SWEEPING PROPOSALS ISSUED BY CMS TO REVISE STARK LAW REGULATIONS

Authors: Ross C. D'Emanuele, Randall Hanson, Jamie Buskirk McCarty, Laura B. Morgan, Alissa Smith, Claire H. Topp, Charis Zimmick

On October 9, 2019, the Department of Health and Human Services (the "Department") Centers for Medicare & Medicaid Services ("CMS") issued a sweeping set of proposals to revise regulations under the federal physician self-referral law ("Stark Law" or "Stark"),[1] which were published in the Federal Register (available here) on October 17, 2019 (the "Proposed Regulations"). The Proposed Regulations are part of the Department's "Regulatory Sprint to Coordinated Care" (the "Regulatory Sprint"), which is a large initiative to modernize many health care regulations. The proposed regulatory changes under the Regulatory Sprint are aimed at reducing barriers to care coordination and value-based arrangements in order to help accelerate the transformation of the nation's health care system to one that incentivizes providers to focus on improved quality, better health outcomes and increased efficiency in health care delivery. Dorsey & Whitney's health care attorneys have been closely tracking the Regulatory Sprint, and more information and links to Dorsey publications on the Regulatory Sprint can be found here.

CMS issued the Proposed Regulations following a June 2018 Request for Information ("RFI") about ways CMS could modify the Stark Law regulations in order to reduce barriers to patient care coordination and value-based

1 As used herein, the term "Stark Law" or "Stark" may refer to the Stark statute at Section 1877 of the Social Security Act and/or the Stark regulations at 42 C.F.R. § 411.350 et seq.

arrangements and to reduce the regulatory burden of complying with the Stark Law generally, which we wrote about here. In response, CMS received nearly 400 comments from stakeholders, which it addressed in the Proposed Regulations and the corresponding preamble text.

CMS explains in the preamble that, when the Stark Law was enacted in 1989, Medicare was primarily a volume-based, fee-for-service payment system. The law was intended to address concerns that physicians may be incentivized to refer more designated health services ("DHS") to entities with which they have financial relationships in order to increase the volume of payments Medicare would make to the entity furnishing that DHS, and, thus, to benefit the physicians' own financial self-interest. CMS acknowledges that significant changes in health care delivery and payment have occurred since the enactment of the Stark Law, including through the Medicare Shared Savings Program and various initiatives by the Center for Medicare and Medicaid Innovation. Further, CMS explains that commercial payors and health care providers have developed and implemented many innovative value-based payment and delivery models and, while these models may not necessarily involve the provision of DHS payable by Medicare, the financial relationships created by these models (just like any other type of financial relationship) may implicate the Stark Law, thus restricting referrals for DHS payable by Medicare.

Because the Stark Law is a strict liability statute and violations and/or alleged violations can lead to significant penalties and/or government and whistleblower action, stakeholders have been reticent to enter into innovative care coordination arrangements when there are not clearly applicable Stark Law exceptions available for them. CMS seeks to alleviate this concern in the Proposed Regulations, as well as to address many other areas where it believes it can reduce the regulatory burden of complying with the Stark Law. Further, while a value-based payment system does not present the same fraud and abuse risks that are present in a volume-based payment system (such as overutilization), a value-based payment system poses other potential risks (such as underutilization, cherry-picking, etc.) that CMS seeks to protect against in the Proposed Regulations.

The Proposed Regulations include proposed new exceptions to the Stark Law for certain value-based compensation arrangements, limited remuneration to a physician, and donations of cybersecurity technology and related services, proposed revisions to certain existing exceptions, and proposed revisions to the "group practice" definition. The Proposed Regulations also provide "critically necessary guidance" related to certain fundamental concepts under the Stark Law. Many of the proposed new and revised regulations would apply beyond financial arrangements related to care coordination initiatives, and thus are crucial for all stakeholders to understand (whether or not they are pursuing care coordination initiatives).

