A STARKLY DIFFERENT LANDSCAPE – A DEEP DIVE INTO CMS' RECENTLY PROPOSED AMENDMENTS TO THE STARK LAW

Date: 7 November 2019

U.S. Health Care Alert

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On October 17, 2019, the Centers for Medicare & Medicaid Services ("CMS") published a Notice of Proposed Rulemaking in the *Federal Register* ("Proposed Rule"), [1] modifying the regulations implementing the federal physician self-referral law (the "Stark Law"). [2] CMS indicates that the main purposes of the Proposed Rule are two-fold: (1) implementation of amendments to key definitions applicable throughout the Stark Law and updates to CMS' policy positions, both aimed at modernizing and streamlining the Stark Law regulations as part of the Department of Health and Human Services' recently launched "Regulatory Sprint to Coordinated Care"; and (2) amendments to the Stark Law in light of the general transition in health care from a volume-based to a value-based system.

This Alert focuses on the proposed definitions, new exceptions (other than those related to value-based arrangements), and significant policy clarifications included in the Proposed Rule. Many of these changes are intended to—and would—provide additional flexibility and reduce administrative burden to health care providers in structuring arrangements to comply with the Stark Law. Proposed changes related to value-based care proposals will be addressed in an upcoming K&L Gates Alert.

I. PROPOSED AMENDMENTS TO FUNDAMENTAL TERMINOLOGY AND STARK LAW REQUIREMENTS

Consistent with commenters' requests, CMS has determined that clear, bright-line rules regarding terminology would ease the burden on providers attempting to comply with the Stark Law and enhance CMS' enforcement capability. As such, CMS proposes to more clearly define certain key terms referenced in many Stark Law exceptions—specifically the definition of "fair market value," commercial reasonableness, and the "volume or value" and the "other business generated" standards.

"Fair Market Value"

Most of the Stark Law exceptions relating to compensation include a requirement that the compensation be consistent with "fair market value." CMS proposes to amend the definition of "fair market value" to more closely align the regulatory definition with the definition set forth in the Stark Law statute. In short, CMS proposes to interpret "fair market value" to relate to the value of like assets or services under like circumstances, consistent with the general market value of the subject transaction. [3] CMS indicates that "general market value" relates to

the value of an asset or service to the actual, identified parties to a transaction that is set to occur within a specified timeframe. [4] Although CMS acknowledges that the amended definition of "fair market value" is merely reorganized for clarity, the Proposed Rule outlines a proposal to more substantively amend the definition of "general market value." [5] Specifically, CMS proposes to equate "general market value" with the recognized meaning of the term in the valuation industry, which focuses on the price resulting from bona fide bargaining between the parties. Finally, CMS proposes to modify the definition of "fair market value" to remove the connection to the volume or value standard, noting that the fair market value requirement is a separate and distinct requirement.

"Commercially Reasonable"

CMS acknowledges the scarcity of guidance related to the concept of commercial reasonableness, despite the fact that it is a requirement of multiple Stark Law exceptions. In an attempt to provide further guidance, CMS proposes two alternative definitions of "commercially reasonable," focusing either on furthering a legitimate business purpose or whether the arrangement makes commercial sense if entered into by reasonable parties (in similar type, size, scope, and specialty). [6] CMS states that the key determination is whether the arrangement makes sense as a means to accomplish the parties' goals and that such determination should be made from the perspective of the particular parties involved.

CMS also emphasizes that the "commercial reasonableness" determination does not turn on whether the arrangement is profitable and highlights that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable. [7] In the Proposed Rule, CMS acknowledges comments explaining the importance and rationale of entering into arrangements that the parties understand in advance may not be profitable but that serve other important needs, such as community need; timely access to health care services; fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act; the provision of charity care; and the improvement of quality and health outcomes. CMS indicates that it finds these concerns to be compelling.

