WHITE PAPER: CMS FINALIZES UPDATES TO THE STARK LAW TO REDUCE REGULATORY BURDENS AND PROVIDE FLEXIBILITY TO PROVIDERS

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Health Care White Paper

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On 2 December 2020, the Centers for Medicare & Medicaid Services (CMS) published a Notice of Final Rulemaking in the *Federal Register* (Final Rule),[1] modifying the regulations implementing the federal physician self-referral law (the Stark Law).[2] In the Final Rule, CMS largely finalizes many of the proposals set forth in the Proposed Rulemaking issued on 17 October 2019 (Proposed Rule),[3] with certain modifications. CMS has indicated that many of the changes to the Stark Law are intended to provide additional flexibility and reduce administrative burden to health care providers in structuring arrangements to comply with the Stark Law, driven by the Department of Health and Human Services' initiative to accelerate the transformation of the health care system to better pay for value and promote care coordination, titled the "Regulatory Sprint to Coordinated Care." The great majority of the final regulations go into effect on 19 January 2021, with the exception of the amendments to the group practice definition in 42 C.F.R. § 411.352, which are effective beginning 1 January 2022.

This White Paper focuses on the amended definitions, new nonvalue-based care exceptions, and significant policy clarifications included in the Final Rule. The changes related to value-based care finalized in the Final Rule, including the new Stark Law exception for value-based arrangements, will be addressed in an upcoming K&L Gates Alert.

I. AMENDMENTS TO FUNDAMENTAL TERMINOLOGY AND STARK LAW REQUIREMENTS

"Fair Market Value"

Nearly every exception to the Stark Law requires that compensation paid to a physician be consistent with "fair market value." Under the final regulation, "fair market value" means the value in an arm's-length transaction that is consistent with the general market value of the subject transaction.[4] Specific definitions of "fair market value" in the context of space and equipment rental are also codified.[5] The Final Rule also includes an amended definition of "general market value," which is focused on considering only the economics of the subject transaction and gives no consideration of other business the parties may have with one another.[6] The amended regulation is structured to include specific definitions of general market value applicable in the context of asset acquisition, compensation for services, and rental of equipment or office space.[7]

Further, CMS finalizes its proposal to eliminate the connection to the volume or value standard in the definitions of "fair market value" and "general market value," noting that the requirement that compensation must be consistent

with fair market value is separate and distinct from the Stark Law's requirement that compensation is not based on the volume or value of referrals or other business generated.[8]

While CMS declined to finalize the proposed analytical framework related to hypothetical transactions, it affirms the position that extenuating circumstances may dictate the parties' decision to veer from the values identified in independent salary surveys and other data compilations.[9] However, while the examples provided by CMS indicate that a highly sought after physician may command a higher compensation rate (which could be consistent with fair market value), the value of a physician's services should be the same regardless of the identity of the purchaser of services.[10]

"Commercially Reasonable"

In the Final Rule, CMS finalizes an interpretation of "commercially reasonable" that combines the two alternative definitions of "commercially reasonable" described in the Proposed Rule,[11] stating that "commercially reasonable" shall mean that the particular arrangement furthers a legitimate business purpose of the parties *and* is sensible when considering the characteristics of the parties, including size, scope, and specialty.[12] CMS stated that the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals, which shall be made from the perspective of the particular parties involved in the arrangement.

CMS reiterated its position described in the Proposed Rule that the "commercial reasonableness" determination does not turn on whether the arrangement is profitable, going so far as to include this statement in the regulation text. CMS further emphasized that it is possible an arrangement would be commercially reasonable even if the parties know in advance that an arrangement may result in losses to one or more parties.[13] Of note, CMS acknowledges the importance 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.[14] However, CMS notes that a "legitimate business purpose" of the parties does not include attracting a physician's business, as this arrangement would not be commercially reasonable in the absence of the physician's referrals.[15]

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

In the Final Rule, CMS finalizes a new approach, and a corresponding amendment to the Stark regulations, that defines exactly when compensation will be considered to take into account the volume or value of referrals or other business generated between the parties. The final regulations describe that compensation will only be considered to take into account the volume or value of referrals when the mathematical formula used to calculate the amount of compensation includes referrals or other business generated as a variable and when the amount of compensation correlates with the number or value of the physician's referrals or business generated.[16] CMS noted that while the volume or value standard is set forth in a "special rule" in the regulation, CMS interprets these in the same manner as definitions.[17]

CMS declined to finalize the previous proposal, which would have defined fixed-rate compensation that was considered to have taken into account the volume or value of referral or other business generated. In this regard, CMS retracted its statement in the Proposed Rule in the context of unit-based compensation,[18] and it explained that if compensation takes into account the volume or value of referrals or business generated, the determination is final and the special rules for compensation cannot then apply to protect the compensation.[19]