This article summarizes each of CMS's proposals, in five sections numbered as follows (using the titles from the Proposed Regulations):

I. Facilitating the Transition to Value-Based Care and Fostering Care Coordination
II. Fundamental Terminology and Requirements
III. Group Practices
IV. Recalibrating the Scope and Application of the Regulations
V. Providing Flexibility for Nonabusive Business Practices

The Proposed Regulations were published contemporaneously with proposed regulations from the Department Office of Inspector General ("OIG") that would make numerous significant changes to the regulations under the Anti-Kickback Statute ("AKS") and the Civil Monetary Penalty Law governing inducements provided to Medicare and Medicaid beneficiaries ("CMPL"). Our summary of the proposed changes to the AKS and CMPL is posted here. As we noted in that summary, although the Stark Law is a civil, strict liability payment law whose regulatory provisions are promulgated by CMS, and the AKS is an intent-based, criminal law whose regulatory provisions are promulgated by OIG, both agencies worked together in the process of developing these sweeping regulatory proposals. The agencies jointly recognize the need to modernize and clarify the Stark Law and AKS, which are often analyzed in tandem. There are a number of differences between the Stark Law and AKS

proposals. However, where there are similar proposals from OIG, the authors of this article have listed those proposals adjacent to our summary of CMS's proposals.

As a word of caution, the preamble provides a detailed discussion of each proposal, and is rich with examples, proposed additional and alternative considerations under review by CMS and repeated requests for specific stakeholder comments. Thus, there may be significant changes to the Proposed Regulations once they are published in final form.

Comments to the Proposed Regulations are due by December 31, 2019 and can be submitted here. Please contact the authors or your regular Dorsey attorney if you would like assistance with submitting comments. Dorsey attorneys will continue to closely monitor the status of these Proposed Regulations as we await final rules from CMS.

The following is a summary of CMS's Proposed Regulations:

I. Facilitating the Transition to Value-Based Care and Fostering Care Coordination

EXCEPTIONS FOR ARRANGEMENTS THAT FACILITATE VALUE-BASED HEALTH CARE DELIVERY AND PAYMENT (proposed 42 C.F.R. § 411. 357(aa))

In order to dismantle certain barriers to the transformation to value-based care, CMS proposes three new Stark exceptions for compensation arrangements intended to achieve certain value-based purposes. A "value-based purpose" under the proposed Stark rules aligns closely with the same term in the OIG's proposed rule to create new safe harbors under the AKS. The term would mean: (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) reducing payor costs or expenditures without reducing the quality of care for a target patient population; or (4) transitioning from healthcare delivery and payment mechanisms based on the volume of items or services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

The proposed Stark exceptions would address arrangements in which participants in a value-based enterprise engage in value-based activities reasonably designed to achieve at least one of these value-based purposes. As in OIG's proposed rule, a "value-based enterprise" would need to be comprised of at least two participants collaborating to achieve a value-based purpose and would need to have a governing document that describes the enterprise and how the participants intend to achieve their value-based purposes.

These three proposed new Stark exceptions would address arrangements between physicians and entities that provide and bill for DHS that differ based on the level of financial risk undertaken by the parties.

Full Financial Risk. The first proposed value-based Stark exception would apply to remuneration paid under a value-based arrangement when the value-based enterprise is at full financial risk. This means that the value-based enterprise would be prospectively financially responsible for the cost of all patient care items and services covered by the payor for each patient in a target patient population for a specified period of time. The compensation would need to be for, or result from, value-based activities undertaken by the recipient for patients in the target population. The remuneration could not be an inducement to reduce or limit medically necessary items or services, and could not be conditioned on referrals of patients who are not part of the target patient population.

The corresponding AKS proposal protecting value-based arrangements that take on full financial risk is found at proposed 42 CFR 1001.952(gg), and includes some differences from the proposed Stark exception.

Meaningful Downside Financial Risk. The second proposed value-based Stark exception would apply when a physician is at meaningful downside financial risk for failure to achieve value-based purposes of the value-based

enterprise during the entire duration of the arrangement. Meaningful downside financial risk would mean that the physician is responsible to pay no less than 25% of the value of remuneration the physician receives under the value-based arrangement (which would include any in-kind remuneration). In this exception, a description of the nature and extent of the physician's downside financial risk would need to be set forth in writing and the payment methodology would need to be set in advance. This exception would include the same controls on inducements which limit medically necessary items or services and referrals of patients who are not part of the target patient population as are proposed in the full financial risk exception (described above).

Value-Based Arrangements. The third related Stark exception would address compensation paid to physicians under arrangements that qualify as value-based arrangements regardless of the level of risk undertaken by the value-based enterprise or any of its participants. This exception would include similar regulatory controls around inducing limitation of medically necessary services and referrals of patients who are not part of the target patient population as the full financial risk and meaningful downside financial risks proposals, but would include more documentation and substantive requirements. Specifically, the arrangement would need to be in writing and signed by the parties, and the contract or other writing would need to include a description of the following:

- Value-based activities to be undertaken;
- How these value-based activities are expected to further the value-based purposes of the enterprise;
- Target patient population;
- Type or nature of remuneration;
- Payment methodology (which must be set in advance); and
- Objective and measurable performance or quality measures against which the recipient will be measured (and any change to the measures must be made prospectively and in writing).

