

## WHITE PAPER: UNDERSTANDING THE FINAL RULES TO REVISE THE STARK LAW REGULATIONS

Authors: Laura B. Morgan, Ross C. D'Emanuele, Randall Hanson, Carson Lamb, Alissa Smith, Claire H. Topp  
January 5, 2021



On November 20, 2020, the Department of Health and Human Services (“HHS”) Centers for Medicare & Medicaid Services (“CMS”) issued a sweeping set of final rules to revise regulations under the federal physician self-referral law (“Stark Law” or “Stark”),<sup>1</sup> which were published in the *Federal Register* (available [here](#)) on December 2, 2020 (the “Final Rules”). The Final Rules are part of HHS’s “Regulatory Sprint to Coordinated Care” (the “Regulatory Sprint”), which is a large initiative to modernize many health care regulations. The 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](#).

The Final Rules were issued just over a year from when CMS published its proposed rules to revise the Stark regulations in the *Federal Register* on October 17, 2019 (which Dorsey wrote about [here](#)) (the “Proposed Rules”). [CMS received](#) nearly 300 [comments](#) from stakeholders on the Proposed Rules, which it addressed in the Final

<sup>1</sup> 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.*

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Rules and corresponding preamble text. The Final Rules have an effective date of January 19, 2021, with the exception of certain changes to the Stark Law's "group practice" definition that do not go into effect until January 1, 2022.

CMS explained in the preamble to the Final Rules 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 acknowledged 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 explained 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 involve Medicare, the financial relationships created between physicians and DHS entities by these models may implicate the Stark Law, which would restrict referrals for DHS payable by Medicare unless an exception is met.

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 actions, 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 Final Rules, 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 or lemon-dropping) that CMS seeks to protect against in the Final Rules.

The Final Rules include 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; revisions to certain existing exceptions, definitions and special rules; and revisions to the "group practice" definition. The Final Rules also provide guidance related to fundamental concepts under the Stark Law, including commercial reasonableness, the volume or value standard, and fair market value. **Many of the new and revised regulations 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).** The majority of the changes made in the Final Rules will likely be welcomed by the regulated industry because they ultimately reduce the burden of complying with the Stark Law. However, the Final Rules also introduce new complications in needing to understand a fresh overlay of agency interpretations and new and revised regulations. Furthermore, it will take time for stakeholders to consider whether and how to enter into and structure new value-based arrangements, or restructure existing value-based arrangements, in reliance on the new value-based exceptions. Finally, changes to the profit-sharing rules under the "group practice" definition (which do not go into effect until January 1, 2022) will add new compliance burdens for many physician practices that will need to modify physician compensation methodologies based on these changes.

This white paper summarizes each of CMS's final rules, in five sections numbered as follows (using the titles from the Final Rules):

- 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

As with the Stark Law Proposed Rules in October 2019, the Final Rules were published contemporaneously with final regulations from the HHS Office of Inspector General ("OIG") that 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"). Dorsey's white paper summarizing the final changes to the AKS and CMPL regulations is posted [here](#). As noted in that summary, although the Stark Law is a civil, strict liability payment law with regulatory provisions that are promulgated by CMS, and the AKS is an intent-based, criminal law with regulatory provisions that are promulgated by OIG, the agencies worked together in the process of developing these sweeping regulatory changes—particularly with respect to the new value-based exceptions/safe harbors and related definitions (as noted in Section I below). Both agencies recognized the need to modernize and clarify the Stark Law and AKS, which are often analyzed in tandem because financial arrangements may implicate both laws.

The following is a summary of CMS's Final Rules:

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

CMS finalized three new Stark exceptions for compensation arrangements that depart, in many respects, from traditional Stark exceptions in order to facilitate the transition to a value-based care delivery and payment system. As in the OIG's new value-based safe harbors under the AKS, the three new Stark exceptions can apply only to compensation arrangements intended to achieve certain value-based purposes. A value-based purpose 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 or services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

A target patient population means an identified patient population selected by a value-based enterprise or its 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 purpose of the enterprise.

The new Stark exceptions 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 the new AKS safe harbors, a value-based enterprise (or VBE) must comprise at least two participants collaborating to achieve a value-based purpose. The value-based enterprise must have a governing document that describes the enterprise and how the participants intend to achieve their value-based purposes, and must have an accountable body or person responsible for its financial and operational oversight. However, the value-based enterprise does not have to be a distinct legal entity, and the written documentation memorializing the arrangement could serve as the required governing document (provided it describes the enterprise and how the parties intend to achieve its value-based purpose(s)).

The Final Rules align the CMS and OIG definitions related to value-based arrangements in nearly all respects. Although differences in the nature and scope of the Stark Law, as a strict liability statute, and the AKS, as an intent-based criminal statute, led to some differences between CMS's value-based Stark exceptions and OIG's value-based AKS safe harbors (some of which are described below), the definitions creating the compliance framework for organizations to meet the exceptions and safe harbors are nearly identical.

