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2021 Offers New Opportunities Amid Healthcare Regulation Changes

2021 Updates to the Stark Law, Anti-Kickback Statute, and Medicare Physician Fee Schedule

By Richard Romero, CVA, ABV, CHFP, PAHM, and Amit Payan, CPA/ABV

RICHARD ROMERO, CVA, ABV, CHFP, PAHM
Senior Vice President

Richard Romero is a senior vice president at Coker Group. His practice focuses on valuation of financial arrangements and businesses, hospital and physician integration, regulatory compliance and litigation support. Richard has over 20 years of previous experience with regulatory compliance, valuation and litigation support.

AMIT PAYAN, CPA/ABV
Vice President

Amit Payan is a vice president at Coker Group. He has over ten years of experience in leading valuations of business enterprises and a variety of clinical and administrative compensation arrangements. His healthcare financial acumen helps clients understand the how and why of conclusions to make informed decisions about fair and defensible agreements at a time of evolving regulatory industry requirements.

The transition from 2020 to 2021 brought with it several changes to the healthcare marketplace. New final rules for the Physician Self-Referral Law (Stark Law) and the Anti-Kickback Statute (AKS) have provided significant flexibility for the healthcare industry to develop new business models to care for patients. The 2021 Medicare Physician Fee Schedule (MPFS) saw the Centers for Medicare and Medicaid Services (CMS) finalize new coding provisions for outpatient evaluation and management codes while reducing the conversion factor used to calculate reimbursement paid under the MPFS. These changes provide a significant opportunity for industry participants while also introducing new complexity. Understanding these changes and how they will impact your organization is key to a successful future.

Value-Based Changes

CMS and the Office of Inspector General (OIG) undertook a highly coordinated effort to reframe regulatory guidelines impacting healthcare service delivery. In addition to new models, they changed key definitions and took the opportunity to restate the long-standing views on various policies. As such, it is essential to be aware of specific definition changes.

In summary, the regulations now allow for the creation of Value-Based Enterprises (VBE) comprised of at least two VBE Participants. The VBE must engage in at least one Value-Based Activity within a Value-Based Arrangement to fulfill a Value-Based Purpose for a Target Patient Population.[1]

Each of the above terms has a specific definition and requirements under these regulations. The key takeaway is that regulatory authorities have attempted to pave the way for innovating new and creative patient care models.

The exceptions and safe harbors under these regulations also consider the level of risk an entity undertakes. The greater risk assumed by an entity, the less stringent the exception or safe harbor requirements. If no risk is assumed, the arrangement may still be subject to fair market value (FMV) requirements. An organization should thoughtfully consider how much risk they are comfortably and operationally capable of bearing.

The new regulations also require the selection of outcome measures to assess performance. If a VBE identifies that it will not succeed in reaching the outcome measures target, it has the responsibility to terminate the VBE or update the measures.[2] Both regulations require monitoring of the arrangements, although the review period varies between the regulations. The outcome measures should be chosen carefully. Additionally, a plan for monitoring performance against those measures should be developed fully. As with all quality and performance assessments, the availability and consistent reporting capability of that data are necessary.

Key Definitional Changes

CMS provided some formal definitions and significantly changed others. One fundamental change is the removal of the volume or value requirement from the definition of FMV. Generally, an arrangement only takes into account the volume or value of referrals if referrals are included in, or can be expressed by, an equation used to calculate remuneration. Hopefully, the definitional change will provide bright-line guidance.

The definition of FMV was changed significantly. FMV was divided into three subjections, and the first, General Market Value, is further subdivided into categories of what is being valued. We repeat the definition below:[3]

1 CMS, "MEDICARE PROGRAM; MODERNIZING AND CLARIFYING THE PHYSICIAN SELF-REFERRAL REGULATIONS" 85 FR 77492, (DECEMBER 2, 2020): 77495, HTTPS://WWW.FEDERALREGISTER.GOV/D/2020-26140/P-33.

2 NOTE THE REQUIREMENTS UNDER THE STARK LAW AND AKS STATUTE ARE NOT IDENTICAL. IF CHANGES NEED TO BE MADE, ENTITIES SHOULD CAREFULLY REVIEW THE REQUIREMENTS, INCLUDING TIMING FOR UPDATES, CHANGES OR TERMINATIONS, UNDER EACH REGULATION.

3 CMS, "MEDICARE PROGRAM; MODERNIZING AND CLARIFYING THE PHYSICIAN SELF-REFERRAL REGULATIONS" 85 FR 77492, (DECEMBER 2, 2020): 77658, HTTPS://WWW.FEDERALREGISTER.GOV/DOCUMENTS/2020/12/02/2020-26140/MEDICARE-PROGRAM-MODERNIZING-AND-CLARIFYING-THE-PHYSICIAN-SELF-REFERRAL-REGULATIONS.

Fair market value means—

(1) ***General.*** The value in an arm's-length transaction, consistent with the general market value of the subject transaction.

(2) ***Rental of equipment.*** With respect to the rental of equipment, the value in an arm's length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) ***Rental of office space.*** With respect to the rental of office space, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) ***Assets.*** With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) ***Compensation.*** With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) ***Rental of equipment or office space.*** With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

It is interesting to note that even while the definition of FMV was updated, some new exceptions are not required to meet the above FMV standard. However, these arrangements must still be considered Commercially Reasonable (CR) as defined below.[4]

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Industry participants recommend that even if an exception or safe harbor does not explicitly require compliance with the FMV or CR standards, remuneration should still be reasonable. The new regulatory framework was not created to increase remuneration in ways that skirt the prior regulations.

