrastructure. It simplifies data collection and data transfer to fulfill MACRA reporting requirements, which is likely to result in higher payments. Also, together they can evaluate the data better to review the number of mistakes made by each physician and create competition by rewarding physicians who made the least mistakes. This will also increase the quality of care and is an effective incentive to save costs from unnecessary follow-up treatments.

Additionally, if the provider receives all the required devices from the same medical device vendor, there is only one maintenance contract to negotiate. Consequently, the maintenance complexity is reduced and more standardization is achieved. Every device is similarly programmed and this leads to simplified usage for every physician. Now only one introduction from the medical device company is needed for the staff to explain how to use a device properly and in the best, fastest way. In general, standardization is essential for faster and more efficient working practice. Also, the reduced complexity of maintenance contracts saves time and resources. Fewer staff members are required to check the contracts with each individual device company and therefore costs are reduced.

However, only a functioning system partnership offers the advantages listed above. If a system partnership does not achieve this there are severe disadvantages which must always be kept in mind.

The many barriers to effective cooperation are seen as a negative aspect. Partners must compromise, a process which distracts the provider from focusing completely on providing health care. Also, medical device companies do not wish to cooperate with every provider. They mainly focus on larger health providers to get better outcomes. Smaller health providers do not have the scope the medical device companies want to reach with those partnerships. Additionally, the larger providers supervise a higher number of patients each day. If they can save costs through system partnerships, it will affect the health care economy more than if the medical device companies would only cooperate with smaller providers. Furthermore, larger providers have a higher negotiation level than smaller ones. They can achieve better conditions for the system partnership due to their size. More medical devices and technologies are needed in larger organizations and it is a greater challenge for the medical device company. Therefore, more costs can be avoided by the providers due to volume discount. However, the medical device company has a secure customer through the system partnership, who relies on its products and to whom it can sell more as an economic benefit despite the volume discount.

A major aspect of the partnership is the dependency between the provider and medical device company. Once a partnership is established, the provider is dependent on the medical device company. The provider needs to believe in the good intentions of the medical device company (KMU-, Krankenhausstudie 2000, 2000, pp. 94-100) and try to keep the possible dependencies as minimal as possible. This can be accomplished through customer-vendor relationships with other medical device companies. Along the same lines, the medical device company is prompted to reveal all its intentions so it is evident that the company does not want to exploit the provider. If such abuse took place, it would first lead to significantly higher costs for the provider and the system partnership would finally end in a collapse.

Nevertheless, the advantages of correctly aligned system partnerships between two parties outweigh the risks of a partnership not properly functioning. Even though it is expensive at first, innovation is necessary. Through this process, quality can be significantly increased and costs decreased due to modification of health care systems in the US through various system partnerships.

6 Conclusion

The health care market is a fast-changing market. MACRA takes a step in a new direction which has significant influence on how providers function. The need for change had been obvious before the law passed through Congress. MACRA now helps the health care market adjust faster to the new circumstances it faces. Providers are now required to change within the next couple of years. They have four years to align with the new payment models and become quality- and value-based providers. System partnerships between providers and medical device companies are a model which will support those

changes and help both parties perform at their best. Though smaller providers will not benefit as much from system partnerships now, they are expected to be attractive for medical device companies as well in a few years.

System partnerships facilitate the repositioning of providers to focus on their core competencies in order to improve medical outcomes. The medical device companies take burdens from providers and support them with technological knowledge and innovations. Clinical effectiveness and economics can significantly be improved through these partnerships as well, creating another benefit for both participants.

Already established partnerships demonstrate the huge advantages both sides have experienced from their system partnership. These also show the possible variety of partnerships. Every system partnership differs and the medical device company has to adjust to each provider. This process leads to creative and innovative solutions which exemplify how system partnerships benefit providers, medical device companies, and the health system as a whole, especially in the future. Therefore, this concept of system partnerships has to be further developed in order to minimize the risks and focus on the advantages.

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