As the OIG did in preamble to its Final Rule, CMS explained in its preamble to the final Stark rule that it declined to broaden the definition of "value-based purpose" to include the reduction in costs to or growth in expenditures of health care providers and suppliers (as opposed to just payors), which would have more clearly related to arrangements such as hospital-physician gainsharing arrangements. However, CMS noted that "nothing in this final rule precludes the sharing of cost savings and other entity-specific savings programs, provided those programs are part of a value-based arrangement for value-based activities reasonably designed to further at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are VBE participants. The compensation to a physician under such a value-based arrangement could include a share of the savings that result from a hospital's internal cost sharing (or gainsharing) program." In addition, while these new value-based exceptions may prove to be helpful in facilitating the transition to value-based care, as CMS explained in preamble to the Final Rules, ". . . nothing in our final policies is intended to suggest that many value-

based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not satisfy the requirements of existing exceptions to the physician self-referral law."

Below are key elements of each of the three new value-based Stark exceptions. These exceptions address arrangements between physicians and entities that provide and bill for DHS, and they differ based on the level of financial risk the parties undertake. The more financial risk undertaken, the lesser the requirements are to comply with the applicable exception.

**Full Financial Risk (42 C.F.R. § 411.357(aa)(1)).** The first new value-based Stark exception applies 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 is 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 time. The exception will apply so long as the value-based enterprise is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement.

The compensation must be for, or must result from, value-based activities undertaken by the recipient for patients in the target patient population. The compensation may not be an inducement to reduce or limit medically necessary items or services.

The compensation may not be conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. If remuneration paid to the physician is conditioned on the physician's referrals of patients in the target patient population to a particular provider, practitioner, or supplier, then that requirement must be set out in writing and signed by the parties, and the requirement may not apply if: (1) the patient expresses a preference for a different provider, practitioner, or supplier; (2) the patient's insurer determines the provider, practitioner, or supplier; or (3) the referral is not in the patient's best medical interests in the physician's judgment. In addition, records of the methodology for determining the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and be made available to the Secretary of HHS upon request.

The full financial risk exception would apply when a network of providers and clinicians take full financial risk (e.g., capitation or global budget) from a payor for a target patient population, and want to compensate physicians for value-based activities the physicians undertake for the target patient population. In contrast to the traditional Stark exceptions, nothing in the full financial risk exception requires the amount of compensation to be fair market value, set in advance, or not take into account the volume or value of referrals or other business generated among the parties. The network would have to document and operate a value-based arrangement that meets the new Stark definitions (i.e., value-based enterprise, value-based purpose, target patient population, value-based enterprise participant). But these new Stark exception elements are oriented toward ensuring the parties are appropriately operating for one or more value-based purposes rather than focused on the nature and amount of compensation paid to the physician participants.

The corresponding AKS safe harbor protecting value-based arrangements that take on full financial risk is found at 42 C.F.R. § 1001.952(gg), and is similar to the Stark exception described above. The Stark exception, however, does not exclude any entities from being eligible to rely on the exception, as the AKS safe harbor does.

**Meaningful Downside Financial Risk (42 C.F.R. § 411.357(aa)(2)).** The second value-based Stark exception applies if the 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 means that the physician is responsible to repay or forgo no less than ten percent (10%) of the total 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 must be set forth in writing, and the payment methodology must be set in advance.

Like the full financial risk exception, this meaningful downside financial risk exception includes the same controls on inducement to limit medically necessary items or services and referrals of patients who are not part of the target patient population. Also like the full financial risk exception, if remuneration paid to the physician

is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, then that requirement must be set out in writing and signed by the parties, and will not apply if patient preference, payor determination or the physician's medical judgment determines the referral should go elsewhere. Finally, this exception has the same record-keeping requirements as the full financial risk exception.

This new Stark exception could apply, for example, where a provider enters into a value-based arrangement with one or more physician(s), under which there is a base compensation paid and an opportunity to earn additional compensation for achieving certain value-based purposes of the enterprise. If the physicians are at risk of repaying or forgoing at least ten percent (10%) of the total compensation, then, so long as all other elements of the exception are met, the bonus compensation can be paid to the physicians, regardless of whether that compensation is fair market value or takes into account the volume or value of referrals from the physicians. As with the traditional Stark exceptions, there remains a set of contractual and operational standards the parties must meet to comply with the exception, and the consequences of failing to comply with all of the exception's standards remain severe and indifferent to the parties' intent; but the nature of those contract terms and standards are fundamentally different than the compensation-focused elements of the traditional Stark exceptions.

The corresponding AKS safe harbor protecting value-based arrangements that take on substantial downside financial risk is found at 42 C.F.R. § 1001.952(ff), and it includes some differences from the Stark exception described above, including differences in what substantial downside financial risk (as opposed to meaningful downside financial risk) means, and how the remuneration must connect to the value-based purposes of the VBE. The Stark exception also does not exclude any entities from being eligible to rely on the exception, as the AKS safe harbor does.

**Value-Based Arrangements (42 C.F.R. § 411.357(aa)(3)).** The third value-based Stark exception addresses 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 includes similar restrictions on inducing the reduction or limitation of medically necessary services and referrals of patients who are not part of the target patient population as the other value-based exceptions, but includes more documentation and substantive requirements. Namely, the arrangement must be in writing and signed by the parties. And the contract or other writing must 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
- Outcome measures against which the recipient of the remuneration is assessed (if any).

Outcome measures are defined as benchmarks that quantify improvement in or maintenance of the quality of patient care, or reductions in the costs to or growth in expenditures of payors while maintaining and improving the quality of patient care. All outcome measures, if any, must be objective, measurable, and selected based on clinical evidence or credible medical support. Any changes to the measures must be made prospectively and in writing.