- **Shadowing**
  Notably, the Final Rule addressed the correlation between productivity payments to physicians by a hospital that are inevitably linked to a facility fee. CMS affirms previous guidance that an association between personally performed physician services and designated health services furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to, or other business generated for, the entity. CMS acknowledges commenters' concerns that the interpretation may contradict the findings in the federal case of *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, and commenters' concerns that entities may have to defend compensation practices in the event of False Claims Act allegations, yet CMS expressly declined to codify this interpretation in regulation text.[20] CMS clarifies in the Final Rule that productivity compensation based solely on a physician's personally performed services, even when linked to a facility fee, would not take into account the volume or value of a physician's referrals.[21]

- **Indirect Arrangements**
  In the context of indirect compensation arrangements, CMS declined to finalize the proposal to remove the term “varies with” the volume or value of referrals from the definition of an indirect compensation arrangement, noting that the proposal would have eliminated most unbroken chains of financial relationships between designated health services (DHS) entities and referring physicians without providing CMS the opportunity to confirm the compensation did not improperly influence the physician's medical decision-making.[22] The final regulations provide that an unbroken chain of financial relationships between an entity and physician will be considered an indirect compensation arrangement if the physician, or physician's immediate family member, receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the DHS entity and either: (i) the individual unit of compensation to the physician is not fair market value, or (ii) the individual unit of compensation to the physician is calculated using a formula that includes either the physician's referrals to the entity or other business generated by the physician, as a variable that results in a positive correlation between the physician's compensation and referrals or other business generated. Further, the DHS entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated.[23]

CMS acknowledges that the new definition of “indirect compensation arrangements” will reduce the number of unbroken chains of financial relationships that are governed by the Stark Law, and it further noted that many unbroken chains of compensation will no longer be required to satisfy the writing requirement set forth in the indirect compensation arrangement exception to the Stark Law. However, CMS emphasized that the federal anti-kickback statute (federal AKS) will still apply and further noted that compliance with the Stark Law is a prerequisite for submitting a claim to Medicare for a DHS service and maintaining a written agreement documenting a permissible financial relationship could be important in the event such a submission is challenged.[24]

II. NEW STARK LAW EXCEPTIONS

In an effort to provide additional flexibility to providers, CMS codifies two new exceptions in the Final Rule, one of which is related to limited compensation to a physician for items or services and the other related to donations of cybersecurity technology. In addition, CMS promulgated new Stark Law exceptions related to value-based care, which will be covered in a forthcoming Client Alert.

- **Limited Remuneration to a Physician.** The Final Rule includes a new exception for certain limited remuneration paid to a physician up to an annual limit of US$5,000 (as adjusted for inflation). This limited annual compensation does not have to be pursuant to a signed, written agreement (Limited Remuneration Exception).[25] CMS indicates that the impetus for adding this new Stark Law exception was borne out of the numerous nonabusive arrangements that were 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 exception because the arrangement was not set in advance in writing. CMS stated in the Final Rule that it did not believe that the provision of limited remuneration to a physician would pose a risk of program or patient abuse, even in the absence of documentation regarding the arrangement and where the amount of or a formula for calculating the remuneration is not set in advance.

  Accordingly, the Limited Remuneration Exception permits an entity to pay a physician up to an annual aggregate amount of US$5,000 (as adjusted for inflation) for the physician's provision of items or services if the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, the compensation does not exceed fair market value for the items or services, and the arrangement would be commercially reasonable without referrals between the parties. In addition, other requirements apply if the remuneration is paid for the lease of space or equipment or if the remuneration is conditioned on the physician's referrals to a particular provider, practitioner, or supplier.[26] The Limited Remuneration Exception also permits the physician to provide items or services through hired employees, through a wholly owned entity, or through *locum tenens* physicians.[27] It is noteworthy that the Limited Remuneration Exception is not applicable to payments from an entity to a physician's immediate family member.

  Further, CMS indicates that the proposed Limited Remuneration Exception could be used in conjunction, or "stacked," with other exceptions to protect an arrangement during the course of a calendar year.[28] CMS explained that parties to an arrangement may piecemeal Stark Law exceptions applicable at different periods during a compensation arrangement in order to shorten an applicable period of disallowance.

