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Value-Based Purchasing and Bundled Services/ Payments – Reconciling Interests of Participating Providers

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Introduction

With increasing pressure to do more with less, health care systems are continuing to focus efforts on finding innovative ways to increase quality while reducing costs. One ongoing trend is the movement toward innovative incentive payment models, including value-based care purchasing and bundled payment arrangements. The goal of such models is to achieve cost reductions based on a higher level of patient care coordination.

Despite 2017 bringing a fair amount of political uncertainty regarding the Centers for Medicare & Medicaid Services (CMS)'s commitment to value-based reimbursement and bundled payment arrangements, for the time being, it appears these alternative payment models are here to stay. The new Secretary of Health and Human Services (HHS), Alex Azar, has re-affirmed his support of value-based care. While the Trump Administration is not pursuing alternative payment models as ambitiously as the Obama administration, they are not backing away either – recognizing the need to continue cost reductions while moving away from strictly fee-for-service payment models. Additionally, we are seeing more commercial payors, employer self-funded plans and provider organizations continue to move forward with value-based payment models fueled by the incentives of the Affordable Care Act (ACA) for development of Accountable Care Organizations (ACO).

In this paper, we will look into how value-based care and alternative pricing arrangements are structured and discuss the options and challenges associated with potential risk sharing, legal and practical considerations.

1. Value-Based Contracting

Overview

Before we can discuss value-based contracting, we first must understand value-based programs. CMS describes value-based programs (VBP) as those which reward health care providers with incentive payments for the quality of care they give to people covered by Medicare. These programs focused on quality measures that affected provider reimbursement as part of achieving the three-part aim of better care for individuals; better health for populations and lower costs. Medicare's value-based programs focused initially on Hospital Value-Based Purchasing (HVBP), Hospital Readmission Reduction (HRR) Program, Value Modifier (VM) Program (also called the Physician Value-Based Modifier or PVBM) and the Hospital Acquired Conditions (HAC) Program. CMS subsequently added the End-Stage Renal Disease (ESRD) Quality Initiative Program, Skilled Nursing Facility Value-Based Program (SNFVBP) and Home Health Value Based Program (HHVBP.) In 2018, CMS reported that although VBP participation was reduced by almost 3%, more hospitals in the program received bonuses than penalties. For pay-for-performance arrangements, it was reported that for FY 2018, 53% of hospitals received bonuses while 43% faced reductions.[1]

[1] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-03.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

Contracting Considerations

The success of any VBR arrangement requires a constellation of many factors. These include a basic foundation based on shared goals and incentives as well as strong leadership and governance. There should be an assessment and careful preparation taking into consideration the following:

- Delivery service area and system infrastructure, resources, and contract scope
- Types of arrangements
- Capacity to assume risk
- Types of risk
- Strategy and contracting plan

Financial and operational assessments should be conducted to include:

- Capital requirements
- Unit Costing and tracking
- Financial/actuarial assessment and planning
- Contracting capabilities
- Data infrastructure and IT

The contracting process should include a credentialing and disclosure component that addresses:

- Initial questions
- Responsibilities and risk
- Financial impact
- Credit risk

Steps in the process should involve prioritizing clinically integrated systems of care to accelerate personalized care and move from an episodic to a managed care delivery model. One must know the network's capabilities including the clinician's ability to furnish high-quality, affordable, personalized care. There must be an infrastructure capable of managing the care and the cost that can transition from fee for service to fee for value by managing the total cost of care (i.e., full provider risk). Contracting strategy should consider both market and population. These are discussed in more detail in the section regarding bundled payments, below.

In moving to new payment models, physicians groups are looking for more predictable reimbursement, hospitals want models that can increase net reimbursement, particularly as more care moves to an ambulatory setting; payors want predictability about cost to help manage medical loss ratio; employers want simplification, lower cost, and convenience; and consumers want affordable, high quality options. Generally, value-based contracting includes payment methodologies where a portion of the provider's total potential payment is tied to a provider's performance on cost-efficiency and quality performance measures. This may include one or more of the following (i) a performance bonus based upon quality and cost; (ii) bundled or episodic payments; (iii) down-side risk or risk corridors with variable payment; (iv) capitation; (v) other similar arrangements or (vi) combinations of the above.