The payment methodology must be set in advance of the value-based activities for which the payment is made. The remuneration must be for, or result from, value-based activities undertaken by the recipient for patients in the target patient population, and the arrangement must be commercially reasonable.

The exception also requires an annual monitoring of: (1) whether the parties have furnished the required value-based activities; (2) whether and how continuation of the value-based activities is expected to further the value-based purposes of the enterprise; and (3) progress toward attainment of the outcome measure(s), if any. If that monitoring finds that the value-based activity is not expected to further the value-based purpose(s) of the

enterprise, the parties must terminate the ineffective value-based activity, by terminating the entire arrangement within 30 days, or modifying the arrangement to modify the ineffective value-based activity within 90 days.

As with the other value-based exceptions, if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, then that requirement must be set out in writing and signed by the parties, and will not apply if patient preference, payor determination or the physician's medical judgment determines the referral should go elsewhere. This exception also has the same record-keeping requirements as the other value-based exceptions.

An example of a value-based arrangement that could meet this exception is a hospital that wishes to implement a new care protocol based on guidelines from a nationally recognized organization, and documents one or more contracts with physicians to compensate the physicians \$10 for each instance that they take an action in accordance with the new care protocol over a two-year period. The hospital would need to ensure that it has fully documented a value-based arrangement under the new Stark definitions, and that the contract includes all of the written standards in the value-based arrangements exception. The hospital would also need to monitor the value-based arrangement to determine, at least annually, whether the new protocol can achieve the value-based purposes of the arrangement. Because the parties are not taking financial risk, this exception has some safeguards regarding the compensation amount (*e.g.*, the compensation must be commercially reasonable). However, unlike the traditional Stark exceptions, the parties would not need to ensure that the compensation is fair market value nor would they need to ensure that it does not take into account the volume or value of referrals between the parties.

The corresponding AKS safe harbor protecting value-based arrangements that focuses on care coordination is found at 42 C.F.R. § 1001.952(ee), and it includes some variations from the Stark exception described above. Two key differences are that the care coordination AKS safe harbor is limited to in-kind remuneration and requires a contribution amount from the recipient. In addition, the Stark exception does not exclude any entities from being eligible to rely on the exception, as the AKS safe harbor does.

***Indirect Compensation Involving Value-Based Arrangements (42 C.F.R. § 411.354(c)(4))***. The Final Rules allow any of the three value-based 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 provision was 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 designated health services.

***Price Transparency***. CMS solicited comments in the Proposed Rules regarding price transparency, including whether to make each of the value-based exceptions contain a requirement such as physicians providing a notice alerting patients that their out-of-pocket costs for items and services for which they are referred may differ based on the site of services and the type of the patient's insurance. In the preamble to the Final Rule, CMS asserted its commitment to establishing policies that facilitate price transparency and referenced separate recent rulemakings related to price transparency requirements for hospitals and health insurance issuers, respectively. Based on feedback from commenters, however, CMS declined to finalize any price transparency provisions as part of the Stark Final Rules.

## **II. Fundamental Terminology and Requirements**

Many of the Stark Law exceptions require that: (1) the compensation arrangement is commercially reasonable; (2) the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some cases, other business generated between the parties); and/or (3) the amount of the compensation is fair market value. CMS proposed "bright-line, objective regulations" for these fundamental requirements in an effort to reduce the burden of complying with the Stark Law, enhance enforcement capability, and achieve the goals of the Regulatory Sprint. CMS finalized a number of revisions to the Stark regulations that it believes provide such bright-line rules. CMS also reiterated that these three

fundamental requirements are separate and distinct from one another and that each requirement must be satisfied when it is included in a Stark exception.

The below describes the provisions of the Final Rules related to these three fundamental requirements, as well as changes made to the “directed referral” provision that relate to changes made to the volume/value and other business generated standards.

**Commercially Reasonable Standard.** First, CMS finalized a definition of the term “commercially reasonable” at 42 C.F.R. § 411.351, which has never before been defined by regulation. This new definition provides as follows: “**Commercially reasonable** means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.” CMS explained 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. Further, the determination of commercial reasonableness is not a question of valuation.

The inclusion of the statement that compensation arrangements that do not result in profit may nonetheless be commercially reasonable is a welcome clarification, as this has been a point of uncertainty for many stakeholders. It is now clearer that parties may enter into an arrangement for legitimate reasons other than profit, such as community need, fulfillment of licensure obligations or the provision of charity care. At the same time, however, CMS stated that it is “not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to a determination of its commercial reasonableness, for instance, in a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no identifiable need or justification—other than to capture the physician’s referrals—for the arrangement.”

Finally, various Stark exceptions require that the arrangement is commercially reasonable “even if no referrals were made,” and CMS stressed that it did not eliminate this requirement from these exceptions, and that “this qualifying language provides critical protection against program or patient abuse.” Further, CMS added a provision about the arrangement being commercially reasonable “even if no referrals were made” to the existing exception for fair market value compensation (discussed in Section IV below), which did not previously contain this condition, and included it in the new exception for limited remuneration to a physician (discussed in Section V below).

