KUTAKROCK

October 25, 2019

2019 Stark Law Proposed Rule

Executive Summary

The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) for the Department of Health and Human Services simultaneously issued proposed rules to address Stark Law, Anti-Kickback Statute and Civil Monetary Penalties barriers to value-based compensation arrangements and certain other issues.[1] While this Client Alert focuses on the Stark Law guidance from CMS, we recommend that clients read the OIG Proposed Rule to gain further clarification regarding the interplay of the Stark Law and the Federal Anti-Kickback Statute. In both the Stark Proposed Rule and the OIG Proposed Rule, the government clarifies that it is more willing to provide exceptions to the Stark Law for certain arrangements given the Stark Law's strict liability standard. On the other hand, the government is more restrictive in creating safe harbors to the Federal Anti-Kickback Statute, as it views the Federal Anti-Kickback Statute, which is an intent-based criminal law, as a "backstop" to the Stark Law to protect the Federal funds against fraud and abuse.

CMS published the Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule on October 17, 2019 (the "Stark Proposed Rule").[2] The Stark Proposed Rule proposes new exceptions to the Physician Self-Referral Law (Stark Law, further defined in the Expanded Summary below) for certain value-based compensation arrangements between or among physicians, suppliers and providers; for certain arrangements where a physician receives remuneration for items or services provided by the physician; and for donations of cybersecurity technology. It also amends the exception for electronic health records items and services and provides clarifying guidance on interpretation of existing Stark Law regulatory exceptions. The Stark Proposed Rule can be found at: 84 Federal Register 55766.

While the Stark Proposed Rule proposes significant (and in our opinion sweeping) revisions to the Stark Law regulatory text, we caution clients that the proposals contained in the Stark Proposed Rule (unless otherwise noted by CMS as part of its long-standing policy) are only proposed at this time. Until finalized, clients should not rely on such proposals to protect financial arrangements that are otherwise subject to the Stark Law.

The Stark Proposed Rule proposes the following new exceptions:

1. **Limited Remuneration to a Physician. 42 C.F.R. § 411.357(z)**. CMS is proposing a new exception to protect limited remuneration (not to exceed $3,500 per calendar year) to a physician, even in

[1] The complete text of the OIG Proposed Rule for the Anti-Kickback Statute and Civil Monetary Penalties can be found here.

[2] The complete text of the Stark Proposed Rule can be found here.

the absence of documentation regarding the arrangement and where the amount of, or formula for, calculating the remuneration is not set in advance of the provision of items or services.

2. **Value-Based Arrangements. 42 C.F.R. § 411.357(aa)**. CMS is proposing new exceptions to the Stark Law for value-based compensation arrangements that satisfy specific requirements based on the structure of the arrangement and the financial risk involved. As proposed, this new exception, which includes three separate models, would apply to services rendered to both Medicare and non-Medicare patients. Further, the OIG is proposing safe harbors intended to facilitate value-based arrangements.[3]
3. **Cybersecurity Technology and Related Services. 42 C.F.R. § 411.357(bb)**. CMS proposes a new exception to protect arrangements involving the donation of certain cybersecurity technology and related services. The OIG is considering a similar safe harbor under the Federal Anti-Kickback Statute.

The full text of the proposed exceptions is set forth at Appendix A.

The Stark Proposed Rule proposes the following new definitions and special rules:

1. **Commercial Reasonableness. 42 C.F.R. § 411.351**. CMS proposes two alternative definitions of "commercially reasonable".
2. **Value-Based Arrangements. 42 C.F.R. § 411.351**. CMS proposes the following new definitions to implement the proposed new exception at 411.357(aa):
    a. Target Patient Population.
    b. Value-Based Activity.
    c. Value-Based Arrangement.
    d. Value-Based Enterprise.
    e. Value-Based Purpose.
    f. VBE Participant.
3. **Isolated Financial Transaction. 42 C.F.R. § 411.351**. CMS proposes to define "isolated financial transaction" to clarify that it does not include payment for services provided over an extended period, even if there is only one payment for such services.
4. **Volume or Value Standard and Other Business Generated Standard. 42 C.F.R. § 411.354(d)(5) and (6)**. CMS proposes two new special rules on compensation to define when a compensation arrangement between a physician (or immediate family member) and an entity takes into account the volume or value of referrals or other business generated between the parties.
5. **Special Rules for Profit Shares and Productivity Bonuses. 42 C.F.R. § 411.352(i)**. CMS proposes new 411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group.

The full text of the proposed definitions is set forth at Appendix A.