"Volume or Value" and "Other Business Generated" Standard

CMS proposed adding multiple new special rules, clarifying what it means for compensation to "take into account the volume or value of referrals or other business generated," which, if finalized, will supersede all previous regulatory guidance regarding the Stark Law's volume or value standard. In the Proposed Rule, CMS explains that the proposed approach would define exactly when compensation will be considered to take into account the volume or value of referrals or other business generated between the parties. In particular, CMS proposes that compensation in a relationship between a physician and entity will only be considered to take into account the volume or value of referrals or other business generated when the compensation formula includes referrals or other business generated as a variable and the amount of the compensation correlates with the number or value of the referrals to the entity or the generation of other business for the entity. [8]

CMS further proposes to clarify its prior guidance acknowledging that fixed-rate compensation may still take into account the volume or value of referrals or other business generated. [9] In this regard, CMS gives the example that even a fixed annual salary or an unvarying per-unit rate of compensation would have been determined in a manner that takes into account the volume or value of referrals or other business generated by a physician if the

parties utilize a predetermined tiered approach to compensation under which the volume or value of a physician's prior referrals act as the basis for determining the fixed compensation amount over the duration of the arrangement. CMS suggests that without a "predetermined, direct positive or negative correlation" between the volume or value of the physician's prior referrals or other business previously generated for the entity, and the exact, prospective rate of compensation to be paid over the entire duration of the arrangement, such a fixed compensation rate would not violate the volume or value standard or the other business generated standard. The Proposed Rule also proposes to update the volume or value standard, including removing the modifier "directly or indirectly" (given CMS's belief that such a modifier is implicit in the volume or value standard).

Of note, the Proposed Rule responds to commenters' questions regarding the application of findings in the July 2, 2015 opinion of the U.S. Court of Appeals for the Fourth Circuit in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, related to whether compensation takes into account the value or volume of referrals or other business generated specifically in regard to productivity bonuses. In the Proposed Rule, CMS reaffirms its prior position regarding the value or volume standard, noting that productivity bonuses will not be considered to have taken into account the volume or value of the physician's referrals solely because corresponding hospital services are billed each time the physician personally performs a service, as long as the requirements of the applicable Stark Law exception are met. [11]

II. PROPOSED NEW STARK LAW EXCEPTIONS

In addition to the new Stark Law exceptions related to value-based care covered in a forthcoming Alert, the Proposed Rule sets forth two new exceptions related to limited compensation to a physician for items or services provided and donations of cybersecurity technology. Similar to the changes outlined above, both exceptions demonstrate that CMS intends to add more flexibility to the current regulations.

- **Limited Compensation to a Physician.** CMS elaborates upon numerous non-abusive arrangements disclosed through the CMS Voluntary Self-Referral Disclosure Protocol ("SRDP") under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician's bona fide provision of items and services to the entity, but which arrangement did not satisfy the technical requirements of an applicable Stark Law exception because the arrangement was not memorialized in writing, in advance. Accordingly, CMS has proposed revising the Stark Law regulations to add a new exception that permits the provision of limited remuneration to a physician, even in the absence of a written documentation of the arrangement or in the event compensation is not set in advance. The proposed new exception for limited remuneration to a physician would be set forth at 42 C.F.R. § 411.357(z) ("Limited Remuneration Exception") and would protect remuneration for the provision of items or services provided by the physician to the entity that does not exceed an annual limit of $3,500 per calendar year (as adjusted for inflation), to the extent additional requirements are met. While the proposed Limited Remuneration Exception would require that the arrangement be commercially reasonable, not exceed fair market value, and not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, notably, the proposed new exception does not require a signed writing between the parties. The Limited Remuneration Exception would also protect certain office space or equipment rentals, to the extent that the rental compensation is not determined using certain percentage-based compensation formulas or per-unit of service

compensation formulas. The proposed exception would not be applicable to payments from an entity to a physician's immediate family member.

> Further, in the Proposed Rule, CMS acknowledges that the proposed Limited Remuneration Exception could be used in conjunction with other exceptions to protect an arrangement during the course of a calendar year, suggesting that the parties may piecemeal Stark Law exceptions applicable at different periods during a compensation arrangement in order to shorten an applicable period of disallowance. CMS is seeking comments as to the appropriateness of the $3,500 limit, as well as comments regarding whether the applicability of the exception should be limited to services personally performed by the physician or items personally provided by the physician.