In the preamble to the Proposed Regulations, CMS provides a hypothetical example of a value-based arrangement that could meet this exception. If a hospital revised its care protocol for screening for a certain type of cancer based on guidelines from a nationally recognized organization, the hospital could enter into contracts with physicians to compensate the physicians $10.00 for each instance that they order testing in accordance with the new screening protocol over a two-year period. To illustrate the obligation to monitor such programs, CMS also points out that if, following the first year, the hospital were to determine that the new screening protocol was ineffective and will not achieve the hospital's goal of improving the quality of care, the hospital must terminate the payment arrangement in order to remain in compliance with Stark.

The corresponding AKS proposal protecting value-based arrangements with value-based purposes is found at proposed 42 CFR 1001.952(ee).

Indirect Compensation Arrangements to which the Above Exceptions are Applicable (42 C.F.R. § 411.354(c)(4)). CMS also proposes to allow any of the three proposed value-based arrangements exceptions to apply whenever the physician recipient of remuneration is a direct party to the value-based arrangement, even if the physician receives compensation indirectly through a chain of compensation or ownership relationships making up the value-based arrangement. This change is necessary so that value-based arrangements made up of a chain of relationships can avoid the restriction found in the indirect compensation exception that compensation not be determined in any manner that takes into account the volume or value of physician referrals for DHS.

II. Fundamental Terminology and Requirements

Many of the Stark Law exceptions require that the compensation under the arrangement is (1) commercially reasonable; (2) not determined in a manner that takes into account the volume or value of referrals; and/or (3) consistent with fair market value. Many commenters that responded to the CMS RFI requested that CMS provide "bright-line, objective regulations" on these three fundamental requirements, and CMS agrees that such "clear, bright-line rules would enhance both stakeholder compliance efforts and our enforcement capability."

CMS proposes a number of revisions to the Stark regulations that it believes provide such bright-line rules.

Commercially Reasonable Standard. First, CMS proposes to include a definition of the term "commercially reasonable" at 42 C.F.R. § 411.351, as this term has never before been defined by regulation. CMS explains that it believes that the key question is "whether the arrangement makes sense as a means to accomplish the parties' goals," from the perspective of the particular parties involved. CMS clarifies, in both preamble text and the proposed regulation language, that compensation that does not result in profit to one or more party may nevertheless be commercially reasonable, as the parties may enter into the arrangement for other legitimate reasons such as community need, fulfillment of licensure obligations, and other reasons.

CMS proposes two alternative definitions for "commercially reasonable," i.e., that (1) "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements" (which is the language in the proposed regulatory text); or (2) "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" (which is described in preamble text only).

CMS points out that various exceptions require that the arrangement is commercially reasonable "even if no referrals were made," and emphasizes that it is not proposing to eliminate this requirement from these exceptions.

Volume/Value and Other Business Generated Standards. Many Stark Law exceptions include a requirement that the compensation under the arrangement does not take into account the volume or value of referrals and some also require that the compensation is not determined in a manner that takes into account other business generated between the parties. CMS acknowledges that objective tests are needed to determine whether a compensation arrangement implicates these standards.

CMS proposes new special rules at 42 C.F.R. § 411.354(d)(5) and (6) that describe compensation methodologies that *would* take into account the volume/value of referrals or other business generated, with separate rules for compensation *to* a physician (or immediate family member) and compensation *from* a physician (or immediate family member). If finalized, other than in the circumstances set forth in these proposed special rules, compensation *would not* be considered to implicate these standards, i.e., the special rules would "define the universe of circumstances under which compensation is considered" to implicate these standards.

Specifically, under the proposed special rules, compensation *from an entity to a physician* (or immediate family member) would take into account the volume or value of *referrals* only if: (1) the formula used to calculate the compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease to the compensation that *positively* correlates with the number or value of the referrals; or (2) there is a predetermined, direct correlation between the prior referrals and the prospective rate of compensation to be paid over the entire duration of the arrangement. There is a parallel proposed special rule for compensation from an entity to a physician (or immediate family member) that would take into account the volume or value of *other business generated*. Further, the proposed special rules for compensation *from a physician* (or immediate family member) *to an entity* generally parallel the proposed special rules related to compensation form an entity to a physician (or immediate family member), except that the compensation would negatively correlate with the number or value of referrals or other business generated (as applicable).