The Stark Proposed Rule proposes the following revisions to existing regulations:

[3] Among the new safe harbors proposed by the OIG are safe harbors for "Care coordination arrangements to improve quality, health outcomes, and efficiency," "Value-based arrangements with substantial downside financial risk," and "Value-based arrangements with full financial risk."

1. **Definitions. 42 C.F.R. § 411.351**. CMS proposes to revise the following definitions:
    a. Designated Health Service.
    b. Fair Market Value.
    c. General Market Value.
    d. Physician.
    e. Referral.
    f. Remuneration.
2. **Compliance with Federal Anti-Kickback Statute and Federal and State laws governing billing or claims submission. 42 C.F.R. §§ 411.353 to 411.357**. CMS proposes to delete the requirement from most Stark Law exceptions that the arrangement does not violate the Anti-Kickback Statute or any Federal or State law governing billing or claims submission.
3. **Period of Disallowance. 42 C.F.R. § 411.353(c)(1)**. CMS proposes to delete the rules on the period of disallowance in their entirety, stating that the rules are overly prescriptive and impractical.
4. **Special Rules on Compensation. 42 C.F.R. § 411.354**.
    a. **Titular Ownership or Investment Interest. 42 C.F.R. § 411.354(b)(3)(vi)**. CMS proposes to extend the concept of titular ownership or investment interests beyond the physician organization context.
    b. **Employee Stock Ownership Program. 42 C.F.R. § 411.354(b)(3)(vii)**. CMS proposes to remove employee stock ownership program interests from the definition of ownership or investment interest for purposes of the Stark Law.
    c. **Indirect Compensation Arrangements. 42 C.F.R. § 411.354(c)**. CMS proposes revisions to the indirect compensation arrangement definition to address value-based payment arrangements.
    d. **Directed Referrals. 42 C.F.R. § 411.354(d)(4)**. CMS proposes to include an affirmative requirement in certain exceptions that, in addition to satisfying the other requirements of the exception, the relevant arrangement must comply with the revised special rule at 411.354(d)(4) relating to directed referrals.
    e. **Temporary Non-Compliance with Writing and Signature Requirements. 42 C.F.R. § 411.354(e)(3)**. CMS proposes to extend the special rule for temporary non-compliance with the signature requirement to also apply to temporary non-compliance with the writing requirement.
5. **Exclusive Use of Space or Equipment. 42 C.F.R. § 411.357(a) and (b)**. CMS proposes clarifying the exclusive use requirement for rental of office space and equipment to only apply to the lessor and persons or entities related to the lessor.
6. **Physician Practice Signature to Recruitment Arrangement. 42 C.F.R. § 411.357(e)**. CMS proposes to revise the recruitment arrangements exception to remove the signature requirement for physician practices when the physician practice receives no financial benefit from the recruitment.
7. **Remuneration Unrelated to the Provision of DHS. 42 C.F.R. § 411.357(g)**. CMS proposes to revise the exception for remuneration unrelated to the provision of DHS to broaden its applicability.
8. **Exception for Payments by a Physician. 42 C.F.R. § 411.357(i)**. CMS proposes to revise the exception for payments by a physician to broaden its applicability.

9. **Fair Market Value Arrangements Exception. 42 C.F.R. § 411.357(l)**. CMS proposes to extend the fair market value arrangements exception to protect arrangements for rental or lease of office space.
10. **EHR Items and Services. 42 C.F.R. § 411.357(w)**. CMS is proposing to update and extend the EHR exception. The OIG is proposing corresponding updates to the analogous safe harbor.
11. **Exception for Assistance with NPP Compensation. 42 C.F.R. § 411.357(x)**. CMS proposes to revise references and definitions related to nonphysician practitioner services and referrals to clarify the scope of the applicable exception.

The Stark Proposed Rule includes clarifying guidance on CMS' interpretation of many regulatory exceptions, including its interpretation of the "set in advance" requirement, the Special Rules on Compensation and profit distributions for group practices. We have provided a high-level summary of such clarifications in the Expanded Summary attached.

Comments to the Stark Proposed Rule must be received by 5 p.m. on December 31, 2019.

CLIENT ALERT

2019 Stark Law Proposed Rule

Expanded Summary

The Centers for Medicare & Medicaid Services (CMS) published the Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule on October 17, 2019 (the "Stark Proposed Rule"). The Stark Proposed Rule proposes new exceptions to the Physician Self-Referral Law (Stark Law, further defined below) for certain value-based compensation arrangements between or among physicians, suppliers and providers; for certain arrangements where a physician receives remuneration for items or services provided by the physician; and for donations of cybersecurity technology. It also amends the exception for electronic health records items and services and provides clarifying guidance on interpretation of existing Stark Law regulatory exceptions. The Stark Proposed Rule can be found at: 84 Federal Register 55766.

