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CMS Completes Sprint to Modernize the Stark Law-Part III

Joan Polacheck, McDermott Will & Emery LLP
Charles Buck, McDermott Will & Emery LLP
Troy Barsky, Crowell & Moring LLP

The Centers for Medicare & Medicaid Services (CMS) published its much-anticipated final Stark rule in the December 2, 2020 *Federal Register*, finalizing the most extensive changes to Stark regulations since the final Stark II rulemaking in the 2000s (the Final Rule).[1] Due to the extraordinary length and complexity of the Final Rule, this is Part III of a three-part series. Part I was published in the January 2021 issue of *Health Law Connections* and focused on CMS' new "volume or value of referrals" and "volume or value of other business generated" definitions, CMS' new approach to directed or required referrals in physician employment and personal services arrangements, and the new "indirect compensation arrangement" definition. Part II was published in the February 2021 issue and covered the new value-based arrangement exceptions. This final installment discusses CMS' new "commercially reasonable" definition and its revised "fair market value" (FMV) definition.

The New "Commercially Reasonable" Definition

The Stark Law's commercial reasonableness standard has never been defined by statute or regulation. The Final Rule now defines "commercially reasonable" to mean "*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.*"[2] The regulatory definition also provides that "*[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties*."[3] Notably, all Stark compensation exceptions, except the value-based arrangement exceptions, that have a "commercially reasonable" element require that the compensation to the physician (or immediate family member) be paid pursuant to an arrangement that would be commercially reasonable (as defined above) *even if there were no referrals by the physician to the employer or between the parties*. This accompanying clause is in the employment, FMV,[4] isolated transaction, space lease, equipment lease, and indirect compensation exceptions, as well as the new exception for "limited remuneration to a physician."[5]

CMS acknowledges that the new definition of "commercially reasonable" is not applicable to the personal services exception because the term does not appear in the exception.[6] Of course, the requirements that "the aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s)," along with other requirements of the exception, result in a similar analysis.[7]

While in the Final Rule CMS declined to give examples of arrangements that may be commercially reasonable, the preamble discussion of the following three elements is instructive.

First, in certain False Claims Act cases predicated on alleged Stark violations, plaintiffs have argued that, absent a justifying explanation, compensating a physician for clinical services at a rate that is not supported by charges and collections for the clinical services, i.e., incurring a financial "loss" on the physician services arrangement, supports a reasonable inference that the arrangement is not commercially reasonable. Therefore, the explicit statement in the definition that an arrangement may be commercially reasonable even if not profitable is extremely helpful. However, while an arrangement with a physician does not necessarily need to be profitable for the entity to satisfy the commercial reasonableness standard, *the economics of the arrangement remain relevant to the analysis of whether the arrangement would be commercially reasonable even if the physician made no referrals to the employer*.[8] CMS recognizes there can be legitimate reasons why an employer would pay a physician-employee more in compensation than the employer's collections from the physician's services will support. However, CMS maintains that medical practice "losses" incurred and tolerated by a health system remain a relevant factor when analyzing an arrangement for commercial reasonableness.[9] Therefore, it is still important to be able to articulate a legitimate business purpose, particularly where the arrangement results in a loss. CMS identifies the following examples of reasons parties might enter into an arrangement involving a loss on clinical services: "community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes."[10]

Second, what has made the "commercially reasonable" standard controversial and ambiguous in application is that accompanying regulatory text includes "even if no referrals were made between the parties." CMS clarifies that the reference to "even if no referrals were made [to the employer] or between the parties" means *designated health services* (*DHS) (Medicare-covered) referrals*, not "other business generated."[11] This is helpful because, if "referrals" is not limited to DHS referrals, it would be difficult to justify arrangements where the very nature of the arrangement makes sense only if there is some level of business generated between the parties. Interestingly, this guidance implies that "other business generated" could be the basis for concluding that an arrangement is commercially reasonable, although we caution that CMS does not state this directly and any such justification of commercial reasonableness could raise other material compliance concerns, including with respect the "legitimate business purpose" requirement discussed below.

Third, CMS indicates that the requirement that an arrangement *furthers a legitimate business purpose* of the parties is not met *if the arrangement violates federal or state law*.[12] Violation of federal or state anti-kickback laws likely would be the primary reason that an arrangement between a DHS entity and physician would violate federal or state

law. Therefore, the commercial reasonableness definition appears to incorporate a requirement of complying with federal and state anti-kickback laws. While perhaps not surprising, this interpretation of the "legitimate business purpose" element of the commercial reasonableness definition reflects that, despite efforts to make the Stark requirements clear cut, a commercial reasonableness determination is still subject to an intent-based facts and circumstances analysis.

New "Fair Market Value" and "General Market Value" Definitions

The Stark statute defines "fair market value" as the value in arm's-length transactions, consistent with the *general market value* and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account intended use), not adjusted 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 referral source.[13]

In regulations, CMS added text to the above FMV definition noting that "usually" the fair market price or compensation is what has been paid in comparable, *bona fide* transactions where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.[14] In the Final Rule, CMS deleted this text to clarify that the "fair market value" and "volume or value" are wholly independent standards. The Final Rule made other changes as well, giving equipment and office space rentals their own FMV definition:

(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 referral source for the lessee, and consistent with the *general market value* of the transaction.[15]

CMS also redefines "general market value" (GMV) in the Final Rule, giving each of three types of transactions its own definition, as set forth below.