- **Donation of Cybersecurity Technology and Related Services**. The Proposed Rule sets forth an additional exception to the Stark Law at 42 C.F.R. § 411.357(bb) to allow for and protect the donation of certain cybersecurity technology and related services, other than hardware ("Cybersecurity Exception"). CMS explains that it is proposing this additional Cybersecurity Exception at the request of commenters, as well as in recognition of the increased cost and need for cybersecurity technology. The proposed Cybersecurity Exception would protect certain nonmonetary donated technology or services that are necessary and predominantly used to implement, maintain, or reestablish cybersecurity, provided that any donation of services is nonmonetary and the donation does not include multi-use technology that is not predominantly used for cybersecurity. Further, the proposed Cybersecurity Exception would require that the donor must not condition the amount of, or eligibility for, cybersecurity donations on referrals or other business generated by the physician, and the recipient may not make the receipt of a cybersecurity donation, or the amount or nature of the donation, a condition of continuing to do business with the donor. The new proposed Cybersecurity Exception would require that the arrangement is documented in a writing that identifies the parties to the arrangement, the timeframe and value of the donations to be made, and further describes the technology and services to be provided over the course of the arrangement. If applicable, the writing must also describe any financial responsibility for the cost of the cybersecurity technology and related services that is shared by the recipient. [12]

> In the alternative, CMS outlines two proposals that would allow for hardware donations in the new exception, with the first alternative proposal covering specific, stand-alone hardware that is necessary for cybersecurity and only serves cybersecurity purposes (for example, a two-factor authentication dongle). The second alternative proposal would permit entities to donate a broader range of cybersecurity technology, including hardware, provided that specified requirements are satisfied, including that a donor must determine that the hardware "is reasonably necessary based on cybersecurity risk assessments of its own organization and the potential recipient." [13]

III. SIGNIFICANT PROPOSED AMENDMENTS AND POLICY CLARIFICATIONS

The Proposed Rule outlines a variety of proposed amendments and policy clarifications that are intended to provide additional flexibility to health care providers and reduced regulatory burden. If the proposals outlined in the Proposed Rule are finalized as proposed, health care providers will likely realize significant flexibility in navigating the technical requirements of the Stark Law.

- **Additional Flexibility Related to the Signature and Writing Requirements**. CMS has reconsidered its position regarding temporary noncompliance with the signature and writing requirements of various Stark Law exceptions. CMS previously clarified in its 2016 rulemaking that the writing requirement included in many Stark Law exceptions may be satisfied with a collection of contemporaneous documents evidencing the course of conduct and, further, that the failure to obtain signatures on such written agreements would not result in noncompliance if the parties obtained missing signatures within 90 days. In the Proposed Rule, CMS proposes a further amendment to the regulatory text to state that the writing requirement or the signature requirement would be deemed to be satisfied if: (1) the compensation arrangement satisfies all other requirements of an applicable exception, and (2) the parties obtain the required writing or signature within 90 consecutive calendar days following the date on which the arrangement failed to satisfy the applicable exception. [14] This change would allow providers to rely on a 90-day grace period if an arrangement was neither in writing or signed at the outset. CMS clarifies that this policy does not change its position on the requirement that compensation be "set in advance"; however, it has changed its position insofar as CMS now clarifies that it is not necessary that the parties reduce the compensation to writing for the compensation to be considered "set in advance." [15]