The Physician Self-Referral Law (also known as the Stark Law, 42 U.S.C. 1395nn) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership, investment or compensation), unless an exception applies; and prohibits the entity from filing claims with Medicare (or billing another individual, entity or third party payer) for those referred services. The Stark Law establishes certain exceptions and grants the Secretary of Health and Human Services authority to establish additional exceptions by regulation for financial relationships that do not pose a risk of program or patient abuse. Where an exception is met, the Stark Law prohibitions on referrals would not apply to the financial arrangement. Notably, the Stark Law is *not* intent-based, but is a strict liability statute. Thus, compliance with an exception is paramount to many physician and supplier/provider arrangements.

When the Stark Law was enacted, Medicare made most payments based on volume. Thus, Medicare reimbursement was largely volume-based – the more services that a provider or supplier furnished, the more Medicare payments it would receive. Now, Medicare is in the process of transforming its payment models to promote value and care coordination, prompting the Stark Proposed Rule, summarized below.

* * *

New Exceptions. The Stark Proposed Rule proposes the following new exceptions:

1. **<u>Limited Remuneration to a Physician. 42 C.F.R. § 411.357(z)</u>**. CMS is proposing a new exception to protect limited remuneration to a physician, 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 of the provision of items or services. CMS is proposing that the exception would apply where the remuneration does not exceed $3,500 per calendar year, adjusted for inflation.
    a. As proposed, such exception would not be available for a physician's immediate family member.
    b. In determining whether payments exceed the annual limit under the proposed exception, CMS indicates that it would not count compensation to a physician for items or services

provided outside of the arrangement, if the items or services are protected under another exception at §§ 411.355 or 411.357.[4]

c. CMS further indicates that the proposed exception could be used in conjunction with other exceptions to protect an arrangement during the course of a calendar year in certain circumstances.[5]

2. **Value-Based Arrangements. 42 C.F.R. § 411.357(aa)**. CMS is proposing a new exception for value-based compensation arrangements that satisfy specific requirements based on the structure of the arrangement and the financial risk involved. As proposed, this new exception, which includes three separate models, would apply (a) to services rendered to both Medicare and non-Medicare patients; and (b) only to compensation arrangements that qualify as value-based arrangements (definition provided in Appendix A).
   a. Notably, as proposed, the exception does not require compensation to (i) be consistent with fair market value or (ii) not be determined in a manner that takes into account the volume or value of referrals or other business generated. Thus, the special rule at 411.354(d)(4) would not apply (permitting certain arrangements to direct the physician's referrals to a particular provider).
   b. However, brief noncompliance with the exception cannot be rectified by making retrospective payment.[6]

---

[4] CMS provides the following examples: "assume an entity has an established call coverage arrangement with a physician that fully satisfies the requirements of § 411.357(d)(1) or § 411.357(l). Assume further that the entity later engages the physician to provide supervision services on a sporadic basis during the same year but failed to document the arrangement in a writing signed by the parties. In determining whether the supervision arrangement satisfies the requirements of the proposed exception for limited remuneration to a physician, we would not count the compensation provided under the call coverage arrangement towards the aggregate $3,500 annual limit. However, if an entity has multiple undocumented, unsigned arrangements under which it provides compensation to a physician for items or services provided by the physician, we would consider the parties to have a single compensation arrangement for various items and services, and the aggregate of all the compensation provided under the arrangement could not exceed $3,500 during the calendar year in order for the proposed exception to protect the remuneration to the physician. To illustrate, assume the entity in the previous example also engaged the physician to provide occasional EKG interpretations during the course of the year, and that the aggregate annual compensation for the supervision services and the EKG interpretation services *taken together* exceed $3,500. Assuming neither arrangement satisfied the requirements of any other applicable exception, the exception for limited remuneration to a physician would not protect either arrangement (which, as noted, we would treat as a single arrangement for multiple services) after the $3,500 limit was exceeded during the calendar year." CMS-1720-P at 254-255.

[5] CMS provides the following: "assume that an entity engages a physician to provide call coverage services, and that the arrangement is not documented or the rate of compensation has not been set in advance at the time the services are first provided. Further, assume that, after the services are provided and payment is made, the parties agree to continue the arrangement on a going forward basis and agree to a rate of compensation. Assume also that the parties have no other arrangements between them. Depending on the facts and circumstances, the parties could rely on the proposed exception to protect the first payments up to the $3,500 annual limit, provided that the requirements of the proposed exception are satisfied. For the ongoing compensation arrangement, the parties could rely on another applicable exception, such as § 411.357(d)(1), to protect the arrangement once the compensation is set in advance and the other requirements of the exception are satisfied." CMS 1720-P at 255-256.