CMS also proposes to remove the modifying phrase "directly or indirectly" related to the volume/value and other business generated standards in various exceptions where it appears, as they believe that this modifier is implicit.

CMS reaffirms the position it took in the Stark Phase II regulation that, for employed physicians, a productivity bonus *does not* take into account the volume or value of referrals just because corresponding hospital services are billed when the physician personally performs a service. CMS also clarifies that this guidance extends to personal services arrangements using unit-based compensation formulas. This clarification is intended to

alleviate concerns expressed by RFI commenters that CMS may not have endorsed the position it took in the Stark Phase II regulation based on the 2015 opinion of the *United States Court of Appeals for the Fourth Circuit in United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*

Finally, CMS proposes to revise the special rule for directed referrals at 42 C.F.R. § 411.354(d)(4), which provides that compensation is deemed not to take into account the volume or value of referrals even if it is predicated on a physician making referrals to a particular provider, practitioner or supplier, if certain requirements are met, including that there must be a carve-out to the directed referral requirement for patient preference, insurance determination, or the physician's professional medical judgment. CMS explains that because of the importance of these protections, it proposes to include in various Stark Law exceptions to which this special rule has typically applied (including the employment compensation exception, personal service arrangement exception, and others) a requirement that if compensation to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions at 42 C.F.R. § 411.354(d)(4). CMS also proposes to revise this special rule to clarify the "set in advance" and fair market value requirements, among other nonsubstantive revisions.

Fair Market Value. CMS proposes to remove the existing definition of "fair market value" at 42 C.F.R. § 411.351 and replace it with new regulatory language that would separately define fair market value for general application, for the rental of equipment, and for the rental of office space. Under each of these separate definitions, "fair market value" would be the value in an arm's-length transaction, with like parties and under like circumstances, consistent with the general market value of the subject transaction, of like assets or services (under the general definition) or of rental property for general commercial purposes (not taking into account its intended use) (under the rental of equipment and office space definitions). Additionally, for the rental of office space definition only, there could not be adjustment to reflect additional value attributable to the proximity to the lessor where the lessor is a potential source of referrals to the lessee.

CMS also proposes to revise the definition of "general market value." Generally, this term would mean "[t]he price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement." For the rental of equipment or office space, this term would mean "[t]he price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement."

CMS points out that "the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard," and certain of its revisions to the definition of "fair market value" are intended to remove the connection to these standards within the definition. CMS includes a discussion in preamble text regarding how it seeks to reconcile its regulatory definitions with recognized valuation principles.

III. Group Practices (42 C.F.R. § 411.352)

CMS included in its RFI a request for comments regarding any perceived barriers to physician groups qualifying as a "group practice" under the Stark Law. Qualifying as a "group practice" under the Stark Law is generally needed in order for a referred service to have the protection of the in-office ancillary services exception at 42 C.F.R. § 411.355(b) (among other implications). CMS acknowledges that commenters believe clarification of many parts of the group practice rules are needed, but specifically limits its proposed revisions to the group practice rules to the main purposes of the Proposed Regulations (i.e., proposed definitions and special rules for fundamental terminology and requirements and the transition to a value-based health care system). However, CMS states that it may consider further revisions in future rulemaking. CMS does not propose to change the "volume or value" regulation text in the group practice definition (because this language mirrors statutory language), but includes in preamble text an explanation of how it interprets this standard in light of prior rulemaking and in light of the new proposed special rules related to the volume/value standard (described

above).

The group practice definition includes special rules for profit sharing and productivity bonuses that permit a physician in the group practice to be paid in a manner that *indirectly* relates to the volume or value of the physician's referrals. CMS proposes a number of changes to these special rules. First, CMS proposes certain clarifying revisions, including revisions to describe how overall profits can be distributed when a group practice has less than five physicians and revisions to remove the reference in the regulations to *Medicaid* DHS.

Notably, in the proposed changes to the special rules for payments based on a share of overall profits, CMS proposes to add the words "all the" before "designated health services." CMS explains that this is a codification of its existing policy that the profits from *all* the DHS of the practice (or a component of the practice that consists of at least five physicians) must be aggregated and distributed. Under the proposed changes to the regulations, a group practice *could not* distribute profits from DHS on a service-by-service basis.