**Volume/Value and Other Business Generated Standards.** Many Stark Law exceptions include a requirement that the compensation under the arrangement is not determined in any manner that takes into account the volume or value of referrals (the “volume/value standard”) and some also require that the compensation is not determined in any manner that takes into account other business generated between the parties (the “other business generated standard”). CMS acknowledged that an objective test was needed to determine whether a compensation arrangement implicates these standards, and finalized special rules to establish such a test. These new special rules, which are found at 42 C.F.R. § 411.354(d)(5) and (6), describe compensation that **does** take into account the volume/value of referrals or other business generated. Other than in the circumstances set forth in these special rules, compensation **does not** implicate these standards, *i.e.*, the special rules “define the universe of circumstances under which compensation is considered” to implicate these standards.

Under these new special rules:

- Compensation **from an entity to a physician** (or immediate family member) takes into account the volume or value of referrals only if the formula used to calculate the compensation includes the physician’s referrals to the entity as a variable, resulting in an increase or decrease in the compensation that **positively correlates** with the number or value of the referrals. There is a parallel positive correlation formula setting forth when compensation from an entity to a physician (or immediate family member) takes into account the volume or value of other business generated. A positive correlation exists between two variables when one variable decreases as the other decreases, or one increases as the other increases.

- Compensation *from a physician* (or immediate family member) to an entity takes into account the volume or value of referrals only if the formula used to calculate the compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that **negatively correlates** with the number or value of the referrals. There is a parallel negative correlation formula setting forth when compensation from a physician (or immediate family member) to an entity takes into account the volume or value of other business generated. A negative correlation exists between two variables when one variable increases as the other decreases, or when one decreases as the other increases.

However, these special rules on volume/value and other business generated do not apply in a number of specified circumstances, including for purposes of:

- A number of specified exceptions, *i.e.*, the exceptions for medical staff incidental benefits, professional courtesy, community-wide health information systems, electronic prescribing items and services, electronic health records items and services, and the new exception for cybersecurity technology and related services. This is because these exceptions have volume or value requirements that are unique, so the special rules do not fit them perfectly. Although the excluded exceptions are generally exceptions where in-kind remuneration is paid, notably, the exception for nonmonetary compensation is not excluded from the applicability of the special rules because the volume/value standard under that exception is similar to those in the exceptions where cash remuneration can be provided.
- Applying the special rules on unit-based compensation at 42 C.F.R. § 411.354(d)(2) and (3), as specified by CMS both in the new special rules and in edits to the existing special rules on unit-based compensation. CMS explained that if a determination is made that compensation takes into account the volume or value of referrals or other business generated under the new special rules, that determination is final, and the unit-based compensation rules cannot then be applied to deem the compensation not to take into account the volume or value of referrals or other business generated. CMS confirmed that, on and after the effective date of the Final Rules, the unit-based compensation rules are essentially superseded by the special rules on volume/value and other business generated, since they will be either unnecessary or inapplicable. However, CMS left the unit-based rules in the regulations to assist parties, CMS and law enforcement in applying historical policies in effect during the existence of a compensation arrangement prior to the Final Rules.
- Determining whether an indirect compensation arrangement exists, given changes that CMS made to the indirect compensation definition at 42 C.F.R. § 411.354(c)(2) as part of the Final Rules. Based on these changes, an indirect compensation arrangement exists if, among other things, the physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing the DHS, and any of the following are true with respect to the individual unit of compensation received by the physician: (1) it is not fair market value for items or services actually provided; (2) it is calculated using a formula that includes the physician's referrals to the entity furnishing DHS as a variable, resulting in an increase or decrease in the compensation that positively correlates with the number or value of the physician's referrals to the entity; or (3) it is calculated using a formula that includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the compensation that positively correlates with the physician's generation of other business for the entity. CMS acknowledged that these changes to the indirect compensation arrangement definition will reduce the number of unbroken chains of financial relationships that will constitute indirect compensation arrangements under the Stark Law.

Next, CMS had reaffirmed in the preamble to the Proposed Rules, and reaffirmed again in preamble to the Final Rules, 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 confirmed that this guidance extends to personal services arrangements using unit-based compensation formulas. These reaffirmations were intended to alleviate concerns expressed by stakeholders 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.* CMS declined to adopt these policies in regulation text, as it believes this is not necessary given policies set forth in the special rules regarding the volume/value and other business generated standards.

Lastly, CMS finalized its proposal to remove the modifying phrase “directly or indirectly” related to the volume/value and other business generated standards in various existing exceptions where that modifier appeared, as CMS believes that this modifier is implicit.

**Patient Choice and Directed Referrals.** The existing Stark regulations contain a special rule regarding directed referrals at 42 C.F.R. § 411.354(d)(4), which provides that compensation to a physician may be conditioned on the physician’s 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. In the Final Rules, CMS made substantial changes to the directed referral rule and related exceptions that are aligned with the new special rules regarding the volume/value and other business generated standards.

As background, CMS explained that it “no longer believe[s] that compensation predicated, either expressly or otherwise, on the physician making referrals of designated health services to a particular provider, practitioner, or supplier should be evaluated for compliance with the volume or value standard.” Rather, it “now believe[s] that the volume or value standard is most appropriately interpreted as relating to how compensation is calculated; that is, what formula is used to determine the amount of the physician’s compensation.” The mathematical formulas under the new special rules regarding volume/value and other business generated are not sufficiently able to identify referral requirements that could lead to program or patient abuse. For this reason, payment predicated on referrals to a particular entity needs to be evaluated for compliance with the special rule for directed referrals.