[6] CMS gives the following example: "assume a hospital donates EHR items and services to Physician A, including ongoing software upgrades, maintenance, and services, for which the vendor charges the hospital monthly in advance of providing the EHR items and services. The regulation at § 411.357(w)(4) requires that, before the receipt

3. **Cybersecurity Technology and Related Services. 42 C.F.R. § 411.357(bb)**. CMS proposes a new exception to protect arrangements involving the donation of certain cybersecurity technology and related services. The OIG is considering a similar safe harbor under the Federal Anti-Kickback Statute.
   a. As proposed, the exception would exclude the donation of hardware, such as a laptop computer or tablet. It would, however, protect encryption software for the laptop or tablet.
   b. CMS also proposes to protect a broad range of services.[7]
   c. The donation of services must be nonmonetary. The exception would not protect the payment of the ransom in a ransomware attack.

The full text of the proposed exceptions is set forth at Appendix A.

New Definitions and Special Rules

1. **Commercial Reasonableness. 42 C.F.R. § 411.351**. CMS proposes two alternative definitions of "commercially reasonable"[8].
   a. CMS reiterates that it believes the key question in evaluating commercial reasonableness is whether the arrangement makes sense as a means to accomplish the parties' goals.
   b. CMS is also proposing to clarify that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.
   c. Thus, the best evidence of commercial reasonableness is likely to consist of the parties' contemporaneous internal documentation of the purposes of the arrangement. It should be noted that any definition of commercial reasonableness that CMS finalizes will not necessarily apply to regulations enforced by the IRS, the OIG or pursuant to State law.
2. **Value-Based Arrangements Definitions. 42 C.F.R. § 411.351**. CMS proposed new definitions to implement the proposed new exception at 411.357(aa) (discussed above):
   a. Target Patient Population.

---

of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The parties agree that Physician A will pay 15 percent of the monthly cost of the EHR items and services prior to the beginning of each month. If Physician A fails to make the July 31st payment as scheduled, the arrangement would no longer satisfy the requirements of § 411.357(w)(4), and Physician A would be prohibited from making referrals for designated health services to the hospital as of August 1st and the hospital would be prohibited from submitting claims to the Medicare program for any improperly referred designated health services. If the arrangement is later brought back into compliance with the requirements of the exception, the physician would again be permitted to make referrals for designated health services to the hospital, and the hospital could submit claims for such designated health services (but not the designated health services referred during the period of noncompliance)." CMS-1720-P at 77.

[7] Services could include: services associated with developing, installing, and updating cybersecurity software; cybersecurity training services; cybersecurity services for business continuity and data recovery services; services associated with performing a cybersecurity risk assessment or analysis; and services associated with sharing information about known cyber threats and assisting recipients responding to threats or attacks on their systems.

[8] CMS proposes to define "commercially reasonable" in accordance with one of the following:

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.

Commercially reasonable means that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.

i. Legitimate and verifiable criteria required by the definition may include medical or health characteristics (patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes); geographic characteristics (all patients in an identified county or set of zip codes); payor status (all patients with a particular health insurance plan or payor); or other defining characteristics.
ii. Selecting a target population consisting of only lucrative or adherent patients and avoiding costly or noncompliant patients or by purely financial concerns would not be legitimate and thus would not meet the definition of target patient population.

b. Value-Based Activity.
   i. Examples of value-based activities include:
      1. A shared savings payment distributed by an entity to a downstream physician who joined with other providers and suppliers to achieve the savings, representing the physician's agreed upon share of such savings rather than a payment for specific items or services furnished by the physician to the entity. CMS-1720-P at 34.
      2. Payments made to encourage a physician to adhere to a redesigned care protocol, which are made, in part, in consideration of the physician refraining from following his or her past patient care practices rather than for direct patient care items or services furnished by the physician. CMS-1720-P at 34.
      3. Where the value-based purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement requiring routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. CMS-1720-P at 34.

c. Value-Based Arrangement.
   i. Such value-based arrangement must be a compensation arrangement and cannot be an ownership or investment arrangement.
   ii. A value-based arrangement is not required to be reduced to writing to satisfy the requirements of the exception.

d. Value-Based Enterprise. CMS intends value-based enterprises to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care system.
   i. *Notably*, an "enterprise" may be a distinct legal entity, such as an accountable care organization, or consist of only two parties.

e. Value-Based Purpose. The value-based purpose is critical to qualifying as a value-based arrangement. A value-based arrangement must be reasonably designed to achieve at least one value-based purpose.

f. VBE Participant. CMS is concerned with potential abuse under a value-based arrangement and is considering excluding laboratories and DMEPOS suppliers from the definition of VBE participant.

