New Wine in Old Wineskins: Mitigating Fraud and Abuse Risks in Value-Based Reimbursement

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Health care providers are facing rapid changes to health care payment and delivery models as the Centers for Medicare & Medicaid Services (CMS) shifts from fee-for-service to value-based payment methodologies. This shift poses unique fraud and abuse risks, particularly where fraud and abuse laws have not evolved to accommodate these new systems. Health care providers must understand and prepare for the new payment methodologies while taking steps to ensure that they are protected against risks from potential enforcement activities in this new era.

Background/Overview

CMS intends to move 50% of traditional fee-for-service Medicare payments to value-based alternative payment methodologies by the end of 2018. The agency met its interim goal, tying 30% of Medicare payments to alternative payment models by the end of 2016, ahead of schedule. Value-based payment models, at their core, aim to reward health care providers for the quality of care and efficiency of services provided, or achievement of cost reductions, rather than the volume of services. CMS anticipates that this move will encourage coordination of care leading to a more seamless approach to patient treatment across providers, which should improve the quality of care.

Quality measures and reimbursement were first linked through the Inpatient Quality Reporting (IQR) program, which was authorized by the 2003 Medicare Prescription Drug, Improvement, and Modernization Act and the Deficit Reduction Act of 2005. The IQR program requires hospitals to report on quality measures to receive annual payment updates.

The Patient Protection and Affordable Care Act (ACA) furthered the move toward value-based payment models and raised the financial stakes by providing for the establishment

of the Center for Medicare & Medicaid Innovation, which supports the development and testing of innovative payment and service delivery models. The ACA also created a number of new payment models, such as the voluntary Medicare Share Savings Program (MSSP). The MSSP allows eligible providers, hospitals, and suppliers to work together as part of an Accountable Care Organization (ACO) to manage and coordinate care for assigned Medicare fee-for-service beneficiaries. Participants may earn a share of the savings generated as a result of reducing the overall cost of providing care. Those electing to participate in a model with both upside and downside risk have the opportunity to share in a higher percentage of reduced Medicare spending. The MSSP encourages providers to create an integrated care model so that coordinated, quality care can be achieved at a reduced cost.

Congress further advanced delivery system reform with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA repealed the Medicare Sustainable Growth Rate[1] and replaced it with a new approach to payment called the Quality Payment Program (QPP), which rewards the quality, rather than volume, of care. According to CMS, the QPP aims to: (1) support care improvement by focusing on better outcomes for patients, decreasing provider burden, and preserving independent clinical practice; (2) promote adoption of alternative payment models that align incentives across health care stakeholders; and (3) advance existing efforts of delivery system reform, including ensuring a smooth transition to a new system that promotes high-quality, efficient care through unification of CMS legacy programs.[2]

The QPP applies to physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who bill Medicare more than $30,000 and see more than 100 Medicare beneficiaries per year.[3] It gives providers two options for participation based upon practice size, specialty, location, or patient population. These options are: the Merit-Based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (AMPs).

MIPS. Providers who elect to continue participation in traditional Medicare Part B will fall under the MIPS where they will earn a performance-based adjustment. MIPS currently consolidates key components of three existing programs, scheduled to end in 2018, to avoid redundancies. These programs are the Physician Quality Reporting System, the Physician Value-based Payment Modifier, and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals. MIPS will continue the focus on quality care, reduced costs, and use of certified EHR technology. MIPS will measure physician performance in the areas of quality, cost, clinical practice improvement, and advancing care information.

Starting in 2017, MIPS-eligible clinicians electing to participate must track and report data. CMS is offering a "Pick Your Pace" phase-in, allowing clinicians to submit minimum or partial amounts of data as they adjust to the QPP. The data will be measured against uniform standards established by CMS and used to generate clinician performance scores. MIPS-eligible clinicians are paid the traditional fee-for-service rate for Medicare Part B services they provide, but such payment is adjusted based off of the clinicians' composite performance score. For the first year (2019 payment adjustments based off of 2017 reporting data), CMS authorized up to a 4% negative payment adjustment and up to a 4% positive payment adjustment.

Advanced APMs. Providers participating in an Advanced APM through Medicare Part B are eligible for incentive payments for participating in an innovative payment model. Available payments are higher than those available through MIPS. Eligible clinicians wanting to participate in Advanced APMs must become Qualifying APM Participants (QPs) to earn incentive payments for their Advanced APM participation; simply participating in any alternative payment model does not qualify providers for such Advanced APM incentive payments. The MACRA Final Rule finalized two types of Advanced APMs: Advanced APMs and Other Payer Advanced APMs, the latter involving a payer such as Medicaid or a commercial insurer. CMS established the following criteria, applicable to both types of Advanced APMs: (1) requires participants to use certified EHR technology; (2) provides payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and (3) requires that participating entities bear more than a nominal amount of risk for monetary losses. QPs participating in Advanced APMs assume more accountability and risk for the cost and quality of care, but receive potentially higher incentive payments for doing so.