Thus, CMS finalized its proposal 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), as well as the new exception for limited remuneration to a physician, 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). This cross-reference to the directed referral provision is not in the new value-based exceptions, but those exceptions incorporate requirements that are similar to the directed referral provision.

CMS also revised the directed referral rule to include a new condition that neither the existence of the compensation arrangement, nor the amount of the compensation, is contingent on the **number or value** of the physician’s referrals to the particular provider, practitioner, or supplier. This revision was made to address a risk of program or patient abuse if a physician would receive no future compensation for failing to refer as required, or if the amount of the physician’s compensation was tied to referrals to the particular provider, practitioner, or supplier. However, CMS added a new provision to the regulations specifying that the requirement to make referrals **may require** the physician to refer an established **percentage or ratio** (rather than number or value) of the physician’s referrals to a particular provider, practitioner, or supplier. Finally, CMS revised this special rule to clarify the “set in advance” and fair market value requirements, as well as to make nonsubstantive revisions.

**Fair Market Value.** CMS removed the existing definition of “fair market value” at 42 C.F.R. § 411.351 and replaced it with new regulatory language that restructured the definition to separately define fair market value for general application (*i.e.*, assets or compensation), for the rental of equipment, and for the rental of office space, and CMS also revised the related definition of “general market value” that was incorporated into each of the foregoing.

Under these revised definitions, “fair market value” means:

- For assets: The value in an arm's-length transaction, consistent with the price that an asset would bring on the date of acquisition of the asset as the result of **bona fide** bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
- For compensation for services: The value in an arm's-length transaction, consistent with the compensation that would be paid at the time the parties enter into the service arrangement as the result of **bona fide** bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
- For the rental of equipment: The value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the price that rental property would bring at the time the parties enter into the rental arrangement as the result of **bona fide** bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.
- For the rental of office space: The value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the price that rental property would bring at the time the parties enter into the rental arrangement as the result of **bona fide** bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

CMS removed the provision that was previously in the definition of fair market value related to the rental of office space that specified that a rental payment does not take into account **intended** use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements. CMS stated that this remains their policy, but because this regulation text appeared to have caused confusion among stakeholders, they removed it from the definition in order to avoid confusion and provide certainty in the revised definitions applicable to rental of office space described above.

CMS addressed salary surveys in the preamble, emphasizing that such surveys do not necessarily provide an accurate determination of fair market value in all cases, and that nothing in CMS's commentary was intended to imply that an independent valuation is required for all compensation arrangements. Consulting salary surveys *is* an appropriate starting point, and may be all that is required in many cases. But, CMS stated: “We continue to believe that the fair market value of a transaction—and particularly, compensation for physician services—may not always align with published valuation data compilations, such as salary surveys. In other words, the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician's services. . . . As we stated in the proposed rule, extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction.”

CMS also retracted its statements in preamble to the Proposed Rules that equated “general market value” under Stark with “market value” as used in the valuation industry, as it realized that this could have had an unintended limiting effect on the regulated community and valuation community. CMS did not mean to limit the valuation of assets, compensation or rental property to the “market approach” or prescribe any particular method for determining fair market value, and clarified that it continues to accept any valuation methodology “that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another.” A range of methods for determining fair market value is acceptable, and the appropriate method depends on the nature of a specific transaction.

CMS highlighted in preamble that the general market value of a transaction should be based solely on a consideration of the economics of the subject transaction, and should not include any consideration of other

business the parties may have with one another. For example, compensation to a physician should not be inflated because the entity paying the compensation (such as a hospital) values the referrals or other business that the physician may generate more than a different potential purchaser of the same services (such as a private equity investor or other physician practice), *i.e.*, the value of the services should be the same regardless of who is purchasing the services. However, CMS also emphasized that the fair market value standard is a separate and distinct requirement from the volume/value standard and the other business generated standard, and certain of the finalized revisions to the definition of fair market value were intended to remove the connection to these standards within the definition.

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

Physician practices generally and primarily rely on the Stark Law's in-office ancillary services exception in order for their physicians' referrals to the practice to not be prohibited under the Stark Law. The in-office ancillary services exception generally requires, among other things, that the physician practice qualify as a "group practice" under the Stark Law at 42 C.F.R. § 411.352. The group practice definition has a number of detailed and technical requirements. One of the requirements is that no physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in a special rule within the definition at 42 C.F.R. § 411.352(i). If specified requirements are met and an exception applies, the practice can take advantage of these special compensation rules that are not available under Stark compensation exceptions, including paying physicians a share of the "overall profits" of the practice in a way that is not **directly** related to the volume or value of referrals by the physician. In the Final Rules, CMS finalized a number of changes to the regulatory text related to the special compensation rules at 42 C.F.R. § 411.352(i), which are not effective until **January 1, 2022**.