- **Definition Revisions**

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> o "DHS" Definition – In response to some confusion over whether certain services, such as consulting services, provided to hospital inpatients constitute designated health services ("DHS"), CMS clarifies that services provided by a hospital to an inpatient do not constitute DHS if the furnishing of the service does not affect the amount of the Medicare payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System ("IPPS"). [16] o "Physician" Definition – CMS proposes to update the regulatory definition of "physician" to cross-reference Section 1861(r) of the Social Security Act. [17] This edit does not result in any substantive change to the definition. o "Referral" Definition – CMS uses the Proposed Rule as an opportunity to clarify its longstanding policy that hospital payments to physicians "for the benefit of receiving the physician's referrals" may not be protected by any exception to the Stark Law, because such referrals are not "items or services" for which payment can be made under Medicare. [18] o "Remuneration" Definition – CMS proposes certain changes to the definition of remuneration to clarify the "used solely" requirement for certain items and devices carved out of the definition. Under the Stark Law statute, the provision of items, devices, or supplies to physicians that are "used solely" to collect, transport, process, or store specimens for the entity providing such items, or to order or communicate the results of tests for the providing entity, are not considered "remuneration" under the Stark Law. [19] Under the current regulatory text, surgical items, devices, and supplies are specifically excluded from the "used solely" carve-out, [20] based on CMS' prior belief that reusable surgical items, devices, and supplies may have value to physicians unrelated to specimen collection and could therefore not meet the "used solely"

> test. [21] CMS proposes removing the current regulatory language that stipulates that the carve-out to the definition of "remuneration" does not apply to surgical items, devices, or supplies. [22] If finalized, this change will permit surgical items, devices, and supplies to be analyzed under the "used solely" test and potentially excluded from the definition of "remuneration." Further, CMS clarifies that it understands that certain items, devices, or supplies could theoretically be used for numerous purposes outside of the statutory purposes; however, CMS notes that the relevant inquiry is where the furnished item was in fact used only for one of the statutory purposes. [23] o "Isolated Financial Transaction" Definition – CMS proposes to add a new definition of "isolated financial transaction" to clarify that the exception for isolated financial transactions does not extend to payments for multiple occasions of services provided over an extended period of time, even if there is only a single payment made for such services. [24] Instead, CMS reiterates its position that the Stark Law exception for isolated financial transactions is intended to protect single events, such as a one-time sale of property or a sale of practice that occurs in a single transaction.

- **Eliminating the Period of Disallowance Rules**. In the Proposed Rule, CMS proposes to remove its previous bright-line guidelines regarding the establishment of periods of disallowance ("PODs") and instead notes that each POD must be analyzed on a case-by-case basis, based on the unique facts and circumstances of each financial relationship. [25] CMS further clarifies that there is a potential that no POD is created in the event that technical errors are identified ***and corrected*** during the term of an arrangement; for example, if payments were made inconsistently with the terms of a written agreement were identified and corrected during the term of the arrangement. [26] CMS believes this policy is indicative of normal business practices and encourages effective compliance programs that actively monitor ongoing financial relationships and compliance with the Stark Law. This change will likely give providers additional flexibility when determining the duration of PODs.
- **Office Space and Equipment Rentals**. In regard to leases of office space and rentals of equipment, CMS clarifies that the "exclusive use" requirement in each exception only requires that the lessor is excluded from using the space or equipment. [27] Accordingly, where a space or equipment is leased to multiple individuals, assuming all other elements of the relevant Stark Law exceptions are met, each of the leases would be compliant so long as the lessor remains excluded from use of the space or equipment.

> Further, in a departure from its previous position, CMS proposes to revise the Stark Law exception for fair market value compensation arrangements at 42 C.F.R. § 411.357(l) ("FMV Exception") to allow office space rental in the scope of the exception. CMS explains that through SRDP disclosures, it has seen legitimate office lease arrangements that could not satisfy either of the Stark Law exceptions for office space rentals or timeshare arrangements. [28] In light of the proposed expansion to the scope of the FMV Exception, CMS also proposes to amend that exception to prohibit certain percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for office space, consistent with the exception for office space rentals.