Under the Advanced APM track, QPs that receive 25% of Medicare payments or see 20% of their Medicare patients though an Advanced APM in 2017 will earn a 5% incentive payment in 2019. Advanced APMs currently available include specialties such as end stage renal disease, oncology, and primary care as well as shared savings programs. Additional models will be added in future years.

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Fraud and Abuse Compliance

Historically, the federal fraud and abuse laws, such as the physician self-referral law, or Stark Law,[4] Anti-Kickback Statute (AKS),[5] and Civil Monetary Penalty (CMP) laws prohibiting beneficiary inducements[6] (collectively, Fraud and Abuse Laws), led to increased scrutiny when health care providers work together or offer incentives to patients related to their care. In the traditional fee-for-service payment model, a collaborative arrangement could pose risks of overutilization or improper cross-referrals. Thus, providers who partnered together did so at their own risk if a regulatory or whistleblower later judged the collaboration to be an improper referral arrangement. The new value-based methodologies, however, can only achieve the desired quality and cost savings with coordination of care among providers.

To address the inconsistency between the Fraud and Abuse Laws and the move to value-based payments, and as required by the ACA to allow the arrangements envisioned by the MSSPs, CMS and the Office of Inspector General (OIG) established a number of waivers: Pre-Participation, Participation, Shared Savings Distribution, Stark Compliance, and Patient Incentive.[7] These waivers provide an additional avenue, beyond the existing Stark exceptions and AKS safe harbors, to structure an arrangement envisioned by the MSSP. The waivers generally function like AKS safe harbors in that the arrangement is protected if all the waiver's conditions are satisfied.

While the above waivers provide flexibility to achieve compliance under the new payment methodologies, they also add new requirements that must be met to ensure ongoing compliance and require detailed tracking of the activities among providers. Additionally, the waivers do not obviate the need to comply with basic requirements, such as ensuring arrangements are at fair market value (FMV) and commercially reasonable under the Fraud and Abuse Laws. Failure to comply with these laws could lead to massive damages and penalties, particularly under the False Claims Act (FCA).

As new payment models are increasingly employed, FCA theories of liability will be applied and adapted to these models. For example, if a provider certifies that it achieved certain quality metrics to obtain incentive payments, but that certification is found to be knowingly false, a relator or the government could seek to hold the provider liable under the FCA.[8] The greater the proliferation of attestations needed in connection with the submission of quality data, the more ways that plaintiffs can challenge the correctness of those attestations. Even if the total incentive payments received are not significant, providers still could be subject to substantial penalties if a plaintiff could show that providers were seeking the payments on a per-claim basis.

Plaintiffs could seek to use quality measures to bolster so-called "quality of care" cases brought pursuant to the FCA that seek to hold providers liable for substandard care. Most courts have held that the FCA cannot be used to pursue low quality of care unless the care was of such poor quality to amount to worthless or no services at all.[9] However, to the extent that quality measures come to be identified with federally defined standards of care, a relator or the government could seek to hold providers liable for submission of false claims for knowing failure to meet those standards of care.[10]

As a final example, although MACRA narrowed the scope of the gainsharing CMP to apply only to payments to reduce or limit medically necessary services, as value-based payment methodologies encourage providers to seek ways to provide services more efficiently, plaintiffs also may argue that underutilization or inappropriate utilization gives rise to FCA liability.

Ensuring Ongoing Compliance

The overall goal of the new payment methodologies is to provide higher quality care in a more efficient manner. While consistent with the mission statements of most health care organizations, operationalizing this goal is a huge undertaking that requires careful and continuous oversight. As the predefined metrics have more impact on a provider's reimbursement and reputation, one of the biggest challenges is driving meaningful change in patient care within each program's metrics while also creating a supportive work environment. This challenge can be met with close collaboration among various stakeholders in the organization.

Collaboration among stakeholders is vital in ensuring that the quality metrics can be supported through required documentation. Gathering the raw data is in itself a monumental task, especially as each program's metrics continue to evolve. But, the nature of these programmatic metrics, including their specificity and potential impact on reputation, add additional importance to tracking and decoding the metrics and turning them into actionable work plans. To support a provider participating in a value-based payment methodology, the various stakeholders can consider establishing a working group and scheduling periodic meetings to monitor performance.

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Working group participants can include representatives from quality, compliance, health information, informatics, clinical care, patient engagement, finance, and legal. This working group can be involved in choosing metrics, understanding best case scenarios, and planning for worst case scenarios. After metrics are selected, an individual or department should be designated as responsible for the components of each metric and should develop a plan for monitoring progress. Clearly defining areas of responsibility offers accountability while day-to-day operations continue.