3. **Isolated Financial Transaction. 42 C.F.R. § 411.351**. CMS proposes to create a separate definition of an isolated financial transaction to clarify that it does not include payment for multiple services provided over an extended period, even if there is only one payment for such services. Significantly, CMS has clarified that the Isolated transactions exception (§ 411.357(f)) is not available to protect service arrangements where a party makes a single payment for multiple services provided over an extended period of time. CMS states that parties have attempted to improperly use the Isolated transactions exception to protect such single payment arrangements where the services have been provided, but were not set forth in writing and the personal services arrangements or fair market value compensation exceptions are not available.
4. **Volume or Value Standard and Other Business Generated Standard.[9] 42 C.F.R. § 411.354(d)(5) and (6)**. CMS proposes new special rules on compensation (the "Proposed Special Rules") to define when a compensation arrangement between a physician (or immediate family member) and an entity takes into account the volume or value of referrals or other business generated between the parties.
    a. The Proposed Special Rules set forth objective and measurable standards to determine if the Volume or Value Standard or Other Business Generated Standard are met with respect to a particular arrangement.
    b. Further, the Proposed Special Rules set forth limited circumstances where CMS considers a fixed-rate compensation (e.g., fixed salary or unvarying per-unit rate of compensation) to violate the Volume or Value Standard or the Other Business Generated Standard.[10]
    c. Significantly, the rules would limit arrangements that "take into account" referrals or other business to those where there is a positive correlation between referrals or other business and compensation. This means that an arrangement would not be held to "take into account" referrals or other business solely because compensation is not fair market value or because of a negative correlation (e.g., compensation to the physician declines as the physician's referrals increase).
    d. CMS cautions that the Proposed Special Rules will only be applicable if the rules are finalized.
5. **Special Rules for Profit Shares and Productivity Bonuses. 42 C.F.R. § 411.352(i)**. CMS proposes new § 411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. This is an extension of the policy outlined in the new Value-based arrangement exception (discussed above). CMS is further considering whether it should permit such distributions to be made from *revenue* or from *profit*.

The full text of the proposed new definitions is set forth in the attached Appendix A.

[9] Various exceptions to the Stark Law require that compensation paid under the arrangement not be determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement (the Volume or Value Standard), and some exceptions require that the compensation not be determined in a manner that takes into account other business generated between the parties (the Other Business Generated Standard).
[10] For example, where the parties use a predetermined tiered approach to compensation under which the volume or value of a physician's prior referrals is the basis for determining the unvarying rate. CMS-1720-P at 114.

Revisions to Existing Regulations

1. **<u>Definitions. 42 C.F.R. § 411.351</u>**.
    a. <u>Designated Health Service</u>. CMS proposes to revise the definition of "designated health service" to clarify that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). Thus, a physician ordering a service for an inpatient that is included in the DRG payment would not be making a referral. Such a revision would significantly impact the analysis under the Stark Law of certain hospital-based specialties, like anesthesia.
    b. <u>Fair Market Value and General Market Value</u>.
        i. CMS proposes to revise the definition of *fair market value* to eliminate the connection to the Volume or Value Standard, which CMS views as an independent requirement of the relevant exceptions. CMS is proposing three definitions for fair market value – the first being of general applicability[11], the second applicable to rental of office space and the third applicable to rental of equipment.
        ii. CMS proposes revisions to the definition of *general market value*. The proposed revised definition is intended to closer track with industry standards and market valuation principles.
        iii. Notably, CMS views the concept of <u>fair</u> market value to relate to the value of an asset or service to hypothetical parties in a hypothetical transaction and views <u>general</u> market value relates to the value of an asset or service to actual parties to a transaction that is set to occur within a specified timeframe.
    c. <u>Physician</u>. CMS proposes to revise the definition of Physician to conform to the statutory text.
    d. <u>Referral</u>. CMS proposes to revise the definition of referral to reiterate its policy that a referral is not an item or service for which payment may be made under the Stark Law.
    e. <u>Remuneration</u>. CMS proposes to revise the definition of remuneration to (i) delete the parenthetical related to single use surgical items, devices or supplies[12] and (ii) to clarify that items, devices or supplies that are *in fact used solely* for one or more of the six enumerated purposes identified in the Stark Law would not be considered remuneration.
2. **<u>Compliance with Federal Anti-Kickback Statute and Federal and State laws governing billing or claims submission. 42 C.F.R. §§ 411.353 to 411.357</u>**. CMS proposes to delete the requirement from the Stark Law exceptions[13] that the arrangement "does not violate the anti-kickback statute or any Federal or State law governing billing or claims submission." In doing so, CMS states that when a compensation arrangement violates the intent-based criminal anti-kickback statute, it will