- **Donation of Cybersecurity Technology and Related Services.** CMS finalizes the new Stark Law exception for the donation of certain cybersecurity technology and related services, other than hardware, codified at 42 C.F.R. § 411.357(bb) (Cybersecurity Exception). The Cybersecurity Exception protects certain nonmonetary-donated technology or services that are necessary and predominantly used to implement, maintain, or reestablish cybersecurity, provided that: (i) neither the eligibility of a physician for the technology or services, nor the nature of the technology or services, is determined in a manner that

takes into account the volume or value of referrals or other business generated between the parties; (ii) the physician or physician's practice does not make receipt of, or amount or nature of, the technology or services a condition of doing business with the donor; and (iii) the arrangement must be in writing. In the final Cybersecurity Exception, CMS modified the permissible types of nonmonetary remuneration that were initially proposed, including but not limited to covering hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity.[29]

III. SIGNIFICANT AMENDMENTS AND POLICY CLARIFICATIONS

In addition to adding new Stark Law exceptions, the Final Rule details multiple significant amendments to Stark Law exceptions and concepts, and it further clarifies CMS's existing policies in order to provide additional flexibility to health care providers and reduced regulatory burden. As to clarifications to CMS's existing policies, the Final Rule commentary is currently effective. As such, depending on the facts and circumstances of the individual arrangement, the commentary in the Final Rule regarding certain CMS interpretations may be applicable to past arrangements or at least may shed light on CMS's analysis of past arrangements.

- **Additional Flexibility Related to the Signature and Writing Requirements.** CMS indicates in the Final Rule that it has reviewed numerous compensation arrangements in the SRDP that fully satisfy all requirements of an applicable exception, except for the writing or signature requirements found in a number of the Stark Law exceptions. In a previous 2016 rulemaking, CMS clarified that that the writing requirement may be satisfied with a collection of contemporaneous documents evidencing the course of conduct, and it further clarified that the failure to obtain signatures on such written agreement would not result in noncompliance if the parties obtained missing signatures within 90 days. In the Proposed Rule, CMS proposed an amendment to the set-in-advance standard to deem certain compensation to be set in advance based on a 90-day grace period.[30] In the Final Rule, CMS finalizes a slightly modified approach. CMS has amended 42 C.F.R. § 411.354(d) to clarify that arrangements are “deemed” to be set in advance if the aggregate compensation, unit of compensation rate, or specific compensation formula is set out in writing before the furnishing of items, services, space, or equipment for which the compensation is to be paid.[31] CMS indicates that compensation may be set in advance even if it is not set out in writing before the furnishing of items or services, as long as the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance.

  In addition, CMS further reiterated its position from prior commentary that this writing may come from a collection of documents pieced together, including but not limited to: informal communications such as emails and texts, internal notes, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services. Notably, CMS expanded its list of documents from the 2016 rulemaking, which may provide health care entities additional flexibility when relying on a contemporaneous collection of written documents.[32] Further, CMS codified its long-standing policy that an electronic signature valid under federal or state law is sufficient to satisfy any signature requirement under various Stark Law exceptions.[33]

  In addition, CMS indicates that compensation may be modified at any time during the course of a compensation arrangement and still satisfy the requirement that such compensation is “set in advance,”

so long as certain requirements are met. In particular, CMS adds a new provision at § 411.354(d)(ii) outlining the requirement for a signed writing where compensation is modified during the term of the arrangement. For such arrangements, modified compensation terms may satisfy the "set in advance" requirement if the arrangement: (i) meets the requirements of an applicable Stark Law exception as of the effective date of the modified compensation, and (ii) the modified compensation is both determined and set forth in writing (in sufficient detail to be objectively verified) before the items, services, space, or equipment, as applicable, are actually furnished.[34]

- **Definition Revisions.** CMS also finalizes a number of its proposals to modify certain terms commonly used in the Stark Law regulatory text.
  - "*DHS*" – CMS finalizes a slightly modified version of its initial proposal to clarify that services provided by a hospital to an inpatient do not constitute DHS if the furnishing of the service does not increase the amount of the Medicare payment to the hospital. In particular, CMS used the Final Rule to incorporate additional payment systems similar to the Acute Care Hospital Inpatient Prospective Payment System.[35]
  - "*Physician*" – CMS finalizes its proposal to update the regulatory definition of "physician" to cross-reference Section 1861(r) of the Social Security Act, primarily to remedy a technical inconsistency.[36]
  - "*Referral*" – CMS also finalizes its proposed update to the definition of "referral," which clarifies what CMS identifies as a long-standing policy that hospital payments to physicians for 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.[37]
  - "*Remuneration*" – CMS had previously proposed several changes to the definition of "remuneration" largely intended to clarify the "used solely" requirement for certain items, devices, and supplies that are carved out of the definition. In its Final Rule, CMS finalizes the revised definition as proposed.