"General market value means—

(1) Assets. With respect to the purchase of an asset, the price that an asset would bring 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 a 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.

(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.[16]

Although CMS initially proposed to redefine "general market value" to mean "market value," as that term is used in the valuation community, CMS retracted this idea in the Final Rule. CMS also dropped the idea of conceiving "fair market value" as the value in hypothetical transactions and "general market value" as the value in an actual transaction and declined to create a fair market value "safe harbor," such as any compensation under the 75th percentile of the physician compensation surveys. CMS also declined even to consider giving DHS entities a rebuttable presumption of FMV.

Most of CMS' preamble commentary in the Final Rule is focused on making two points. First, although "fair market value" is independent of the "volume or value" requirement, CMS discusses, at length, its policy that the GMV is inconsistent with any consideration of other business the actual parties to the transaction may have with one another. CMS makes this point most emphatically as follows: "Compensation to or from a physician should not be inflated or reduced simply because the entity paying or receiving the compensation values the referrals or other business that the physician may generate more than a different potential buyer of the item or services. This means that the hospital may not value a physician's services at a higher rate than a private equity investor or another physician practice simply because the hospital could bill for designated health services referred by the physician . . . ."[17]

To implement this policy, CMS restructured its proposed definition of "general market value" to focus on the price or compensation that would be paid at that time as a result of *bona fide* bargaining between well-informed parties "that are not otherwise in a position to generate business for each other."

CMS does not explain where the industry can find what parties "that are not in a position to generate business for the other" would pay under these hypothetical circumstances. The physician compensation survey data largely comes from health system and hospital employers of physicians. Even group practices reporting compensation data report

compensation to physicians in a position to refer patients to other physicians in the group, e.g., general or clinical cardiologists hired by a group of invasive and interventional cardiologists, or in a position to grow the group practice's ancillary business. CMS has clearly not ruled out the market approach to valuation, but it is hard to see how to reconcile use of current market data with the "not in a position to generate business for each other" element of the GMV definition.

This brings us to CMS' second key point: FMV compensation for physician services is not necessarily what the physician compensation survey data would dictate. As the agency states, "It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases."[18] Further, CMS expressly disavowed having any policy that compensation set at or below the 75th percentile of the physician compensation survey data is always appropriate, and that compensation above the 75th percentile is "suspect, if not presumed inappropriate."[19]

Although CMS abandoned its proposed distinction between "hypothetical" and "actual" transactions, it still affirms the examples it gave in the proposed rule illustrating how the physician compensation survey data may not reflect the fair market value in an actual transaction. Each example is discussed below.

Orthopedic Surgeon Compensation Example. In this example, a hospital is negotiating employment compensation with an orthopedic surgeon. The survey data indicates that $450,000 per year would be "appropriate." However, the surgeon is a "superstar," sought after by professional athletes with knee injuries. CMS concludes that, in this case, compensation substantially higher than $450,000 per year "may be fair market value."[20] It is certainly true that there are "superstar" physicians with affluent patients willing to pay "top-dollar" out-of-pocket for their treatment. However, patient volumes funded by conventional insurance still matter to both the surgeon and her employer. For every professional athlete or other affluent patient, there are going to be many more high school athletes, college athletes, and "weekend warriors" where the "superstar" is reimbursed by conventional insurance products and out-of-pocket cost sharing (i.e., reimbursed substantially the same as a non-superstar). Thus, while the employer's cost of paying extraordinary compensation, coupled with the cost of the surgeon's highly skilled clinical support staff, might possibly be covered by the employer's receipts from the surgeon's professional services, it may not, and in some cases the gap could be significant. In that case, the employer appears to have accounted for the surgeon's referral value, contrary to CMS' policy as stated in the preamble. CMS' point that the compensation surveys do not control determinations of FMV is helpful, but to suggest that extraordinary compensation levels for "superstar" surgeons is solely a function of how talented or skilled these surgeons are is arguably misleading and ignores the "elephant in the room," which is the ability of these superstars to generate significant facility fees.

Rural Family Physician Example. In this example, a hospital is negotiating the compensation of a family practice physician. Compensation surveys indicate an annual

salary of $250,000 is "appropriate." The cost of living for the local area is low, with good schools and "desirable recreation opportunities." Further, "due to declining reimbursement rates and a somewhat poor payor mix, the hospital's financial position is tenuous." In these circumstances, CMS states: "the fair market value of the physician's compensation may be less than $250,000 per year."[21] In a contrasting example, a "commenter requested that . . . [CMS] acknowledge that there are other factors that may justify higher levels of compensation rates for physician services in markets that may have relatively low cost of living standards due to market supply and demand."[22] CMS agreed with the commenter, "especially where there is a compelling need for the physician's services."[23]

It is undoubtedly helpful that CMS has expressly rejected the idea that the "survey says" approach to valuation is the last word on fair market value. There are also the income and cost approaches to valuation, and valuators are supposed to at least consider all of them.[24] Moreover, if valuators gave any weight to the income approach, practice "losses" (not warranted for benign reasons) would go down.[25] However, to have a *Medicare payment rule* like the Stark Law that holds every non-group practice employer in the country to a fair market value standard, without at least giving them a rebuttable presumption of FMV or a reasonable "safe harbor," leaves such employers with some amount of FMV risk or the costly alternative of independent, third-party valuations.