[11] Fair market value generally means the value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction.
[12] CMS clarifies that it no longer believes that the mere fact that an item, device or supply is routinely used as part of a surgical procedure means that the item, device or supply is not used solely for one of the six purposes listed in the Stark Law.
[13] The exceptions for referral services (411.357(q) and obstetrical malpractice subsidies (411.357(r)) will continue to require compliance with the specific Anti-Kickback Statute safe harbors.

likely also fail to meet one or more of the more key requirements of an exception to the Stark Law, namely compensation is likely not fair market value or is determined in a manner that takes into account the volume or value of the physician's referrals or other business generated for the entity.

3. **Period of Disallowance. 42 C.F.R. § 411.353(c)(1)**. CMS proposes to delete the rules on the period of disallowance in their entirety, stating that the rules are overly prescriptive and impractical.
   a. Notably, CMS provides clarifying guidance that suggests that an effective compliance program that detects and corrects administrative or operational errors or discrepancies *during* the course of the arrangement may be permissible to address noncompliance and avoid self-disclosure. Specifically, "an entity that detects a problem in an active financial relationship and corrects the problem while the financial relationship is still active is addressing a current problem and is not 'turning back the clock' to fix past noncompliance. On the other hand, once a financial relationship has ended, we believe that parties cannot retroactively 'cure' previous noncompliance by recovering or repaying problematic compensation." CMS-1720-P at 181. Significantly, this means that an entity that discovers administrative errors may make its situation worse if it terminates the arrangement before the errors are corrected.
4. **Special Rules on Compensation. 42 C.F.R. § 411.354**.
   a. Titular Ownership or Investment Interest. 42 C.F.R. § 411.354(b)(3)(vi). CMS proposes to extend the concept of titular ownership or investment interests to the rules governing ownership or investment interest at § 411.354(b), rather than limiting it to physician organizations. Such clarification is intended to provide physicians greater flexibility in states where the corporate practice of medicine is prohibited.
   b. Employee Stock Ownership Program. 42 C.F.R. § 411.354(b)(3)(vii). CMS proposes to remove employee stock ownership program interests from the definition of ownership or investment interest for purposes of the Stark Law.
   c. Indirect Compensation Arrangements. 42 C.F.R. § 411.354(c). CMS proposes revisions to the indirect compensation arrangement definition to address value-based payment arrangements where the value-based payment arrangement is the link in the chain closest to the physician (e.g., where the physician is a direct party to the value-based arrangement). Such revisions are necessary to address value-based arrangements which inherently may take into account the volume or value of referrals generated or may not be consistent with fair market value, thus falling outside the protections of the indirect compensation arrangements exception.
   d. Directed Referrals. 42 C.F.R. § 411.354(d)(4). CMS proposes to include an affirmative requirement in certain exceptions that, in addition to satisfying the other requirements of the exception, the relevant arrangement must comply with the revised special rule at § 411.354(d)(4). The applicable exceptions include: the *bona fide* employment relationships, personal service arrangements, physician incentive plans, academic medical centers, group practice arrangements with a hospital, fair market value compensation and indirect compensation arrangements.
   e. Temporary Non-Compliance with Writing and Signature Requirements. 42 C.F.R. § 411.354(e)(3). CMS proposes to extend the special rule for temporary non-compliance with the signature requirement to also apply to temporary non-compliance with the

writing requirement. If finalized, the new Special Rule for Temporary Non-compliance would deem the signature or writing requirement of the applicable compensation exception to be satisfied if the requirements under the special rule are met. This change would give increased flexibility for implementing arrangements on an expedited basis.