    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.[38] Further, under the current regulatory text, surgical items, devices, and supplies are specifically excluded from the "used solely" carve-out,[39] 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. However, CMS finalizes the removal of the caveat for all surgical items, devices, and supplies, stating that the relevant inquiry is whether these items would qualify under the "used solely" test.[40] Under its modified approach to the "used solely" test, CMS clarified that the item must be used solely for one of the listed statutory purposes in order to meet the remuneration carve-out; this change is intended to clarify that while such could be used for an alternative purposes, it would not automatically mean that the furnishing of such item is "remuneration."[41]
  - "*Isolated Financial Transaction*" – CMS finalizes its proposed definition of "isolated financial transaction" to clarify that such transactions are intended to protect single events, such as a one-time sale of a property or sale of a practice, that occurs in a single transaction. CMS emphasized that this

definition would not be applicable to payments for multiple services provided over an extended amount of time, even if there is only a single payment made for such services. CMS also codified in the regulation its long-standing policy that instances of debt forgiveness (including where installment payments are provided) in connection with settlement of a bona fide dispute is a separate compensation arrangement and not part of the compensation arrangement giving rise to the bona fide dispute, as permitted under the exception. Thus, entities may rely on the isolated transactions exception at § 411.357(f) to protect settlements of bona fide disputes arising from an arrangement for multiple, repeated, or ongoing services, though the exception is not intended to protect single payments for such multiple services.[42]

- **Eliminating the Period of Disallowance Rules and Correcting Discrepancies During the Arrangement.** In the Proposed Rule, CMS proposed removing its previous bright-line "safe harbor" guidelines regarding the establishment of periods of disallowance (each, a POD) and instead noted that each POD must be analyzed on a case-by-case basis, based on the unique facts and circumstances of each financial relationship.[43] Notably, in the Final Rule CMS further clarifies that it is possible that no POD is created in the event that administrative or technical errors are identified **and corrected** during the term of an arrangement. For example, CMS describes a compensation arrangement in which a hospital pays a physician the wrong hourly rate for services provided during the initial months of the term but then identifies the discrepancy, corrects the rate moving forward, and reconciles the previous payments during the term of the arrangement. In this regard, CMS finalizes a new special rule protecting parties from Stark Law liability for an arrangement so long as all discrepancies in compensation are reconciled within 90 consecutive days following the expiration or termination of a compensation arrangement.[44] 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. In providing a 90-day window following the expiration or termination of a compensation arrangement for parties to correct errors, CMS explains that discrepancies should be corrected within the same period that has been afforded in other Stark Law regulations for resolving temporary noncompliance occurring for reasons beyond the control of the entity.[45] However, CMS comments that while the new special rule allows parties to avoid violating the billing prohibition of the Stark Law if the parties reconcile payment discrepancies within the 90-day grace period, parties that fail to reconcile known payment discrepancies risk establishing a second financial relationship, such as the forgiveness of debt or provision of an interest free loan, which must satisfy the requirements of an applicable Stark Law exception.[46]

- **Office Space and Equipment Rentals.** CMS finalizes its proposal regarding leases of office space and rentals of equipment as initially proposed. Specifically, CMS clarified that the "exclusive use" requirement in each exception only requires that the *lessor* (or any other person or entity related to the lessor) is excluded from using the space or equipment.[47] Accordingly, where a space or equipment is leased to multiple individuals, assuming all other elements of the relevant Stark Law exception are met, each of the leases would be compliant so long as the lessor remains excluded from use of the space or equipment.

  CMS finalizes its change to previous rulemakings to allow parties to rely on the fair market value exception at 42 C.F.R. § 411.357(l) (FMV Exception) for the lease or use of office space. CMS explained 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 because the term was less than one year or for

timeshare arrangements because the arrangement conveyed a possessory leasehold interest.[48] CMS explained that the FMV Exception may now be used for short-term rentals of office space that would not otherwise meet the one-year requirement in the rental of office space exception, though similar to other compensation arrangements, the parties may only enter into one arrangement for rental of the same office space in the course of a year. In light of the proposed expansion to the scope of the FMV Exception, CMS also finalizes its proposal to amend the FMV 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.[49]

Included as aside to the overall discussion on the FMV Exception, CMS also revealed its position on holdovers under this exception. Referencing the codified indefinite holdover provisions in the exceptions for rental of office space, rental of equipment, and personal service arrangements, which allow the arrangements to continue or "holdover" without a new written agreement so long as the parties continue to adhere to the same terms, one commenter requested that CMS permit indefinite holdovers for arrangements under the FMV Exception. While CMS rejected the proposal to codify a holdover component of the FMV Exception, it noted that 42 C.F.R. § 411.357(l)(2) allows an arrangement to be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Further, CMS clarified that such renewals are not required to be in writing. As such, § 411.357(l)(2) effectively serves the same purpose as the holdover provision in the other exceptions.[50]