CMS also proposes a new special rule that would allow profits from DHS "that are *directly* attributable to a physician's participation in a value-based enterprise" to be distributed to the participating physician. CMS explains that this would include downstream compensation derived from payments made to a group practice that relate to the physician's participation in a value-based arrangement. In this context, CMS *would not prohibit* remuneration that takes into account the volume or value of a physician's referrals, which CMS explains is an extension of its policy at proposed 42 C.F.R. § 411. 357(aa) (related to value-based arrangements, as described above).

IV. Recalibrating the Scope and Application of the Regulations

CMS has previously stated in its Stark Phase I regulation that its intent is "to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent." CMS states that one purpose of the Proposed Regulations is to reexamine the regulations and determine "whether we have held true to that intention." For this reason, in the Proposed Regulations, CMS proposes certain revisions to and deletions of various Stark Law regulatory requirements and exceptions that "may be unnecessary at this time." These proposals are described below.

DECOUPLING STARK FROM THE AKS

Many Stark Law exceptions currently require that the arrangement does not violate the AKS and that the arrangement does not violate any Federal or state law or regulation governing billing or claims submission. CMS proposes to remove the requirement that the arrangement not violate the AKS, or Federal or state law or regulation governing billing or claims submission from the Stark Law exceptions that include it (as well as to remove the requirements from the definitions at 42 C.F.R. § 411.351 the term "does not violate the anti-kickback statute"), concluding it is no longer "necessary or appropriate to include" such requirements. CMS clarifies that its proposed revisions do not affect the parties' compliance obligations under the foregoing laws.

DEFINITIONS (42 C.F.R. § 411.351)

Designated Health Services. The current definition of "designated health services" includes DHS "payable, in whole or in part, by Medicare, and does not include services that would otherwise constitute designated health services, but that are reimbursed by Medicare as part of a composite rate, except to the extent that the services are specifically identified in 411.351 and are themselves payable through a composite rate." CMS proposes to revise the definition of "designated health services" to clarify that a service provided by a hospital to an inpatient does not constitute DHS 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"). CMS acknowledges that not all hospitals are paid under the IPPS, and CMS solicits comments as to whether the proposal should be extended to analogous services provided by hospitals that are not paid under the IPPS and whether CMS should extend the proposal to outpatient hospital services or other categories

of DHS.

Physician. The term "physician" under the Stark Law is defined in part as "a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in Section 1861(r) of the [Social Security Act (the "Act")]." CMS explains that the definition of the term "physician" under the Stark Law does not include all of the limitations of the definition of the term in the Act. To harmonize the definitions, CMS proposes to define the type of practitioners who qualify as "physicians" for purposes of the Stark Law by cross-reference to Section 1861(r) of the Act.

Referral. Currently, certain Stark exceptions protect "items or services" provided by a physician. CMS proposes to clarify that a physician's referrals are not "items or services" for which payment made be made under Stark. This change makes explicit CMS's longstanding policy that a referral is not an item or service for the purposes of the Stark statute and regulations.

Remuneration. Currently, the definition of "remuneration" under the Stark Law includes a parenthetical stating that the provision of surgical items, devices and supplies do not qualify for the carve-out to the definition of "remuneration" for "items, devices, or supplies" that are "used solely to collect, transport, process, or store specimens for the entity providing the items, devices or supplies, or to order or communicate the results of tests or procedures for such entity." CMS proposes to remove the parenthetical because there may be some surgical items, devices or supplies that are used solely for the purposes described above.

Transaction. Section 1877(e)(6) of the Act and a regulatory exception at 42 CFR § 411.357(f) excludes an "isolated financial transaction" from the definition of a compensation arrangement under the Stark Law in certain circumstances. CMS proposes to add a new definition for "isolated financial transaction" which clarifies that the exception for isolated transactions is not available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all of the services. CMS proposes corresponding revisions to the exception at 42 C.F.R. § 411.357(f).

PERIOD OF DISALLOWANCE (42 C.F.R. § 411.353)(c)(1))

Under the current Stark regulations, a "period of disallowance" begins when a financial relationship fails to satisfy the requirements of any applicable exception. When the noncompliance is unrelated to the payment of compensation, the period of disallowance ends no later than the date that the financial relationship satisfies all requirements of an applicable exception. On the other hand, where the noncompliance is related to the payment of excess or insufficient compensation, the period of disallowance ends no later than the date on which the excess compensation was repaid or the additional required compensation was paid and the arrangement satisfies all of the elements of an applicable exception.