5. **Exclusive Use of Space or Equipment. 42 C.F.R. § 411.357(a) and (b)**. CMS proposes to add clarifying language to the text of the regulations for rental of office space and equipment to confirm its longstanding policy that the exclusive use requirement only applies to exclude the lessor and persons or entities related to the lessor from using the space during the lessee's rental period. The lessee may permit others to use the space or equipment during its rental period.
6. **Physician Practice Signature to Recruitment Arrangement. 42 C.F.R. § 411.357(e)**. CMS proposes to revise the recruitment arrangements exception to remove the signature requirement for physician practices when the physician practice receives no financial benefit from the arrangement – for example, where a physician joins a practice during the forgiveness phase of the arrangement. The requirement that the physician practice sign the recruitment arrangement would continue where the physician practice retains some of the remuneration to cover costs incurred in recruiting the physician.
    a. *Notably,* even though the signature element may be removed, the exception would require that the physician practice not impose "unreasonable practice restrictions" on the physician. Presumably, a recruiting hospital would need to make its support to the physician contingent on the physician not agreeing to any unreasonable practice restrictions.
7. **Remuneration Unrelated to the Provision of DHS. 42 C.F.R. § 411.357(g)**. CMS proposes to revise the exception for remuneration unrelated to the provision of DHS to broaden its applicability to hospital and physician arrangements. Specifically, CMS proposes to revise the language to clarify that the remuneration does not relate to the provision of DHS if the remuneration is for items or services not related to patient care services. CMS maintains the qualification that such remuneration cannot be determined in a manner that takes into account the volume or value of the physician's referrals, as such would inherently be related to the provision of DHS. Therefore, if the services can be legally provided by a person who is not a licensed medical professional and the service is of the type that is typically provided by such persons, then payment is unrelated to the provision of DHS; provided that it is not determined in a manner that takes into account the volume or value of the physician's referrals.
    a. Remuneration that is *related* to patient care services:
        i. Provision of patient care services to hospital patients.
        ii. Payment for call coverage services.
        iii. Payment for medical director services.
        iv. Payment for utilization review services.
        v. Rental of medical equipment.
        vi. Purchasing of medical devices.
        vii. Rental of office space where patient care services are provided.
    b. Remuneration that is *unrelated* to patient care services (provided the remuneration is not determined in a manner that takes into account the volume or value of referrals):
        i. *A*dministrative services of a physician pertaining solely to the business operations.

ii. Serving on a community board (with non-medical professionals) and receiving stipends or meals that are available to other board members.
iii. When a physician joins another practice and sells his/her furniture to a hospital.
iv. Rental payments from a teaching hospital to a physician to use the house as a residence for a visiting faculty member.

c. Significantly, because this exception does not contain a fair market value requirement, this would make it possible for above-market payments to referring physicians in arrangements unrelated to the provision of DHS to qualify for this exception (but such payments might still be subject to the Anti-Kickback Statute challenge.)

8. **Exception for Payments by a Physician. 42 C.F.R. § 411.357(i)**. CMS proposes to revise the exception for payments by a physician to broaden its applicability by stating that such exception cannot be used if one of the statutory exceptions at § 411.357(a) through (h) is available, but can be used even if another exception (including the fair market value exception) could be available.
9. **Fair Market Value Arrangements Exception. 42 C.F.R. § 411.357(l)**. CMS proposes to extend the fair market value arrangements exception to protect arrangements for rental or lease of office space. This proposal, if finalized, would permit office lease arrangements of less than one year.
10. **EHR Items and Services. 42 C.F.R. § 411.357(w)**. CMS is proposing to update the EHR exception pertaining to interoperability and data lock-in, clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the sunset provision, and modify the definitions of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act. The OIG is proposing updates to the analogous safe harbor under the Federal Anti-Kickback Statute.
11. **Exception for Assistance with NPP Compensation. 42 C.F.R. § 411.357(x)**. CMS proposes to revise references and definitions related to nonphysician practitioner (NPP) services and referrals to clarify the scope of this exception. Further, CMS proposes to require that the compensation arrangement between the hospital and the physician commences before the physician enters into the compensation arrangement with the NPP.

Clarifying Guidance

In the Stark Proposed Rule, CMS provided clarifying guidance on its interpretation of many regulatory exceptions. The following is a high-level summary of these clarifications:

1. "Set in advance". The Stark Proposed Rule clarifies that the "set in advance" requirement does not require that the compensation be set forth in writing. The special rule on compensation at § 411.354(d)(1) is a "deeming provision" that if met, deems the compensation to have met the "set in advance" requirement of the corresponding exception. CMS-1720-P at 69.
2. "Special Rules on Compensation". CMS reiterates that the Special Rules on Compensation (42 C.F.R. § 411.354(d)(2) and (3)) are intended to be safe harbors, and there may be situations not described in § 411.354(d)(2) or (3) where an arrangement does not take into account the volume or value of referrals or other business generated between the parties. CMS 1720-P at 107.
3. "Group Practice Profit Distributions". 42 C.F.R. § 411.352. CMS provides clarifying guidance of its policy related to distribution of group practice profits to subsets of physicians based on the type of designated health service provided. Specifically, CMS clarifies that with respect to the Group Practice exception, the profits from *all* the designated health services of the practice must be

aggregated and distributed, with profit shares not determined in any manner that directly takes into account the volume or value of a physician's referrals. Thus, a physician practice that desires to qualify as a group practice could not distribute profits from DHS on a service-by-service basis or, apparently, distribute profits from some DHS but not others. CMS-1720-P at 144.