- **Expanded EHR Donation Exception.** CMS finalizes the proposal to extend the scope and application of the current electronic health record (EHR) donation exception at 42 C.F.R. § 411.357(w) (EHR Exception) indefinitely by removing the sunset provision in the existing regulation. CMS indicates in the Final Rule that the Cybersecurity Exception is broader and includes fewer requirements than the EHR Exception as applied to cybersecurity software and services that are necessary and used predominantly to protect EHRs, in part because the Cybersecurity Exception does not require recipients to contribute to the cost of the donation.[51] In this regard, CMS finalizes an expansion to the EHR Exception to expressly include cybersecurity software and services to clarify that an entity donating EHR records software and providing training and related services may also utilize the EHR Exception to protect donations of related cybersecurity software and services.[52] CMS did not finalize the proposal to eliminate or reduce the requirement that the recipient of the donation contribute at least 15 percent, though the Final Rule does amend the required timing of the contribution payment.[53] In the context of prohibitions on donors engaging in information blocking, CMS declined to finalize the proposed language in this regard and further removed 42 C.F.R. § 411.357(w)(3) from the regulations entirely.[54]
- **Requirements With Directed Referral Provisions.** CMS finalizes its proposal to amend certain Stark Law exceptions 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.[55] The Final Rule states that while the amended interpretation of the "volume or value" standard may apply in fewer instances, the special rule on compensation related to directed referral requirements remains important for preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization.[56] In addition to expressly incorporating the directed referral requirements into the applicable exceptions, CMS also replaces the

special rule on compensation that set forth directed referral requirements. In this regard, the amended regulation continues to require an arrangement with a directed referral provision to be set forth in a signed writing, including the compensation terms, and requires the compensation to be consistent with fair market value. However, the amended directed referral requirements no longer specify that the compensation arrangement must be set in advance for the term of the arrangement and now permit certain prospective modifications to the compensation terms.[57]

The amended regulations state that neither the existence of the compensation arrangement nor the amount of physician's compensation may be contingent on the number or value of the physician's referrals. CMS comments that this determination also applies in the context of flat-rate compensation paid to a physician with a directed referral requirement, such as a salary.[58]

- **Group Practice Profit Shares and Productivity Bonuses.** CMS finalizes the proposed amendment to the definition of "overall profits" to clarify that "overall profits" means all DHS profits of the group or the component of at least five physicians, emphasizing that a group practice may not allocate DHS profits based on service line (described as "split pooling").[59] CMS clarified, however, that a group practice may utilize different distribution methodologies to distribute shares of the overall profits from all DHS of each of its components of at least five physicians, provided that the distribution to any physician is not directly related to the volume or value of the physician's referrals, and noting that all profits from DHS furnished by the group and referred by any physician in the component must be aggregated.

  CMS also amended one of the methods for distributing overall profits that is deemed permissible in the group practice definition, namely that the overall profits are distributed based on the distributions of the group practice's revenues attributed to services that are not DHS. The amended methodology clarifies that profits may be distributed based on the distribution of the group's revenues from services other than those in the categories of services that are DHS, meaning that the services are not DHS and would not be considered DHS if they were payable by Medicare.[60]

  CMS also finalizes the proposal 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 finalizes a provision related to the distribution of profits from DHS that are directly attributable to a physician's participation in a value-based enterprise, to allow such profits to be distributed directly to the participating physician without being considered as directly related to or taking into account the value or volume of that physician's referrals. As indicated above, the amendments to the group practice definition regulations are not effective until 1 January 2022, as CMS noted that group practice overhead expenses and revenues must be distributed according to methodologies that are set in advance, and CMS is cognizant that some group practices may have already established the distribution methodology to be effective as of 1 January 2021.[61]

- **Payments by a Physician.** CMS finalizes its proposed amendments to 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 it was not addressed by another regulatory exception.[62] In response to prior comments arguing that restricting the exception to circumstances where no other exception applies is unreasonably narrow, CMS finalizes its proposal to

remove references to other regulatory exceptions, leaving only the eight statutory exceptions applicable to compensation arrangements.[63] CMS notes that the exception functions as a catch-all, and this change will generally allow parties to rely on this exception to protect any FMV payments by a physician to an entity for items or services furnished, even if another regulatory exception may be applicable.[64]