Most notably, in changes to the special rules for payments based on a share of overall profits, CMS added the words "all the" before "designated health services." CMS explained 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 before distribution. Under the revised regulations, a group practice may not pool and distribute profits from DHS on a service-by-service basis (sometimes referred to as "split pooling"). Many stakeholders—particularly large, multi-specialty physician practices—have until now interpreted the overall profits rule to permit such split pooling. CMS recognized this, and recognized that group practices need time to modify their physician compensation methodologies in light of the revised regulations codifying CMS's policy. CMS further recognized that many group practices establish their compensation methodologies prior to the beginning of the calendar year, and that an element of the group practice definition essentially requires a group practice's compensation methodology to be established prospectively. For this reason, CMS delayed the effective date of revised 42 C.F.R. § 411.352(i) until January 1, 2022. Until that time, the definition of "overall profits" will remain unchanged.

While CMS stated that this regulatory change is a codification of its existing policy, it did not indicate that group practices that have historically used or currently use the split pooling methodology, based on an interpretation of the overall profits rule that led them to conclude such split pooling was permitted, historically or currently run afoul of the special compensation rules under the group practice definition. But it is clear that as of January 1, 2022, such split pooling will run afoul of the special compensation rules, which would mean the group would not meet the definition of a "group practice" and it could not rely on the in-office ancillary services exception. If no other exception applies, all of practice physicians' referrals to the group would be prohibited under the Stark Law. Therefore, it is essential for group practices that use the split pooling methodology to proceed to modify their physician compensation methodologies by January 1, 2022 in light of the revised regulations.

CMS clarified a statement it made in the Proposed Rules related to the use of different distribution methodologies for overall profits within the group, based on comments received from stakeholders. CMS confirmed in the Final Rules that a group practice may utilize different **distribution methodologies** to distribute shares of overall profits from all the DHS of each of its components of five or more physicians (for example,

per capita or based on personal productivity). But a group practice has to utilize the same methodology for distributing overall profits for every physician within a single component.

CMS finalized a number of other changes to the regulatory text related to the special compensation rules at 42 C.F.R. § 411.352(i), which are also not effective until January 1, 2022 to coincide with the effective date of the revised definition of "overall profits," in order to avoid complications associated with the restructuring of that regulation text. These include:

- Profits from DHS that are directly attributable to a physician's participation in a value-based enterprise can be distributed **directly** to the participating physician, without having to aggregate the profits with the overall profits of the group practice or a component of five or more physicians within the group practice. 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 (whether or not the group practice participates in the value-based arrangement). In this context, CMS **would not prohibit** remuneration that directly takes into account the volume or value of a physician's referrals, which CMS explained is an extension of its policy at 42 C.F.R. § 411.357(aa) under the new exceptions for value-based arrangements, as described in Section I above.
- Certain revisions that restructured and reordered the regulation text, and certain clarifying 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 and otherwise more accurately reflect the definition of the term "designated health services" under 42 C.F.R. § 411.351.

Finally, although the group practice definition uses the terms "based on" and "related to" in regulation text in the context of volume/value standard requirements (which mirrors statutory language), CMS affirmed that it interprets these requirements as incorporating the "take into account" volume/value standard used elsewhere in the Stark regulations. And, as stated in Section II above, the new special rules related to the volume/value standard define the universe of compensation that CMS considers to be determined in a manner that takes into account the volume or value of a physician's referrals, and apply in all instances where the volume/value standard appears in the Stark regulations (except as specified in the special rule). For this reason, with respect to the volume/value standard and the special compensation rules under the group practice definition, **the new special rules regarding compensation that takes into account the volume/value of referrals applies**. These special rules are described in detail in Section II above. Given that these special rules are effective January 19, 2021, presumably CMS's interpretation of their application to the group practice definition is applicable as of that date as well.

#### **IV. Recalibrating the Scope and Application of the Regulations**

CMS previously stated in its Stark Phase I regulation and the Proposed Rules 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 stated that one purpose of the Proposed Rules was to reexamine the regulations and determine "whether we have held true to that intention." For this reason, in the Final Rules, CMS made 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. In its Proposed Rules, CMS proposed 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 from 42 C.F.R. § 411.351 the defined term "does not violate the anti-kickback statute"), concluding it is no longer "necessary or appropriate to include" such requirements. CMS clarified that its proposed revisions do not affect the parties' compliance obligations under these laws.

CMS finalized its proposal to remove the requirement that the arrangement does not violate the AKS from all regulatory exceptions that contained this requirement *other than* the fair market value compensation exception at 42 C.F.R. § 411.357(l). After reviewing comments in response to its proposal, CMS concluded that it is not appropriate to remove the requirement that the arrangement does not violate the AKS from the exception for fair market value compensation, as this requirement functions as an important safeguard that substitutes for certain requirements included in many statutory exceptions, such as the exclusive use requirement in the exceptions for the rental of office space and equipment, but omitted from the fair market value compensation exception. Finally, CMS removed requirements pertaining to federal or state laws or regulations governing billing or claims submissions from all the regulatory exceptions that contained this requirement, including the fair market value compensation exception.

#### **DEFINITIONS (42 C.F.R. § 411.351)**

**Designated Health Services.** The definition of “designated health services” (or “DHS”) includes DHS “payable, in whole or in part, by Medicare,” and does not include services that are paid by Medicare as part of a composite rate, except to the extent that the services are themselves payable under a composite rate (such as home health services and inpatient and outpatient hospital services). In its Proposed Rules, CMS proposed 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 acknowledged that not all hospitals are paid under the IPPS, and CMS solicited 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.