Understanding the Requirements

Physicians are the key decision makers in most phases of care, and finding an optimal network size with aligned, committed physicians is one of the biggest challenges to moving to a value-based care model. To effectively implement successful value-based contracting arrangements, providers will need to prioritize clinically integrated systems of care to accelerate personalized care. This can be a challenge where fee-for-service payment still largely rewards episodic care and not population health or a true managed care delivery model. To the extent though, that payors are willing to recognize and financially reward providers for managing the health of members or beneficiaries, providers will first need to be able to identify areas of high-cost. If payors are serious about delivering value-based care to their networks, then the payors should be cooperative in providing claims and other data. Where providers have developed an effective clinically integrated network, the physicians will need resources to help identify opportunities for cost reduction. In many cases, this will mean focusing on a smaller number of high cost patients to help manage matters such as medication compliance, routine physician visits, and in some cases identifying resources for other social factors that impact health.

Most providers struggle with access to timely data to target the high-need patients and high-cost areas for improvement. For this reason, both cooperation from payors and an investment in information systems infrastructure are key elements to successfully transition to value-based care. Although opportunities for collaboration exist with pay-for-performance value-based contracts even with less sophisticated tools, especially where providers are shielded from down-side risk, to move to arrangements with downside risk or even capitation, it will become increasingly important to have the right tools; including:

- Development of a clinically integrated network that is aligned financially to promote consistent evidence-based care and manage referrals within an efficient network;
- Ability to receive and analyze claims data;
- Access to timely data (not just retrospective information) about patients being managed and ability to respond appropriately to real-time feedback;
- Cooperation between providers and payors to create the right benefit design to steer patients into the best, personalized plans;
- Consistent, standardized metrics that will actually help deliver high quality efficient care without creating too much of an administrative burden for physicians (e.g. if every payor plan has different measurements, this will likely make care more difficult rather than more standardized);
- The personnel and information systems necessary to act on timely quality and cost data;

- A cross-disciplinary team to identify and implement the areas for improvement or opportunities (e.g. medical director, care management, actuarial support, financial modeling experts, leadership support, physicians, non-physician clinical providers, and sometimes even lawyers);

- Especially in cases where hospitals and physicians are cooperating on referral coordination and aligned financial incentives, sound policies and legal guidance to ensure compliance with Stark, the AKS statute, state insurance rules regarding risk, anti-trust, and other applicable regulations.

As will be discussed later in this paper, the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) has placed pressure on physicians to either consolidate into larger groups, sometimes bringing large physician practice management companies into the market who compete for large physician groups, or to join hospital-affiliated practices. MACRA also presents some interesting challenges for hospitals that try to navigate regulatory compliance (when the very methods being implemented impact future fair market valuations) associated with physician compensation.

2. Alternative Pricing Arrangements / Focus on Bundled Payment Arrangements

The Bundled Payments for Care Improvement initiative was developed by CMS's Innovation Center. The Innovation Center was created by the ACA to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care for beneficiaries. Since the creation of the Innovation Center, CMS has released a number of bundled payment initiatives – some mandatory.

However, in November 2017, under former Secretary Tom Price, HHS lifted the mandate that required providers to participate in bundled payment models for hip fractures, cardiac care and cardiac rehabilitation. Additionally, in 33 of the 67 selected geographic areas, CMS switched participation in the Comprehensive Care for Joint Replacement models from mandatory to voluntary. Then, in early January of this year, CMS announced a new *voluntary* episode payment model, Bundled Payments for Care Improvement Advanced (BPCI Advanced) that will test bundled payment for 32 Clinical Episodes beginning in October 2018.[2]

As such, although CMS, under the current administration, has moved away from making such payment arrangements mandatory we can still expect such arrangement to continue on a voluntary basis- for now.

i. Bundled Payments Overview

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[2] Rich Daly, Emerging Value-Based Payment Trends Transforming Health Care in 2018, HFMA.org, December 29, 2017, available at https://www.hfma.org/Content.aspx?id=57412

A bundled payment is a method of reimbursing a provider, or a group of providers, for the provision of multiple health care services associated with a defined episode of care.[3] Bundled payments allow government and commercial payors to reimburse providers for all the care a patient receives for a specific episode of care by one or multiple providers using one single predetermined payment amount. By structuring payment around an entire episode of care, bundled payments can lead to better care coordination, better outcomes for patients and a reduction of the cost of the services.