- **Unrelated to DHS.** In a noteworthy change, CMS proposes to broaden the applicability of the Stark Law exception for remuneration provided by a hospital to a physician that is unrelated to the furnishing of DHS ("Unrelated to DHS Exception"). [29] Under the proposed changes to the regulatory text, CMS would incorporate patient care services as the touchstone for determining when remuneration is related to the provision of health care services. CMS notes that payments to a physician for call coverage, medical director services, or utilization review relate closely to the furnishing of DHS and patient care and would be excluded from the scope of the Unrelated to DHS Exception. In contrast, remuneration for administrative services pertaining solely to the business operations of a hospital, such as stipends or meals provided to a physician in exchange for services on a governing board, may be protected under this exception. [30] In the example of remuneration for administrative services pertaining to the business operations of a hospital, CMS notes that the relevant inquiry is whether the services are also provided by non-physicians, and whether the payments for such services are on the same terms whether or not the individual is a physician.
- **Expanded EHR Donation Exception**. CMS proposes to extend the scope and application of the current EHR donation exception at 42 C.F.R. § 411.357(w) ("EHR Exception") indefinitely by removing the sunset provision in the existing regulation. The Proposed Rule also proposes to amend the deeming provision in the EHR Exception regarding interoperability, add prohibitions on the donor engaging in information blocking, and amend the scope of the EHR exception to clarify that donations of certain cybersecurity software and services are allowable and protected. Further, CMS sets forth proposed amendments to the definitions of "interoperable" and "electronic health record," each intended to align the terminology in the EHR Exception with the 21st Century Cures Act. [31]
- **Requirements With Directed Referral Provisions**. In light of its proposed interpretation of the "volume or value" standard, CMS intends to reiterate the importance of the special rule on compensation related to directed referral requirements. CMS proposes to amend the applicable Stark Law exceptions to which the special rule applies to include an express requirement that, if any compensation paid to the physician is conditioned on the physician's referrals, the compensation arrangement must also comply with the special rule. [32]
- **Group Practice Profit Shares and Productivity Bonuses**. CMS proposes to add flexibility to a group practice's distribution of payments that the group receives that are related to a physician's participation in a value-based arrangement. To encourage physicians to participate in value-based care models, CMS proposes to amend the regulations so that DHS profits that are directly attributable to a physician's participation in a value-based enterprise would be deemed not to directly take into account the volume or value of the physician's referrals. This proposal would allow a group practice to directly distribute to a physician in the group the DHS profits furnished by the group that are derived from the physician's participation in a value-based enterprise, without jeopardizing the group's ability to qualify as a group practice.

> CMS also proposes to amend the definition of "overall profits" to clarify that the profits derived from all DHS must be aggregated and distributed, noting that a physician practice that wishes to qualify as a group practice could not distribute DHS profits on a service-by-service basis. [33] The Proposed Rule further

> includes a proposed revision to the deeming provision related to the physician's total patient encounters or RVUs to state that a productivity bonus will be deemed not to take into account the volume or value of a physician's referrals if the bonus is based on the physician's personally performed patient encounters or RVUs.