In its Final Rules, CMS extended the proposed policy to apply to hospital services furnished to inpatients that are paid under additional prospective payment systems, but did not extend the proposed policy to hospital services furnished to outpatients. Specifically, CMS revised the definition of “designated health services” to state that, for services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare’s payment to the hospital under any of the following prospective payment systems (PPS): (i) Acute Care Hospital Inpatient (IPPS); (ii) Inpatient Rehabilitation Facility (IRF PPS); (iii) Inpatient Psychiatric Facility (IPF PPS); or (iv) Long-Term Care Hospital (LTCH PPS).

**Physician.** The term “physician” has been 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 explained that the definition of the term “physician” under the Stark Law did not include all of the limitations of the definition of the term in the Act. To harmonize the definitions, CMS proposed 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. After reviewing the comments received in response to the Proposed Rules, CMS finalized the definition of “physician” as proposed.

**Referral.** Certain Stark exceptions address remuneration for “items or services” provided by a physician. CMS proposed to clarify that a physician’s referrals were not “items or services” for which payment may be made under these Stark exceptions. In its Final Rules, CMS finalized its modification of the definition of “referral” as proposed. This change made explicit CMS’s longstanding policy that a referral is not an item or service for the purposes of the Stark statute and regulations.

**Remuneration.** The definition of “remuneration” under the Stark Law has included 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 proposed to remove the parenthetical because it stated that there may be some surgical items, devices or supplies that are used solely for the purposes described above. After reviewing

comments it received on this proposal, CMS finalized its revision of the definition of "remuneration" as proposed but noted that, even if the provision of an item, device, or supply is carved out of the definition of "remuneration" under Stark, the provision of such items, devices, and supplies implicates the AKS.

**Transaction; Isolated Financial Transaction.** A Stark statutory exception at Section 1877(e)(6) of the Act and regulatory exception at 42 CFR § 411.357(f) exclude an "isolated financial transaction" from the definition of a compensation arrangement under the Stark Law when specified requirements are met. CMS proposed to add a new definition for "isolated financial transaction" which clarified that the exception for isolated transactions was 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 proposed corresponding revisions to the exception at 42 C.F.R. § 411.357(f). In its Final Rules, CMS finalized its proposed independent definition of "isolated financial transaction" at 42 C.F.R. § 411.351 and corresponding revisions to the exception at 42 C.F.R. § 411.357(f), with the following modifications: First, the final definition of "isolated financial transaction" specifies that an isolated transaction is a one-time transaction. Second, subparagraph (2) of the definition of "isolated financial transaction" at § 411.351 and the introductory language in § 411.357(f) provide as an additional example of an isolated financial transaction a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute. Third, CMS clarified at §411.357(f)(4) that an isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute. Fourth, in response to comments, CMS modified the definition to remove the phrase "or process," believing that the phrase may have suggested to some that an exception is available to protect a single payment for multiple services provided over an extended period of time.

#### **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 proposed to delete the rules on the period of disallowance at 42 C.F.R. § 411.353(c)(1) in their entirety. CMS clarified in the preamble to the Proposed Rules that the effect of deleting the period of disallowance rules did 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 proposed an analysis on a case-by-case basis taking into account the unique facts of each financial relationship. In the preamble of the Proposed Rules, CMS also provided 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 clarified 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.

In the Final Rules, CMS finalized its proposal to delete the rules on the period of disallowance at 42 C.F.R. § 411.353(c)(1) in their entirety. CMS noted, however, that nothing in the Final Rules affects the billing and referral prohibitions at 42 C.F.R. § 411.353(a) and (b). In addition, CMS reincorporated the example from the Proposed Rules described above in the Final Rules, noting that, "We did not state in the proposed rule, nor is it our view, that every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of an exception or that every error or mistake must be corrected in order to maintain compliance with the Stark law. However, if parties identify an error that would cause the compensation arrangement to fail to satisfy the requirements of an exception to the physician self-referral law, they cannot simply 'unring the bell' by correcting it at some date after the termination of the arrangement."

Notwithstanding the forgoing, CMS indicated that it was persuaded that a limited "grace period" to reconcile payment discrepancies following the expiration or termination of a compensation arrangement would not pose a risk of program or patient abuse. Therefore, CMS finalized at 42 C.F.R. § 411.353(h) a special rule that permits an entity to submit a claim or bill for DHS, and permits payment to be made to the entity for such DHS, if (1) all payment discrepancies under the arrangement are *reconciled within 90 consecutive calendar days* of expiration or termination of the compensation arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and (2) except for such discrepancies in payments, the compensation arrangement fully complies with an applicable Stark exception.

#### ***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 proposed 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. CMS finalized its proposal, without modification.

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 proposed 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 sought 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.

In the Final Rules, CMS adopted 42 C.F.R. § 411.354(b)(3)(vii) as proposed, without modification, finding that the legal and regulatory protections applicable to ESOPs are sufficient to prevent program or patient abuse. However, CMS noted that employer contributions to the ESOP are considered part of an employee's overall compensation arrangement with his or her employer and thus, when determining whether a compensation arrangement satisfies all the requirements of an applicable exception, including the requirements pertaining to fair market value and the volume or value of the physician's referrals, employer contributions to the ESOP must be considered as part of the employee's compensation under the arrangement.