Contacts

Kelsey E. Fohner	Rogers	(479) 250-9708	kelsey.fohner@kutakrock.com
Christopher D. Phillips	Omaha	(402) 231-8787	christopher.phillips@kutakrock.com

This Client Alert is a publication of Kutak Rock LLP. It is intended to notify our clients and friends of current events and provide general information about healthcare issues. This Client Alert is not intended, nor should it be used, as specific legal advice, and it does not create an attorney-client relationship.

© Kutak Rock LLP 2019 – All Rights Reserved. This communication could be considered advertising in some jurisdictions. The choice of a lawyer is an important decision and should not be based solely upon advertisements.

APPENDIX A

1. **<u>Definitions Proposed at 42 C.F.R.. § 411.351</u>**

Commercially reasonable (Proposed at § 411.351) means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Isolated financial transaction (Proposed at § 411.351) —

(1) Isolated financial transaction means a transaction involving a single payment between two or more persons or a transaction that involves integrally related installment payments, provided that—
  (i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and
  (ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).

Target patient population (Proposed at § 411.351) means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that –

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and
(2) Further the value-based enterprise's value-based purpose(s).

Value-based activity (Proposed at § 411.351) —

(1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
  (i) The provision of an item or service;
  (ii) The taking of an action; or
  (iii) The refraining from taking an action.
    (2) The making of a referral is not a value-based activity.

Value-based arrangement (Proposed at § 411.351) means an arrangement for the provision of at least one value-based activity for a target patient population between or among—

(1) The value-based enterprise and one or more of its VBE participants; or
(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) (Proposed at § 411.351) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;
(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
(4) That have a governing document that describes the value-based enterprise and how VBE participants intend to achieve its value-based purpose(s).

Value-based purpose (Proposed at § 411.351) means—

(1) Coordinating and managing the care of a target patient population;
(2) Improving the quality of care for a target patient population;
(3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant (Proposed at § 411.351) means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

2. <u>Volume or Value Standard and Other Business Generated Standard. (Proposed at § 411.354(d)(5) and (6))</u>

(d) *Special rules on compensation*. The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

…

(5)(i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if—

(A) 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; or
(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for 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 physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) applies only to section 1877 of the Act.

(6)(i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if—

(A) The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) applies only to section 1877 of the Act.

3. **Special Rules for Profit Shares and Productivity Bonuses. (Proposed at § 411.352(i)(3).**

(3) Value-based enterprise participation. Profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined in §411.351, are distributed to the participating physician.

4. **Limited Remuneration to a Physician. (Proposed at § 411.357(z))**.

(z) Limited remuneration to a physician—(1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $3,500 per calendar year, as adjusted for inflation in accordance with paragraph (z)(2) of this section, if all of the following conditions are satisfied:

(i) 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.
(ii) The compensation does not exceed the fair market value of the items or services.
(iii) The arrangement is commercially reasonable.
(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—
    (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or
    (B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
(v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on—
    (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or
    (B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.
(2) The annual remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website.

5. **Arrangements that facilitate value-based health care delivery and payment (Proposed § 411.357(aa).**

(aa) *Arrangements that facilitate value-based health care delivery and payment.*

(1) Full financial risk - Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:
  i. The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

ii. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

iii. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

iv. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

v. If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of 411.354(d)(4)(iv).

vi. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

vii. For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) Value-based arrangements with meaningful downside financial risk to the physician – Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:

i. The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

ii. A description of the nature and extent of the physician's downside financial risk is set forth in writing.

iii. The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

iv. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

v. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

vi. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

vii. If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv).

viii. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

ix. For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician –

1. Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or
2. Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

(3) Value-based arrangements – Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met –

i. The arrangement is set forth in writing and signed by the parties. The writing includes a description of –
   A. The value-based activities to be undertaken under the arrangement;
   B. How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;
   C. The target patient population for the arrangement;
   D. The type or nature of the remuneration;
   E. The methodology used to determine the remuneration; and
   F. The performance or quality standards against which the recipient will be measured, if any.
ii. The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.
iii. The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.
iv. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
v. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
vi. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
vii. If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv).
viii. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

6. <u>Cybersecurity Technology and Related Services. (Proposed § 441.357(bb)).</u>

(bb) Cybersecurity technology and related services—

(1) Nonmonetary remuneration (consisting of certain types of technology and services), if all of the following conditions are met:
   (i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.
   (ii) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes

into account the volume or value of referrals or other business generated between the parties.

(iii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iv) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology other than hardware.