Another key change was made to the group practice definition, and the change was delayed a year to allow the industry to adjust compensation plans to the new definition. CMS highlighted the inappropriate use of the isolated transaction exception[5] for remuneration. If your entity has relied on inappropriate use of the exception or providers received reimbursement based on it, you should carefully review the situation. Consistent use of the exception indicates the organization should design and implement an updated and appropriate compensation plan. However, if the total remuneration is under $5,000, a new exception may be available for use.[6]

4 IBID.
5 IBID.
6 IBID.

Notable Changes in the MPFS

On December 1, 2020, CMS issued their Final Rule for the 2021 MPFS. The implication of the Final Rule is an overall increase to the relative value units (RVUs) primarily associated with Evaluation and Management (E/M) CPT codes and a decrease to the conversion factor used to convert those RVUs into reimbursement amounts due to budget neutrality requirements.

CMS subsequently updated the 2021 MPFS Final Rule after a COVID-19 stimulus package was included within the Consolidated Appropriations Act, 2021 (CRA) signed by President Trump on December 27, 2020. The CRA included provisions that updated the 2021 MPFS Final Rule, such as:[7]

- $3 billion that funds a 3.75 percent increase in 2021 PFS payments for all providers to "…support physicians and other professionals in adjusting to changes in payment for physicians' services during 2021…"
- Suspension of the 2.00 percent sequestration adjustment through March 31, 2021.
- Increased payments for the work component of physician fees in areas where the labor cost is determined to be lower than the national average through December 31, 2023, by reinstating the 1.0 floor on the work Geographic Practice Cost Index.
- Delaying the implementation of the inherent complexity add-on E/M code G2211 until January 1, 2024.

The CRA largely mitigated budget neutrality cuts originally contemplated within the 2021 MPFS Final Rule, though changes to RVUs are

7 "CONSOLIDATED APPROPRIATIONS ACT, 2021," 116 CONGRESS OF THE U.S., ACCESSED MARCH 8, 2021, HTTPS://WWW.CONGRESS.GOV/116/BILLS/HR133/BILLS-116HR133ENR.PDF.

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still effective for 2021. Given the predominant fee-for-service environment within the U.S. healthcare industry, organizations that employ physicians and advanced practice providers tend to utilize work RVUs (wRVUs) to derive provider compensation. Thus, the revised 2021 MPFS Final Rule may presage a significant increase to provider compensation vis-à-vis the E/M RVU increases.

Over the last few years, virtually all organizations have felt the pressure of decreasing reimbursement and increasing operational challenges. The 2021 E/M changes increase the complexity of these challenges by impacting key revenue (e.g., reimbursement) and expense (e.g., provider compensation) drivers.

On the revenue side, leaders contemplate ways to use the E/M updates to their advantage and how best to avoid precipitous revenue decline. The simple answer is that it depends on the specialty mix. Specialties with a high focus on procedures and hospital-based specialties (e.g., radiology, anesthesiology) are expected to experience the most significant negative impact. In contrast, specialties focused on office visits (e.g., endocrinology, family practice) are expected to experience the most significant positive impact.

On the expense side, provider compensation is unsurprisingly the most considerable expense for organizations. The vast majority of employed/aligned providers are on a wRVU-based compensation plan. These providers will still see an increase in compensation due to the increase in all office-based E/M code wRVUs, assuming that their employing organization has not yet adjusted the conversion factor.

Organizations have historically relied on survey data as the primary means to set provider compensation. Over the last few years, compensation increases observed from survey data did not correlate with historical reimbursement changes. With the 2021 E/M changes, the gap between physician compensation and flat reimbursement will be even more pronounced. As such, organizations need to consider the financial ramifications of the conversion factor changes on a specialty-by-specialty basis, thus reducing blind reliance on setting compensation based on survey data that may not be relevant to their situation (brought on by their unique specialty mix and existing compensation structure).

Because of the 2021 RVU changes and 2022 payment uncertainties, Coker recommends organizations adopt a three-step call to action:

1. Freeze physician wRVU payment rates at 2020 levels and take time to analyze the situation.
2. Run CPT level scenario projections to understand top-line revenue changes and the associated physician compensation impact.
3. Review the results, weigh the alternatives, and implement a plan. Select the appropriate course of action and move forward with implementation. Proactively communicate the plan with your physicians and administrators.

New Opportunities

Several trends suggest potential substantial changes to how care will be provided in the near- and longer-term future. The flexibility offered by recent regulatory changes, CMS's public statements about increasing care in the home, and support for virtual care suggest fertile ground for innovation and improved care. As technology such as remote patient monitoring develops and artificial intelligence is applied in new ways to improve care for patients, historical operations and care pathways may be fundamentally changed. Focused technology along with expanded communication infrastructure may also facilitate at least partial mitigation of access inequity.

As models, reimbursement, and regulations change, your opportunities are also opportunities for your competitors, increasing your organization's risk. Analyzing and understanding the risks and opportunities to provide care in new and innovative ways while appropriately availing yourself of new opportunities will be imperative to future success.

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Do you have questions about the new regulations?

Request a call with Richard or Amit to discuss your situation.