CMS proposes to delete the rules on the period of disallowance at 42 C.F.R. § 411.353(c)(1) in their entirety. CMS clarifies in the preamble to the Proposed Regulations that the effect of deleting the period of disallowance rules does not permit a party to a financial relationship to make referrals for DHS and to bill Medicare for the services when that financial relationship does not satisfy all requirements of an applicable exception. Rather, the intent in deleting the provision is "merely to no longer prescribe the particular steps or manner for bringing the period of noncompliance to a close." CMS explained that the current rules were intended to establish an "outside, bright-line limit for the period of disallowance" but, in application, they had become overly prescriptive and impractical. Instead, CMS proposes an analysis on a case-by-case basis taking into account the unique facts of each financial relationship.

CMS also provides in the preamble some "general guidance on how to remedy compensation problems." If a hospital has paid a physician the wrong amount due to an "administrative or other operational error," the parties may, while the arrangement is ongoing during the term initially anticipated, correct the error by collecting the overage or making up the underpayment, if that is the case. CMS clarifies that fixing the issue during the term of

the arrangement is not "turning back the clock" to fix past noncompliance and is therefore permitted. However, if the parties fail to identify the error during the term of the arrangement as anticipated, they "cannot simply 'unring the bell' by correcting it at some date after the termination of the arrangement." If the parties fail to identify the error, then CMS would look at the actual amount paid, not what was stated in the contract, and determine if it was fair market value. If the actual amount paid was within fair market value, then the compliance issue is that the actual arrangement was not properly documented in writing, in which case the parties would look for another Stark exception to see if the parties could address the noncompliance. If the actual amount paid was not fair market value, then "the failure to collect money that is legally owed under an arrangement may potentially give rise to a secondary financial relationship between the parties" which is subject to Stark and for which an exception may not be available.

OWNERSHIP OR INVESTMENT INTERESTS (42 C.F.R. § 411.354(b))

Titular Ownership or Investment Interest. Currently, for the purposes of determining whether a "compensation arrangement" between an entity and a physician organization is deemed to be a compensation arrangement between the entity and the physicians associated with the organization, a physician whose ownership or investment interest in the physician organization is merely titular in nature does not "stand in the shoes" of the physician organization. A "titular ownership or investment interest" is an interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of a sale or similar returns on investment. CMS proposes to extend the concept of titular ownership or investment interest to rules governing ownership or investment interests, so that ownership or investment interests for purposes of the Stark Law would specifically exclude titular ownership or investment interests.

Employee Stock Ownership Program ("ESOP"). Currently, a retirement plan offered by an entity to a physician (or an immediate family member) through the physician's (or immediate family member's) employment with the entity is not considered an "ownership or investment interest" under the Stark Law. CMS proposes to also exclude from what is considered an "ownership or investment interest" under the Stark Law a physician's interest in an entity arising through participation in an ESOP. CMS seeks comment on whether safeguards on ESOPs that are imposed by the Employee Retirement Income Security Act ("ERISA") are sufficient to ensure that ESOPs do not pose a risk of program or patient abuse, and if not, what additional safeguards CMS should include.

SPECIAL RULES ON COMPENSATION ARRANGEMENTS (42 C.F.R. § 411.354(e))

CMS proposes a new special rule for signature and writing requirements that would be applicable to all compensation arrangement exceptions under Stark. Specifically, the proposal would provide that the writing requirement or signature requirement each would be satisfied if:

1. The compensation arrangement satisfies all other requirements of an applicable exception (except the writing and signature requirements); and
2. The parties to the compensation arrangement obtain the writing or signatures within 90 calendar days immediately after the date on which the arrangement failed to satisfy the writing or signature requirements under the applicable compensation exception.

CMS notes that the newly proposed rule would not apply to short-term arrangements (arrangements for 90 days or less, which are permitted under the exception for fair market value compensation), and that the rule would not be applied to circumvent the requirement that compensation must be set in advance. CMS clarifies that the rate of compensation does not need to be set out in writing in order to be "set in advance" of an arrangement, but that there must be evidence, such as informal communications or a pattern of payment, that shows that the parties agreed to a rate of compensation in advance of performing under a certain arrangement. With this new rule, CMS attempts to emphasize substance over form compliance, understanding that temporary form non-compliance poses relatively low risk of fraud and abuse.

EXCEPTIONS FOR RENTAL OF OFFICE SPACE AND RENTAL OF EQUIPMENT (42 C.F.R. § 411.357(a) and (b))

CMS has taken the opportunity in the Proposed Regulations to clarify its position on the appropriate application of the exceptions for the rental of office space and rental of equipment, stating that Stark does not prohibit multiple lessees from sharing rented space or equipment at the same time, so long as the lessor is not also sharing in use of the space or equipment. CMS proposes revisions to each of these exceptions accordingly.