- **Payments by a Physician**. CMS has reconsidered its position regarding the exception for payments by a physician for certain compensation arrangements. Historically, this exception to the Stark Law has excepted payments made by a physician for certain items and services so long as another regulatory exception did not apply. [34] In response to comments arguing that restricting the exception to circumstances where no other exception applies is unreasonably narrow, CMS proposes to remove references to other regulatory exceptions. CMS anticipates that this change would generally allow parties to rely on this exception to protect any fair market value payments by a physician to an entity for items or services furnished, even if another regulatory exception may be applicable. However, CMS clarifies that this exception would not be applicable to cash or cash equivalents, or for arrangements for the rental of office space or equipment, given that CMS does not consider cash or cash equivalents, or office space, to be either an "item" or a "service." [35]
- **Recruitment Agreements**. CMS proposes amending its previous position regarding recruitment agreements between hospitals and physicians who join existing physician practices. While its prior policy was that each of the hospital, physician, and employing physician practice were required to sign a recruitment agreement, CMS now clarifies that if the physician practice receives no financial benefit from the recruitment arrangement, it is no longer required to sign the recruitment agreement. [36] However, CMS believes that the signature of the physician practice would continue to be required when remuneration is retained by the practice.
- **Assistance to Compensate a NPP**. CMS has also reconsidered its position regarding remuneration provided by a hospital to a physician to compensate a non-physician practitioner ("NPP") to provide patient care services. As currently codified, the exception requires that the NPP has not been employed or otherwise engaged to provide patient care services by a physician or physician organization located in the geographic area served by the hospital within the last year. [37] To clarify confusion as to whether certain patient care services provided by an individual prior to becoming an NPP (for example, in the capacity of a registered nurse) would preclude the individual from fitting within the exception, CMS proposes to revise the regulatory text to specify that patient care services performed by an individual who is not an NPP at the time would not be included in this restriction (for example, if employed as a registered nurse prior to becoming a nurse practitioner). Further, the Proposed Rule aims to clarify the timing of these arrangements through a proposed amendment to the regulatory text requiring that the compensation arrangement between the hospital, federally qualified health center, or rural health clinic and the physician must commence before the physician enters into the compensation arrangement with the NPP. [38]
- **Decoupling Stark and Federal AKS**. Consistent with one of the overall themes of the Proposed Rule to streamline and remove unnecessary regulatory language, CMS is proposing to recalibrate the scope of the Stark Law regulatory exceptions to eliminate the requirements pertaining to compliance with the

federal anti-kickback statute ("federal AKS") and federal and state laws governing billing and claims submission. [39] CMS notes that such intermingling is unnecessary, particularly as CMS is unaware of any instance in which noncompliance with the Stark Law turned solely on a violation of the federal AKS or other laws governing billing or claims submission, as an arrangement that would violate such laws would typically also violate one or more separate requirements of an exception to the Stark Law.

- **Ownership and Investment Interests.** CMS proposes to modify 42 C.F.R. § 411.354(b) to exclude titular ownership or investment interests from the definition of an ownership and investment interest under the Stark Law, consistent with prior guidance that individuals with a mere titular ownership or investment interest do not stand in the shoes of the physician organization for purposes of determining compensation arrangements. [40] Further, CMS solicits comments on whether additional language should be included regarding employee stock ownership programs (each, an "ESOP"), including for example, whether it is necessary to restrict the number or scope of entities owned by an ESOP that would not be considered an ownership or investment interest of its physician employees. [41]

IV. CONCLUSION

As described in this Alert, these long-awaited proposed amendments and the policy clarifications are significant and wide-ranging in their scope and may potentially impact a multitude of arrangements between institutional health care providers and physicians.

Comments on the Proposed Rule are due by December 31, 2019. Hospitals and other health care providers impacted by Stark Law requirements should consider whether to submit comments to CMS on the Proposed Rule. K&L Gates' health care practice and public policy and law practice regularly facilitate stakeholder engagement with federal regulatory agencies, including through the development and submission of public comments. In addition, we routinely assist health systems, hospitals, and other providers and suppliers with legal advice regarding Stark Law and federal AKS compliance, including provider contracting, transactional due diligence, internal compliance reviews and submission of SRDPs, and general strategic considerations.

NOTES:

[1] Medicare Program, Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55,766 (proposed Oct. 17, 2019).
[2] 42 U.S.C. 1395nn; 42 C.FR. 411.350 *et seq.*
[3] With respect to the rental of equipment, CMS proposes "fair market value" to mean the value, in an arm's-length transaction with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. With respect to the rental of office space, CMS intends "fair market value" to mean the value in an arm's-length transaction, with like parties and under like circumstances, 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. Proposed Rule at 55,797.