The first important initial step when designing a bundled care arrangement is to ascertain the organization's commitment and capacity to implement such an arrangement. Seeing that care redesign, data sharing, quality and risk sharing are all elements of a bundled care arrangement, it is important the organizational key leadership members are committed to such implementation of a bundled care payment arrangement.

Next, given that bundled payments are based on an episode of care, it is important to expressly define and understand all the different components of care and related services in the episode (e.g., hospital admissions, ambulatory care, pre and post care follow ups, and/ or pharmacy). The definition should also include the period of time covered by the bundled payment. The definition should take into account if certain patients are excluded as well as certain complications of care which might put the provider at additional risk. This analysis should include, at a minimum, a look at clinical guidelines treatment protocols and a consultation with providers.

It is crucial to have a financial understanding of what the treatment for the episode of care currently costs, further understand the outliers, and potential future cost increases in order to establish a baseline cost. This analysis should include, at a minimum, a look at historical reimbursement data as well as costs for the included supplies and equipment. Once the baseline is established, an organization can evaluate how its providers perform on cost and quality metrics with others and look into ways to reduce spend and increase quality of the services.

Additional considerations include how the other providers participating in the bundled payment will be identified and selected (e.g., does the arrangement include post-acute care providers such as a skilled nursing home); and if mechanisms are in place to allow provider to identify and confirm eligibility for targeted members.

Lastly, the importance of strong quality data monitoring measures cannot be understated. Providers with the best data tracking abilities are the ones that generally perform better and achieve higher cost savings.

ii. Incentive Payments

Providers may be awarded for meeting certain quality metrics through certain bonus payments built into the bundled payment contract. These measures can enable continued

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[3] CMS, *Bundled Payments for Care Improvement Initiative*, available at https://innovation.cms.gov/Files/x/Bundled-Payment-Request-for-Application.pdf and MITRE Corporation, Contracting for Bundled Payment https://www.mitre.org/sites/default/files/pdf/Contracting_Bundled_Payment.pdf (2012).

improvements in care. Organizations should understand quality measures and make sure such measures align with their intended purposes. The bundled payment arrangements/ contracts should also clearly articulate the quality measures needed for continued participation in such arrangement.

iii. Risk Sharing Considerations

Contracts should specify how the providers will bear the risk of loss, if at all. Depending on the structure of the bundled payment, plans and provider should also ask if the arrangement complies with state insurance laws for "risk-bearing" entities.

iv. Additional Legal Considerations

a. Antitrust Considerations

Antitrust law makes clear that a horizontal price fixing conspiracy – an agreement between competitors (who are not financially or clinically integrated) to fix prices at which they sell/deliver goods or services, or to maintain the market conditions so that the price is maintained at given level by controlling supply and demand - is per se illegal. Accordingly, if a group of unintegrated, competing physicians came together to set fixed prices with third party payors, they run the risk of such conduct being held per se illegal. However, according to Federal Trade Commission (FTC) and Department of Justice (DOJ) guidance, if the providers are financially or clinically integrated and the agreement is reasonably necessary to achieve procompetitive benefits of the integration, the agreement will be evaluated under the rule-of-reason. The FTC and DOJ have long realized that provider collaboration designed to promote quality and contain cost can greatly benefit health care consumers. CMS, *Bundled Payments for Care Improvement Initiative*, available at https://innovation.cms.gov/Files/x/Bundled-Payment-Request-for-Application.pdf [4]

Still, it is important to note that the effect of achieving clinical or financial integration does not guarantee antitrust law exemption; rather, it moves the conduct out a per se analysis into a rule-of-reason approach – meaning a detailed analysis of financial risk sharing, an examination into the resulting efficiencies and the cost-effectiveness of care, ensuring systems are in place to measure and monitor provider performance, and a detailed look into the which provider specialties comprise the network and the resulting market power is needed.

b. Fraud and Abuse Considerations

The framework of a bundled payment arrangement could implicate the physician self-referral law (the "Stark Law" or "Stark") and the Anti-Kickback Statute (AKS) if arranged in a certain manner.