- **Recruitment Agreements.** CMS finalizes its proposed position on signature requirements in physician recruitment agreements. CMS's prior policy in the context of recruitment assistance provided to a physician joining a physician practice was that each of the hospital (or recruiting rural health clinic or federally qualified health center), physician, and physician practice were required to sign a recruitment agreement. In the Final Rule, CMS clarified that if the physician practice receives no financial benefit from the recruitment arrangement, it is no longer required to sign the recruitment agreement. However, CMS explained that the signature of the physician practice would continue to be required where the hospital provides recruitment assistance to the physician indirectly through the practice and the practice does not pass through all of the received remuneration to the physician.[65]
- **Assistance to compensate a NPP.** CMS finalizes the proposal to expand the Stark Law exception for remuneration provided by a hospital to a physician to compensate a nonphysician practitioner (NPP) to provide patient care services. The exception for assistance to compensate a NPP (NPP Exception) previously required 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.[66] The Final Rule includes an amendment to the NPP Exception 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) and to clarify the timing of the compensation arrangement between the hospital, federally qualified health center, or rural health clinic and the physician.[67]
- **Decoupling Stark Law and Federal AKS.** One of the primary goals of the Final Rule identified by CMS is to streamline the regulatory language of the Stark Law and to recalibrate the Stark Law exceptions to eliminate multiple references to compliance with the federal AKS and federal and state laws governing billing and claims submission. One of the main arguments in favor of such decoupling was that because the Stark Law is a strict liability statute, inclusion of a requirement for compliance with the federal AKS—an intent-based statute—introduces a component of intent that is not otherwise contemplated under the Stark Law and effectively raises the burden of proof for providers to show that a referral and claim for DHS does not violate the Stark Law.[68]

  In the Final Rule, CMS finalizes its proposal to remove the requirement that arrangements do not violate the federal AKS for all exceptions other than the FMV Exception. CMS explained the rationale behind leaving this requirement in the FMV Exception to be that while most arrangements (e.g., rental of office space) may fit under another applicable Stark Law exception, there is a possibility that certain potentially abusive arrangements that would not fit into one of the more narrowly tailored statutory exceptions could be protected under the broader FMV Exception.[69] In this regard, the requirement that arrangements are also structured to fit within the federal AKS is intended to be an additional safeguard to the more open-ended FMV Exception.

- **Ownership and Investment Interests.** CMS finalizes its proposed amendment to 42 C.F.R. § 411.354(b) to exclude titular ownership or investment interests from the requirements of ownership and investment interest in an effort to provide additional flexibility for entities, particularly in states where the corporate practice of medicine is prohibited.[70] Further, CMS finalizes the removal of the reference to interests in employee stock ownership programs (ESOPs) from § 411.354(b)(3)(vii), on the basis that a physician's interest in an ESOP qualified under IRC § 401(a) does not pose significant risk of program or patient abuse given there are additional legal and regulatory protections applicable to such ESOPs.[71]
- **Unrelated to DHS.** CMS declined to finalize the flexibility that it proposed in the context of the existing Stark Law exception for remuneration provided by a hospital to a physician that is unrelated to the furnishing of DHS (Unrelated to DHS Exception).[72] In the Final Rule, CMS indicated that it is continuing to evaluate the best way to restore utility to the exception and may revisit the proposal in the future.

FOOTNOTES

[1] Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020) (hereinafter "Final Rule").

[2] 42 U.S.C. § 1395nn; 42 C.F.R. §§ 411.350 *et seq*.

[3] Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55,766 (proposed Oct. 17, 2019) (hereinafter "Proposed Rule").

[4] In the Final Rule, CMS retracted its statements from the Proposed Rule that equated "general market value" with "market value," noting that these terms are not interchangeable in the valuation industry.

[5] With respect to the rental of equipment, CMS finalizes a definition of "fair market value" that means 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. With respect to the rental of office space, CMS intends "fair market value" to mean 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. CMS declined to finalize the reference to compensation being related to "like parties and under like circumstances" that had been included in the proposed definition of fair market value. Final Rule at 77,553.

[6] See amended section 42 C.F.R. § 411.351.

[7] As amended, "general market value" of an asset purchased is 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. "General market value" of compensation for services means the compensation that would be paid at the time the parties enter into the services arrangement as a result of bona fide bargaining between well-informed parties not otherwise in a position to generate business for each other.

[8] Final Rule at 77,552.

[9] *Id*. at 77,554.

[10] *Id*. at 77,555.

[11] Proposed Rule at 55,790.

[12] 42 C.F.R. § 411.351.

[13] Final Rule at 77,530.

[14] *Id.* at 77,531.

[15] *Id*. at 77,533.

[16] See new section at 42 C.F.R. § 411.354(d)(5) and (6). CMS also removes the modifier "directly or indirectly," noting that this is implicit in the requirements that compensation is not determined in "any" manner that takes into account the volume or value of referrals.