Collaboration among departments also helps a health care organization provide periodic education to its staff on various value-based programs and their requirements. These training opportunities are particularly important in large organizations where defined groups of individuals play distinct roles in each value-based program. For example, certain organizations participating in the Oncology Care Model (OCM) have obtained permission from CMS to provide incentives to patients within the program framework. Establishing appropriate guardrails related to the program is necessary to protect against individuals in adjacent departments informally "adopting" aspects of the OCM, such as the provision of patient incentives. Even with periodic education, ensuring appropriate oversight of these programs and all operations is critical, particularly because few people outside of the specific program will understand the specific requirements related to that program.

Allocating savings and penalties from the various programs also requires close collaboration, particularly where departments evolve and clinicians move from facility to facility. Because the payment adjustments often lag months or years behind the submission of data, it may sometimes appear that individuals or groups are benefiting from work performed by others while some are being penalized for work others failed to perform. Ensuring that the organization communicates a specific, consistent (and transparent) approach in advance of payment is crucial to organizational success.

New compliance challenges will inevitably arise in this changing payment and delivery landscape. In-house counsel must not lose sight of the core tenets of any health care arrangement: FMV and commercial reasonableness. Each arrangement should continue to be evaluated independently to ensure that payments are made for needed services. Each arrangement also should be evaluated as part of a big-picture analysis of all inter-related relationships to ensure that increased alignment and collaboration are for appropriate reasons. For new or unique arrangements and transactions, consider obtaining an independent FMV appraisal—especially when data is lacking or it is difficult to apply existing data. Thorough documentation of an arrangement's purposes is crucial, as the burden of establishing FMV continues to be borne by the parties to that arrangement.

The payment and delivery shifts also require parallel shifts in internal monitoring. Historically, compliance and quality assurance departments may not have been involved in each other's respective auditing programs, but the coming overlap will require creation of increasingly cohesive programs. Quality should be included as a compliance audit metric, with measurable benchmarks and targets. Additionally, validation of the statements made as part of payment program attestations should be considered to ensure that all attestations are accurate and supported by underlying documentation. C

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Endnotes

1 The Medicare Sustainable Growth Rate (SGR) was a formula used to calculate Medicare payments under the Medical physician fee schedule. Introduced in 1997, the SGR aimed to curtail Medicare costs. It used the Gross Domestic Product (GDP) to set a growth rate for target Medicare expenditures. Under the SGR formula, if overall physician costs exceeded the SGR target, there would be reductions in payments. While the cuts were blocked each year by Congress, this caused great uncertainty in physician payments year to year and did not account for the value or quality of services provided. With the SGR's repeal, MACRA ended these large cuts and helped shift the focus toward value-based payment methodologies.

2 Center for Medicare and Medicaid Services, *Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models*, 81 Fed. Reg. 77008 (Nov. 11, 2016).

3 *Id.*

4 The federal physician self-referral law, commonly referred to as the Stark Law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies. 42 U.S.C. § 1395nn.

5 The AKS is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce or reward the referral of federal health care program business. 42 U.S.C. § 1320a-7b.

6 42 U.S.C. § 1320a-7a(a)(5).

7 (1) Pre-participation Waiver applies to the establishment of an ACO and include activities such as infrastructure and creation, network and management, mechanisms for care coordination, clinical management or quality improvement, staff hiring, information technology, training costs and capital investments; (2) Participation Waiver relates to arrangements entered into by and among ACOs and their participants, providers and suppliers and includes activities such as investment, initiation of operations, and ongoing operations; (3) Shared Savings Distribution Waiver relates to distributions of shared savings earned by an ACO and protects arrangements created by the distribution of shared savings within an ACO and for payment of shared savings to parties outside the ACO; (4) Stark Compliance Waiver waives the need to separately analyze compliance under the AKS if the arrangement qualifies under an applicable Stark exception; and (5) Patient Incentive Waiver allows ACOs and its participants and providers and suppliers to provide beneficiaries with free or below market items and services to advance preventive care, adherence to treatment, drug or follow-up care, or management of chronic conditions. CMS, *Medicare Program; Final Waivers in Connection With the Shared Savings Program*; Final Rule, 80 Fed. Reg. 66727 (Oct. 29, 2015).

8 *See Univ. Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016) (discussing FCA false certification liability).

9 *See, e.g., United States ex rel. Absher v. Momence Meadows Nursing Ctr.*, Inc., 764 F.3d 699 (7th. Cir. 2014).

10 *See United States v. Villaspring Health Care Ctr., Inc.,* 2011 WL 6337455, *5 (E.D. Ky. Dec. 19, 2011) (when alleging claims for worthless services, "[i]t is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that 'patients were not provided the quality of care' which meets the statutory standard").