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[4] Fed. Trade Comm'n & Dep't of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Saving Program, 76 Fed. Reg. 67026 (Oct. 28, 2011).

c. Data Sharing Considerations

In order for the bundled payment model to work effectively, a certain amount of data sharing between providers is required. As such, the current legal framework for accessing the data to be shared must be handled in compliance with current state and federal laws.

d. Medical Staff Considerations

Hospital relationship with physicians as members of the medical staff will be affected by the introduction of VBR and the quality-based reporting programs. New forms of relationships will create new practice standards and areas of dispute, some of which may flow into the traditional medical staff peer review and credentialing process. "Bad" doctors may not just be those who have a reportable action, but eventually include those who have "unacceptable" quality scores and lower performance than their colleagues. The use of quality information as a peer review tool has come under some scrutiny for which, in one case, was considered discoverable by the court despite efforts to claim state law privilege. [5]

e. Practical Considerations

Providers need sophisticated analytics to help them measure financial and quality performance for each patient population. They need to be able to measure performance on a continuous basis. Furthermore, if they aren't meeting quality standards, they need to be able to pinpoint the cause: Does performance differ by facility? Which providers are performing best and what can be learned from them? They don't want to learn that their reimbursement is going to be poor when it's too late to do anything about it.

Having the data systems capable of capturing, storing, analyzing and delivering the information necessary to implement alternate fee arrangements is a requirement for any effective VBR program. Many CIOs and hospitals struggle with how to access or use the information available to them. The major challenges to implementing a model for measuring performance in health care settings include: (i) identifying the sources of and acquiring the data; (ii) building and validating the evaluation model; (iii) implementing the model; and (iv) disseminating it throughout the organization. One of the major issues is the provider's ability to capture, track and report the required data. Does the practitioner have a HIPAA compliant system for managing health care data? Can the practitioner participate in the required audits? Does the provider even understand how to interpret the information they receive regarding performance? The type of information required to move from fee-for-service to value-based compensation requires the providers to:

- Understand their costs
- Understand how shared savings works
- Track quality measures
- Improve performance

[5] See IN RE: Memorial Hermann Hospital System; Memorial Hermann Physician Network; Michael Macris, M.D.; Michael Macris, M.D., P.A.; and Keith Alexander, Relators, NO. 14–0171. Decided: May 22, 2015

- Streamline operations
- Reduce waste
- Improve margins

According to a study by the American Academy of Family Physicians (AAFP), physicians surveyed reported that the main barriers to their effective participation were (a) lack of time; (b) unpredictable revenue stream; (c) understanding the complexity of the financial risk; and (d) lack of resources to report, validate and use data.[6]

3. MACRA/ MIPS[7]

In November of 2017, CMS published its second "final rule with comment period" implementing the MACRA. This second final rule sets forth new details, conditions and timelines for the physician payment changes that will follow from MACRA.[8] MACRA is the bipartisan legislation that repealed and replaced the unpopular sustainable growth rate ("SGR") formula for calculating annual Medicare payment changes for physicians. MACRA replaced the SGR formula with the Medicare Quality Payment Program or "QPP". The QPP provided two options for future clinician payments from Medicare: (i) participation in the Merit -Based Incentive Payment System or "MIPS"; or (ii) participation in one or more Alternative Payment Models or "APMs." Both options will transition clinicians away from traditional "volume-based" payment criteria to newer "value-based" payment criteria and assigns a positive, neutral, or negative payment adjustment accordingly.