[17] In examples provided throughout the Final Rule, CMS states that both outcomes-based bonuses and "system success" bonuses could fall within the circumstances of the special rules at (d)(5) and (d)(6) depending on how they are structured and whether the physician's referrals to the entity are variables anywhere in the mathematical equation. Final Rule at 77,542. In the event a physician is paid by a physician organization that does *not* qualify as a group practice, and compensation is based on a percentage of collections attributed to the physician, including both personally performed services and DHS ordered by the physician but furnished by the physician organization, the physician's compensation does take into account the volume or value of his referrals. *Id*. at 77,538.

[18] In the Proposed Rule, CMS stated that unless the new special rule regarding unit-based compensation applies and is met, compensation to a physician would take into account the volume or value of that physician's referrals.

[19] Final Rule at 77,538. CMS further noted that after the effective date of the Final Rule, the special rules at 42 C.F.R. § 411.354(d)(2) and (3) will either be inapplicable or unnecessary to deem unit-based compensation not to take into account the volume or value of a physician's referrals or other business generated, but CMS is not removing the regulations. CMS noted the importance of preserving the regulations "to assist parties, CMS and law enforcement in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance" with the Stark Law. *Id*. at 77,544.

[20] *Id*. at 77,539–40.

[21] *Id*. at 77,541.

[22] *Id*. at 77,544.

[23] *Id*. at 77, 546.

[24] *Id.*

[25] 42 C.F.R. § 411.357(z).

[26] *Id*.

[27] Final Rule at 77,624.

[28] *See, e.g., id.* at 77,582 ("The new exception finalized at § 411.357(z) for limited remuneration to a physician may be available to protect the first $5,000 paid to the physician (if the exception has not yet been utilized during the current calendar year). In addition, the parties could rely on the special rule for writing and signature requirements finalized at § 411.354(e)(3), coupled with the clarification of the writing requirement at § 411.354(e)(2), to establish that the actual amount of compensation provided under the arrangement was set forth in writing within 90 consecutive calendar days of the commencement of the arrangement via a collection of documents, including documents evidencing the course of conduct between the parties. The 90-day clock would begin when the parties could no longer use (or were no longer using) the exception at § 411.357(z).") *See also id*. at 77,592–93, 77,597.

[29] *Id*. at 77,637.

[30] In the Proposed Rule, CMS proposed an 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, which would effectively allow providers to rely on a 90-day grace period if an arrangement was neither in writing or signed at the outset. Proposed Rule at 55,814.

[31] Final Rule at 77,591.

[32] *Id*. at 77,592.

[33] *Id.*

[34] *Id.* at 77,594. CMS also clarified that these requirements are applicable only for modified compensation terms and not generally applicable to other changes to the details of the arrangement that do not impact compensation. *Id*. at 77,595.

[35] *Id*. at 77,571. The amended regulations specify the applicable prospective payment systems to include the Acute Care Hospital Inpatient Prospective Payment System, the Inpatient Rehabilitation Facility Prospective Payment System, the Inpatient Psychiatric Facility Prospective Payment System, and the Long-Term Care Hospital Prospective Payment System.

[36] *Id*. at 77,573.

[37] *Id*.

[38] Section 1877(h)(1)(c)(ii) of the Social Security Act.

[39] 42 C.F.R. § 411.351.

[40] Final Rule at 77,574.

[41] *Id*. Also of note, CMS states its belief that items, devices, or supplies carved out from the definition of remuneration should be "low value," though it does not propose a monetary limit for the carve-out. Further, CMS also reaffirmed its traditional position that items, devices, or supplies provided to a physician must have little to no independent value to the physician and they must serve a purpose for the entity, rather than the individual physician. *Id*. at 77,575.

[42] *Id*. at 77,576.

[43] Proposed Rule at 55,809.

[44] Final Rule at 77,581–82.

[45] 42 C.F.R. § 411.353(h).

[46] *See id*. § 411.353(f).

[47] Final Rule at 77,584.

[48] *Id*. at 77,598. In response to stakeholder feedback, CMS specifically rejected the proposition that if a hospital leases space to a physician practice, such practice could sublease back an exam room to the hospital for use by a hospital-employed physician or technician. CMS stated that this type of arrangement is susceptible to abuse and further reiterates that the "exclusive use" requirements are intended as a safeguard against sham or "paper" leases where a lessor collects rent while continuing to use leased space.

[49] *Id*. at 77,605.

50 *Id.* at 77,606. As noted above, CMS declined to remove the requirement for compliance with the federal AKS from the FMV Exception. Instead, CMS argues that compliance with the federal AKS is a significant component of the FMV Exception and serves as a safeguard for requirements that are included in other statutory exceptions to protect against program or patient abuse. *Id*. at 77,607.