PHYSICIAN RECRUITMENT EXCEPTION (42 C.F.R. § 411.357(e))

CMS clarifies that, in physician recruitment arrangements where remuneration flows from a hospital to a physician practice, which then immediately distributes such remuneration to the recruited physician, the practice simply is acting as an intermediary and does not itself receive a financial benefit from the hospital. For this reason, CMS proposes to revise the writing requirement of the physician recruitment exception to clarify that the writing need only be signed by the physician practice if payments are made by the hospital indirectly to the physician through the physician practice and the physician practice does not pass directly through to the physician all of the payments from the hospital.

REMUNERATION UNRELATED TO DHS EXCEPTION (42 C.F.R. § 411.357(g))

CMS proposes broadening the application of the exception for remuneration unrelated to the provision of DHS by emphasizing the concept of patient care services, i.e., remuneration from a hospital to a physician would not relate to the provision of DHS if the remuneration is for items or services that are not related to patient care services. The exception would still prohibit remuneration that takes into account the volume or value of the physician's referrals, but would permit remuneration for services that are also provided by persons who are not licensed medical professionals when the physician is compensated on the same terms and conditions as the non-medical professionals. The service must also be of the type typically provided by persons who are not licensed medical professionals. For example, if a physician is a member of a governing board with persons who are not licensed medical professionals, and the physician receives stipends or meals that are available to the other board members, the remuneration would not relate to DHS and would be permissible under this exception.

PAYMENTS BY A PHYSICIAN EXCEPTION (42 C.F.R. § 411.357(i))

CMS explains that the Stark Law statutory exception for payments by a physician functions as a catch-all to protect legitimate compensation arrangements not otherwise covered by another statutory Stark Law exception, but that CMS no longer believes that the regulatory exceptions should limit the scope of the payments by a physician exception. Thus, CMS proposes to remove from the payments by a physician exception the reference to *regulatory* exceptions, other than those regulatory exceptions that are a codification of statutory compensation exceptions (at 42 C.F.R. §§ 411.357(a) through (h)). Under the proposal, parties would generally be able to rely on this exception to protect fair market value payments by a physician to an entity for items or services furnished by the entity, even if certain other regulatory exceptions may be applicable. CMS stresses that the "items or services" furnished by the entity may not include cash or cash equivalents.

FAIR MARKET VALUE COMPENSATION EXCEPTION (42 C.F.R. § 411.357(l))

Currently, the fair market value compensation exception specifically excludes compensation resulting from an arrangement for the rental of office space, and CMS now proposes allowing the fair market value compensation exception to protect arrangements for the rental of office space. The fair market value compensation exception does not require a one-year term, unlike the exception for the rental of office space. Therefore, the Proposed Regulations would allow short-term arrangements for the rental of office space, as long as the parties only enter into one arrangement for the rental of the same office space during the course of a year. CMS also proposes to incorporate into the fair market value compensation exception the prohibition on percentage-based and per-unit

of service compensation for rental charges under an office lease.

ELECTRONIC HEALTH RECORDS ITEMS AND SERVICES EXCEPTION (42 C.F.R. § 411.357(w))

CMS proposes to further modify the electronic health records ("EHR") software exception created in 2006 (and first modified in 2013) in order to create consistency with the 21st Century Cures Act, specifically related to the "deeming" provision and "information blocking" condition, described below.

First, "deeming" is the process by which relevant parties may demonstrate their arrangement for EHR software fits the exception by showing that such software *has been* certified. CMS proposes to modify this language to instead state that there must be a showing that such software is certified. In other words, the certification would need to be current as of the date of the donation, as opposed to the software having been certified at some point in the past but no longer maintaining certification on the date of the donation.

Second, the "information blocking" condition currently prohibits the donor, or any person on the donor's behalf, 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 does not propose any rules that would substantively change this condition. Instead, CMS proposes changes that would better align this condition with the 21st Century Cures Act by, for example, updating definitions to be consistent.

Finally, CMS proposes to clarify that certain cybersecurity software and services are protected under this exception. Furthermore, CMS proposes to remove the sunset provision created in 2013 which stated that this exception would sunset in 2021. CMS is also considering three additional rules including updating the current 15% recipient contribution requirement, allowing replacement technology, and expanding the scope of donors protected by this exception.