In revising these important Stark Law definitions, CMS attempted to create brighter lines between compliant and non-compliant arrangements. Overall, we believe that they succeeded in moving closer to that goal. Yet, as demonstrated in both the commercial reasonableness definition and the revised definition of FMV, CMS did not completely reach their desired outcome. Because of the strict penalties under the Stark Law, as well as the ever-present False Claims Act risk for failure to meet the exact standards under the Stark Law exceptions, CMS (or Congress) still has more work to do in the years ahead to provide greater regulatory (or statutory) clarity.

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1 85 Fed. Reg. 77492 (Dec. 2, 2020). The Final Rule indicates an effective date of January 19, 2021. CMS' amendments to 42 C.F.R. § 411.352(i), the special rules for profit shares and productivity bonuses, is not effective until January 1, 2022, to give those group practices who need it time to restructure their compensation.

2 85 Fed. Reg. at 77657, *codified at* 42 C.F.R. § 411.351 (defining "commercially reasonable") (emphasis supplied).

3 *Id.* (emphasis supplied).

4 This element was added to the FMV exception in the Final Rule.

5 42 U.S.C. §§ 1395nn(e)(1)(A)–(B), 1395nn(e)(2)(C), and 1395nn(e)(6)(A); 42 C.F.R. §§ 411.357(a)–(b), 411.357(c)(3), 411.357(f)(2), and 411.357(z)(iii).

6 85 Fed. Reg. 77492, 77535.

7 *Id.* CMS states: "Thus, although the exception for personal service arrangements does not include a requirement that the arrangement is commercially reasonable, the other requirements in the exception guard against program or patient abuse in an important and essentially equivalent way."

8 *Id.* at 77534.

9 *Id.* at 77534.

10 *Id.* at 77533, acknowledging that a "loss" on a physician's clinical services might be consistent with a "legitimate business purpose" because the "loss" is warranted by the factors quoted above. However, this list is neither exhaustive nor prescriptive; the ultimate determination of whether an employment or personal services arrangement furthers a "legitimate business purpose" depends on the facts and circumstances.

11 *Id.* at 77534.

12 *Id.*

13 42 U.S.C. § 1395nn(h)(3).

14 42 C.F.R. § 411.351 (defining "fair market value").

15 85 Fed. Reg. 77492, 77658 (emphasis supplied), *codified at* 42 C.F.R. § 411.351.

16 *Id.*

17 *Id.* at 77555.

18 *Id.* at 77557.

19 *Id.* at 77558.

20 *Id.* at 77554.

21 *Id.*

22 *Id.* at 77556.

23 *Id.* at 77557.

24 *See* Timothy Smith, *Chapter 7. Using Multiple Approaches and Methods as a Prudent Practice in Compensation Valuation*, *in* BVR/AHLA Guide to Valuing Physician Compensation and Healthcare Service Arrangements 65-72 (T. Smith & M. Dietrich (2017)).

25 *See* Timothy Smith, *Chapter 44. Analyzing the Economics of Losses in Health System Physician Practices: Why They Occur and Why They Matter for Regulatory Risk, in* BVR/AHLA Guide to Valuing Physician Compensation and Healthcare Service Arrangements 775-802 (T. Smith & M. Dietrich (2017)) *and* Mark O. Dietrich, *Chapter 45. Physician Practice Losses and Commercial Reasonableness: The Math of It*, *in* BVR/AHLA Guide to Valuing Physician Compensation and Healthcare Service Arrangements 803-820 (T. Smith & M. Dietrich (2017)).

Joan Polacheck is Senior Counsel at McDermott Will & Emery LLP and advises clients on health care compliance and regulatory issues, including fraud and abuse, Stark Law, Anti-Kickback Law, and Medicare reimbursement issues. She represents a broad range of health care industry clients, including hospitals, physician groups, DME suppliers, IDTFs and drug and device companies.

Charles (Charlie) R. Buck is a Partner at McDermott Will & Emery LLP and advises health care enterprises on complex transactions and regulatory compliance. He represents a wide range of clients, including proprietary and tax-exempt hospital systems, academic medical centers and faculty practice groups, accountable care organizations, and health maintenance organizations, and other health insurers.

Troy Barsky is a Partner in Crowell & Moring's Washington, DC office where he focuses on health care fraud and abuse, Medicare and Medicaid law and policy, and value-based care. He also defends clients seeking resolution of government health care program overpayment issues or fraud and abuse matters through self-disclosures and negotiated settlements with the United States. Troy has extensive prior government experience, serving at HHS for 11 years, most recently as the Director of the Division of Technical Payment Policy at CMS where he oversaw Stark Law policy.