[51] *Id*. at 77,608.

[52] *Id*. at 77,612.

[53] *Id.*

[54] In particular, the revised regulation requires the physician to pay 15 percent of the donor's cost for the items and services before receipt of the initial donation of the items and services or the donation of replacement items and services. After the initial donation of items and services or donation of replacement items or services, the physician is required to pay 15 percent of the donor's cost "at reasonable intervals," instead of requiring the contribution to be paid in advance of receiving the item or service (such as an update). 42 C.F.R. § 411.357(w)(4); *see also* Final Rule at 77,618.

[55] Final Rule at 77,615. This regulatory section previously prohibited the donor of EHR items or services from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems. CMS notes this change is due, in part, to the fact that other enforcement agencies are now addressing information blocking, including the ONC Final Rule: "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," 85 Fed. Reg. 25,642 (May 1, 2020).

[56] Final Rule at 77,547. CMS amended the Stark Law exceptions for academic medical centers, bona fide employment relationships, personal service arrangements, certain physician incentive plans, group practice arrangements with a hospital, fair market value compensation, indirect compensation arrangements, and the new exception for limited remuneration to a physician.

[57] The amended provisions are for the Stark Law exceptions for academic medical centers, bona fide employment

relationships, personal service arrangements, certain physician incentive plans, group practice arrangements with a hospital, fair market value compensation, indirect compensation arrangements, and the new exception for limited remuneration to a physician. *Id*.

[58] 42 C.F.R. § 411.354(d)(4).

[59] Final Rule at 77,548. For example, CMS commented if the hospital increases compensation based on the physician making a targeted number of referrals, or if the hospital refuses to renew employment unless the physician referred a sufficient number or value of referrals to the hospital, these compensation arrangements would not satisfy the conditions of the new special rules. However, CMS states that the special rule does not prohibit directed referral requirements based on an established percentage of the physician's referrals being to the entity, rather than the number or value of referrals that would be prohibited. *Id.* at 77,550.

60 *Id*. at 77,561. CMS provided the example that, if a practice wishes to qualify as a group practice, it may not distribute the profits from clinical laboratory services to one subset of its physicians and distribute the profits from diagnostic imaging to a different subset of its physicians.

[61] See amended section at 42 C.F.R. § 411.352(i)(1)(iii)(B).

[62] The Final Rule also includes a correction to the regulation to remove the reference to “designated health services payable by Medicaid” in the definition of overall profits, noting that this reference was not congruently omitted with other references to Medicaid when the 1998 proposed rule was finalized. In the Final Rule, CMS acknowledges that “designated health services” only include those services payable in whole or in part by Medicare and, thus, finalizes the deletion of “Medicaid.” Final Rule at 77,562.

[63] 42 C.F.R. § 411.357(i).

[64] For reference, the enumerated exceptions are found at 42 C.F.R. §411.357(a) through (h) and include: rental of office space, rental of equipment, bona fide employment relationships, personal service arrangements, physician recruitment, isolated transactions, certain arrangements with hospitals unrelated to DHS, and risk-sharing arrangements. CMS clarifies that parties seeking to protect an arrangement for the rental of office space or equipment must structure the arrangement to satisfy the requirements of the exceptions at § 411.357(a), (b), (l), or (p), as applicable. While CMS stated in the Proposed Rule that this exception would not be applicable to 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,” in the Final Rule CMS formally retracted prior statements that office space is neither an “item” nor a “service.” Though the exception cannot be used for office space leases, CMS stated that this exception may be available to the lease or use of space that is not office space, such as storage space or residential real estate.

[65] Proposed Rule at 55,820.

[66] Final Rule at 77,600.

[67] 42 C.F.R. § 411.357(x)(1)(v)(B).

[68] Final Rule at 77,620. The amended regulation requires the compensation arrangement between the hospital and physician or physician practice to commence before the physician or physician practice enters into the compensation arrangement with the NPP.

[69] Final Rule at 77,567.

70 *Id*. at 77,568.

[71] *Id*. at 77,587.

[72] *Id*. at 77,589. However, CMS reminded parties that employer contributions to ESOPs are still considered part of an employee's overall compensation arrangement with the employer, and as such, the fair market value and volume or value of such contributions should continue to be considered as part of the employee's compensation when applying an applicable exception.

[73] Proposed Rule at 55,818. Under the proposed changes to the regulatory text, CMS would have incorporated patient care services as the touchstone for determining when remuneration is related to the provision of health care services and provided latitude to entities and physicians to rely on the Unrelated to DHS Exception to protect 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.

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