The corresponding AKS proposal to modify the current EHR safe harbor is found at proposed rule 42 CFR 1001.952(y). Because the AKS EHR safe harbor is similar to the Stark exception, comments on the AKS safe harbor may impact the final version of the Stark proposal.

ASSISTANCE TO COMPENSATE A NONPHYSICIAN PRACTITIONER EXCEPTION (42 C.F.R. § 411.357(x))

CMS proposes to modify the current exception for assistance to compensate a nonphysician practitioner ("NPP"), which allows a hospital to provide remuneration to a physician to compensate a NPP to provide patient care services if certain requirements are met.

There have been several inquiries about the meaning of the term "patient care services" set out in the current Stark exception, which states that the NPP may not have, within one year of starting his or her compensation arrangement with a physician, been employed or engaged to provide patient care services by a physician that has a medical practice site in the hospital's geographic service area.

To clarify the meaning of "patient care services" for purposes of this exception, CMS proposes to revise the rule to change the references to "*NPP* patient care services." Under the proposed definition of "NPP patient care services," services provided by an individual who is not a NPP at the time the services are provided would not be *NPP* patient care services for purposes of the rule. Thus, if an individual works in the geographic area served by the hospital providing the assistance (for example, as a registered nurse) for some period immediately prior to the commencement of his or her compensation arrangement with the physician or physician organization in whose shoes the physician stands, but has not worked as a NPP in that area during that time period, this Stark exception would be available to protect remuneration from the hospital to the physician to compensate the NPP to provide NPP patient care services, provided that all of the requirements of the exception are satisfied. Additionally, CMS proposes to further clarify the terms "referral" and "practiced" in order to remove ambiguity.

UPDATING AND ELIMINATING OUT-OF-DATE REFERENCES

CMS proposes two updates that would eliminate out-of-date references. First, in 2003 the Medicare+Choice program was renamed Medicare Advantage. As such, CMS proposes to change any reference in the Stark regulations from Medicare+Choice to Medicare Advantage. CMS seeks comments on whether the rule's current reference to the Medicare+Choice program is broad enough to protect DHS delivered under the full range of Medicare Advantage plans that exist today. Second, CMS proposes to change any reference in the rules from "web site" to "website" to conform to the spelling of the term in the Government Publishing Office's Style Manual and other current style guides.

V. Providing Flexibility for Nonabusive Business Practices

As an additional indication of CMS's desire to provide greater flexibility under the Stark Law for nonabusive business practices, CMS proposes to add two new exceptions to the Stark Law: (1) limited remuneration to a physician; and (2) cybersecurity technology and related services. (These proposed new exceptions are in addition to the proposed new exceptions for arrangements that facilitate value-based health care delivery and payment, described above.)

LIMITED REMUNERATION TO A PHYSICIAN EXCEPTION (proposed 42 C.F.R. § 411. 357(z))

CMS proposes a new exception that would protect limited remuneration from an entity to a physician, not to exceed $3,500.00 per year (to be adjusted for inflation), for items or services actually provided by the physician to the entity. This exception would apply in instances when the amount of, or a formula for, calculating the remuneration is not set in advance of the provision of the items or services. The exception would prohibit the compensation from being determined in any manner that takes into account the volume or value of referrals or other business generated by the physician. The exception would include a fair market value and commercial reasonableness requirement. CMS also proposes to include restrictions on how the compensation formula could be determined (i.e., the formula could not be based on a percentage of the revenue raised, earned, billed or collected, or based on per-unit of service fees under certain circumstances).

CYBERSECURITY TECHNOLOGY AND RELATED SERVICES EXCEPTION (proposed 42 C.F.R. § 411. 357(bb))

CMS also proposes a new exception that would protect arrangements involving the donation to physicians of certain cybersecurity technology (i.e., software or other types of information technology other than hardware) and related services. Under this proposed exception, the technology and services would need to be necessary and predominantly used to implement, maintain or reestablish cybersecurity. For example, the technology may include malware prevention software, software security measures to protect end points that allow for network access control, business continuity software that mitigates the effect of cyberattacks, data protection and encryption, and e-mail traffic filtering. Further, neither the eligibility of a physician for the cybersecurity technology and related services, or the amount or nature of the services, could be determined based on the volume or value of referrals or other business generated between the parties. Finally, the donation could not be a condition of doing business with the donor and the arrangement would need to be documented in writing.

The corresponding AKS proposal protecting the donation of cybersecurity technology and related services is found at proposed 42 CFR 1001.952(j), and is generally aligned with the Stark proposal (with some exceptions).