i. Overview of MIPs

MIPS rolls existing Medicare Physician Fee Schedule payment programs into one budget-neutral pay-for-performance program that will score clinicians based on quality, advancing care information, improvement activities, and cost. Clinicians participating in MIPS will be subject to Medicare payment adjustments (which may be positive or negative) based on performance in four categories of measures: (i) quality, (ii) advancing care information, (iii) clinical practice improvement activities, and (iv) cost. MIPS is designed to provide incentives for quality and value improvements in healthcare delivery while maintaining Medicare budget neutrality. There will be both "winners" and "losers" under MIPS as a certain number of eligible clinicians will be subject to reimbursement reductions in order for others to achieve reimbursement enhancements. There is a two-year lag between the period during which MIPS performance data is collected (the "measurement period") and the period during which corresponding payment adjustments are made (the "payment period"). A physician or practice that fails to report data or whose reports suggest relatively poor performance during a measurement period will suffer the consequences two years later. Although reporting requirements and performance standards have been relaxed for the immediate measurement periods, CMS has said that for 2019 and beyond, the standards will be more stringent. This suggests that payment reductions may be looming for more

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[6] http://humananews.com/wp-content/uploads/2017/11/Data-Brief2017_Value-Base_FINAL4.pdf

[7] Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015 (MACRA), P.L. No. 114-10 (Apr. 16, 2015).

[8] The second final rule was published on November 16, 2017 at 82 FR 53568.

physicians beginning 2021 with a payment differential of up to 18% by 2022 (based on +/- 9% from a baseline).[9]

ii. Overview of APMs

Eligible clinicians may avoid participation in MIPS by participating in qualifying APMs. Qualifying APMs must meet specific criteria related to: (i) use of certified electronic health record technology ("CEHRT")[10] , (ii) payments conditioned on achievement of quality criteria that are comparable to the quality criteria in the quality performance category of MIPS[11] , and (iii) entity risk-bearing for poor performance and monetary losses.[12] Providers who participate in qualifying APMs may receive a 5% annual incentive bonus beginning in 2019, with potentially higher incentive payments later. However, achievement of these bonuses is likely to require some upfront expenditure – for example, expenditures for new IT, and/or for enhanced care management processes. One might reasonably speculate that the inevitable need for upfront investment may blunt the net economic benefit of the available incentive payments, at least initially. Moreover, participation in a qualifying APM (an "Advanced APM") requires downside risk in that payments must be subject to a minimum percentage reduction for failure to achieve benchmark standards, and more than a nominal portion of the risk of loss must be borne by participating clinicians in order for the clinicians to qualify for APM participation as an alternative to MIPS.[13] A physician could be affiliated with an entity that is intended to be a qualifying APM, but not experience sufficient volume in the alternative payment plan to gain exemption from MIPS. Thus, physicians who seek to participate in qualifying APMs could be penalized if they fail to meet the required standards.

iii. Regulatory Implications to Hospitals and Health Systems

The potential for dramatic changes in reimbursement poses some risk for hospitals and health systems that acquire practices and employ physicians. Recent False Claims Act litigation has focused attention on hospital losses from physician compensation as an indicator of inappropriate physician compensation, and specifically, as an indication of non-fair market value (FMV) and non-commercially reasonable compensation. Some qui tam plaintiffs have successfully argued that such losses are evidence of non-FMV, non-commercially reasonable compensation that fails the requirements of the Stark Law or implies violation of the AKS. If current litigation and enforcement trends continue, hospital-affiliated employers may face substantial financial risk if their employed physicians fail to meet the required benchmarks for full reimbursement under MACRA but their employment compensation does not adjust accordingly. Fixed rates of compensation per work relative value unit ("wRVU"), which were once considered a fairly safe bet for regulatory-compliant physician employment models, have the potential in the future to become fraught with risk.

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[9] See CMS, The Quality Payment Program.
[10] 81 Fed. Reg. 77408-9
[11] 81 Fed Reg. 77408
[12] 81 Fed. Reg. 77406, 77408
[13] 81 Fed. Reg. 77422.