[4] *Id.* at 55,796–55,797.
[5] *Id.* at 55,978 (commenting that the current definition of “general market value” is “unconnected to the recognized valuation principle of 'market value' and itself may be the driver of valuation industry policy and procedure.”).
[6] *Id.* at 55,790.
[7] *Id.*
[8] *Id.* at 55,793. CMS clarifies that the under policy proposed at § 411.354(d)(5)(i)(A), “compensation from an entity to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity.” *Proposed Rule at 55,793.*
[9] CMS has proposed language at 42 C.F.R. § 411.354(d)(5)(i)(B), (ii)(B), (d)(6)(i)(B), and (ii)(B).
[10] Proposed Rule at 55,794.
[11] A recent decision by the U.S. Court of Appeals for the Third Circuit relied upon a similar interpretation of the Stark Law's “volume or value” test as the Fourth Circuit set forth in the *Tuomey* case. In *United States ex rel. J. William Bookwalter, III, M.D. v. UPMC*, the court allowed relators to proceed to discovery based simply on the *correlation* between the amount of the productivity-based compensation paid to the surgeons by UPMC and the volume of the surgeons' referrals for inpatient hospital services.
[12] Proposed Rule at 55,833.
[13] *Id.* at 55,834.
[14] *Id*. at 55,814.
[15] *Id.* at 55,815. Instead, CMS states that records of a consistent rate of payment over the course of an arrangement, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from similarly situated physicians for similar items or services may be sufficient to establish that the amount of the compensation or formula for calculating such compensation was in fact set in advance.
[16] Id. at 55,805. The Proposed Rule sets forth the example of an outside consulting specialist ordering an x-ray for a patient who is already admitted to a hospital, noting that unless the x-ray results in an outlier payment, the x-ray would not affect the payment received by the hospital for the patient, because the hospital is paid based on the established diagnosis-related group. CMS acknowledges that its proposed clarification is limited to the IPPS and requests comments regarding whether this concept should be similarly extended to analogous services provided by hospitals that are not paid under the IPPS. *Id.*
[17] *Id.*
[18] *Id.* at 55,806.
[19] Section 1877(h)(1)(c)(ii) of the Social Security Act.
[20] 42 C.F.R. § 411.351.
[21] Proposed Rule at 55,806.
[22] *Id.* at 55,807. CMS explains that the agency has reconsidered its position on these items, and it is no longer convinced that the mere fact that certain items, devices, or supplies are routinely used as part of a surgical procedure means the item is not “used solely” for one of the six purposes identified by statute.
[23] *Id.* To illustrate the issue, CMS notes that a specimen lockbox could theoretically be used for several

purposes (e.g., storing unused supplies, acting as a doorstop, etc.). However, if the specimen box is not used for outside purposes and is, in fact, used only for one or more of the statutory purposes, then the furnishing of the specimen lockbox would not be considered remuneration.
[24] *Id.* at 55,808.
[25] *Id.* at 55,809.
[26] CMS provides the example of a hospital that realizes that it had been overpaying a physician with whom it contracted for medical director services as a result of an unintended administrative error for the first six months of a one-year contract with the physician. The Proposed Rule indicates that, provided the arrangement otherwise fit within the an applicable exception, if the error is identified and promptly corrected within the one-year term of the contract, the Stark Law has not been violated.
[27] Proposed Rule at 55,815.
[28] *Id.* at 55,820.
[29] *Id.* at 55,818.
[30] *Id.*
[31] Pub. L. No. 114-255 (Dec. 13, 2016).
[32] Proposed Rule at 55,795–55,796.
[33] The Proposed Rule provides an example that a group practice may not "distribute the profits from clinical laboratory services to one subset of its physicians or using a particular methodology and distribute the profits from diagnostic imaging to a different subset of its physicians (or the same subset of its physicians but using a different methodology)." Proposed Rule at 55,801.
[34] 42 C.F.R. § 411.357(i).
[35] Proposed Rule at 55,820.
[36] *Id.* at 55,816. For example, a physician practice may not be required to sign the agreement in instances where the hospital provides remuneration directly to the recruited physician; the hospital provides remuneration to the physician practice, but the practice passes through all received remuneration to the recruited physician; or if the recruited physician joins the practice after the income guarantee but before the physician's community service repayment obligation is completed. *Id.*
[37] 42 C.F.R. § 411.357(x)(1)(v)(B).
[38] Proposed Rule at 55,827.
[39] *Id.* at 55,803.
[40] *Id.* at 55,811.
[41] *Id.* at 55,812.

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