The unintended consequence of MACRA to a hospital purchaser is that under the current regulatory enforcement environment, the financial impact of an acquisition involving a practice with poor or questionable economics might expose the purchaser to liability risk under the Stark Law, AKS Statute and/or False Claims Act, particularly if the FMV or commercial reasonableness of the transaction or subsequent physician compensation is not justifiable based on unanticipated losses associated with MACRA. The difficulty in projecting future revenue arises from both (i) uncertainty about the state of the market, and (ii) uncertainty about the performance of individual eligible providers under MIPS or their chosen APM.

The competing desires for economies of scale and mitigation of consolidation risk may increase interest and participation in clinically integrated networks ("CINs") and accountable care organizations ("ACOs"). Participation in a CIN or ACO may allow providers to share and spread the cost of IT, analytics and care management resources without transferring ownership or accountability for practice performance. However, participation in a CIN or ACO comes with its own set of financial questions, particularly for the hospitals, health systems and affiliates that already employ physicians and may be the primary owner and funding source for CIN or ACO operations. A CIN or ACO can be costly to establish and operate. Therefore, there is significant financial risk related to poor performance. Does this financial risk become a regulatory compliance risk if losses are not appropriately spread or accounted for in the CIN's or ACO's relationships with participating providers and/or in its revenue allocation and distribution plans? Is the risk allocation appropriate to allow the participating providers to qualify as APM participants under the MACRA final rule? Answers to such questions are intertwined with the answers to questions about what constitutes a commercially reasonable and FMV financial arrangement for a provider in the post-MACRA world. Unfortunately, hospitals often rely on compensation survey data that, at best, reflects information that is historical and was not developed with current MACRA in mind. To the extent that MACRA is changing or has changed the amount and under what conditions providers will be paid, currently-available survey data might not be the best basis to determine reasonable or FMV compensation for the post-MACRA era.

iv. Impact of MACRA on Physicians and Structure of Medical Practices

Physician practice expenses may increase under MACRA, related to investment in the infrastructure necessary to achieve the upside benefits of MIPS and APMs. Larger practices may have the most substantial expenditures, but may also have the benefit of being able to spread their costs over a greater number of revenue generators. Smaller practices with more limited purchasing power, including sole providers and small physician-owned groups, may find themselves without access to adequate infrastructure, particularly with respect to IT, and may be at a disadvantage in responding to the reimbursement changes. The most expensive of these items are an IT infrastructure (e.g., electronic health records and other tools to permit tracking, aggregation and analysis of data); and (ii) support systems to identify and plan necessary changes in practice patterns. Since Medicare is usually an important source of payment for physicians, certain types of specialties will be particularly affected (e.g. nephrology - renal disease, cardiology - heart disease and orthopedics - joint replacement). To the extent private payors follow Medicare, the economic impact may be significant.

Physician practice models have evolved and transformed several times in recent decades with increased consolidations, mergers and acquisitions and physician employment by hospitals or their affiliated organizations. The implementation of MACRA and associated reporting requirements will require an infrastructure to support the enhanced obligations that will materially affect physician compensation. The increased cost of compliance compels many independent physicians to consolidate or become hospital employees.

One of the newer forms of physician organization allowed by CMS and being established in response to MACRA is a "virtual group" that reflects "communities" of smaller practices. These groups have a single tax ID number (TIN), each contain 10 clinicians or less, and are rated for MIPS as if under a group sharing a single TIN. The challenge is in the details of governance and management.

Conclusion

While there are still many challenges in the transition from fee-for-service to value-based payment, increasing budgetary pressures from state and federal governments, consumer demand, advanced technologies, and employer/payor cost pressures will likely accelerate this trend over the next 5-10 years. With increasing consolidation within the healthcare industry, including new collaborations between providers, payors, pharmaceutical companies, and retail outlets, all stakeholders are likely to see increasing pressure to adapt to new payment models with more downward pressure on reimbursement. Whether the industry is ready or not, value-based payments will drive the success (or failure) of many within the healthcare sector.