## **SPECIAL RULES ON COMPENSATION AND COMPENSATION ARRANGEMENTS (42 C.F.R. § 411.354(d) and (e))**

CMS finalized a number of new special rules related to requirements of various Stark exceptions. With these new rules, CMS attempted to emphasize substance over form compliance, understanding that temporary form non-compliance poses relatively low risk of fraud and abuse.

First, CMS finalized certain modifications to the special rule at 42 C.F.R. § 411.354(d)(1) regarding the “set in advance” standard that is found in many Stark compensation exceptions. Under 42 C.F.R. § 411.354(d)(1)(i), compensation is **deemed** to be set in advance if the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid (among other requirements). CMS clarified in preamble to the Final Rules that this is just a deeming provision, and compensation may be set in advance **even if it is not set out in writing** before the furnishing of items or services as long as the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance.

CMS also codified at 42 C.F.R. § 411.354(d)(1)(ii) a special rule regarding modifying compensation (or the formula for determining the compensation) during the course of an arrangement. This rule provides that compensation may be modified **at any time** during the course of a compensation arrangement and satisfy the requirement that it is “set in advance” if all of the following requirements are met: (1) all requirements of an applicable exception are met on the effective date of the modified compensation (or formula for determining the modified compensation); (2) the modified compensation (or formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid; and (3) **before** the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. For purposes of this final requirement, the 90-day grace period for the signature and writing requirement at 42 C.F.R. § 411.354(e)(4) (described below) does **not** apply. CMS stated that this means that parties will **not** have 90 days to reduce the modified compensation (or formula for determining the modified compensation) to writing.

Next, CMS finalized a new special rule at 42 C.F.R. § 411.354(e)(4) which provides a 90-day grace period for the signature **and writing** requirements that is applicable to all compensation exceptions under Stark that contain such requirements. Previously, a similar special rule applied only to the signature requirement of such exceptions. Specifically, the Final Rules provide that the writing requirement or signature requirement is satisfied if (1) the compensation arrangement satisfies all other requirements of an applicable exception (except the writing or signature requirement of the exception); and (2) the parties to the arrangement obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the writing or signature requirements under the applicable compensation exception. CMS clarified that a party may rely on this special rule if an arrangement is neither in writing nor signed at the outset, provided both the required writing and signatures are obtained within 90 consecutive calendar days and the arrangement otherwise satisfies all the requirements of an applicable exception. CMS noted that the new rule does 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 will not apply to circumvent the requirement that compensation must be set in advance.

Finally, CMS included in the Final Rules a codification of its longstanding policy on electronic signatures. Specifically, 42 C.F.R. § 411.354(e)(3) provides that an electronic or other signature valid under federal or state law is sufficient to satisfy the signature requirement of applicable Stark exceptions. In addition, while CMS stopped short of codifying its policy on electronic documents, CMS reaffirmed its policy that such electronic documents may be used to satisfy the writing requirements.

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

CMS took the opportunity in the Final Rules 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 finalized revisions to each of these exceptions accordingly.

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

CMS clarified 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 revised 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))***

In an effort to restore utility to the statutory exception for remuneration unrelated to the provision of DHS, CMS included a proposal in the Proposed Rules to broaden the application of the regulatory 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, and other requirements were met). After consideration of comments received on the Proposed Rules that expressed concerns that, without substantial guidance and examples of the application of the broadened exception, there would be a risk of program or patient abuse, CMS decided not to finalize its proposed revisions to this exception. CMS indicated that it would continue to evaluate the best way to restore utility to the statutory exception and may address this in future rulemaking.

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

CMS explained 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 finalized its proposal, without modification, 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 (*i.e.*, 42 C.F.R. §§ 411.357(a) through (h)).

Based on this change, parties are generally 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. ***This is a welcomed change for stakeholders, as it considerably broadens the utility of this exception.*** Most notably, since the fair market value compensation exception (at 42 C.F.R. § 411.357(l)) is not a codification of a statutory exception, even if that exception is applicable to the compensation, the payments by a physician exception could still also be applicable. This is particularly helpful since the fair market value exception has more requirements than the payments by a physician exception, and applies to a broad range of compensation (now including rental of office space, as described below).

Note that CMS emphasized that the "items or services" furnished by the entity under the exception for payments by a physician may not include cash or cash equivalents, so a physician cannot make "payments" to the entity that are actually in-kind items/services in exchange for cash from the entity.

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

CMS made a number of changes to the fair market value compensation exception (some of which were for organizational purposes and not substantive). Of note, CMS finalized its proposal to expand this exception to protect arrangements (meeting specified conditions) for the ***lease of office space***, in addition to arrangements for the lease of equipment and for the provision of items or services. This change is significant because the fair market value compensation exception does not require a one-year term, unlike the exception for the rental of office space. ***Therefore, short-term arrangements for the lease of office space can now be protected under the***

*fair market value compensation exception*, as long as the parties only enter into one arrangement for the lease of the same office space during the course of a year and other requirements of the exception are met. CMS also finalized its proposal 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.

CMS did not, however, finalize its proposal to remove the requirement that the arrangement does not violate the AKS (although it did finalize its proposal to remove the requirement that the arrangement not violate any federal or state law or regulation governing billing or claims submission), for the reasons explained above in this white paper in the section titled "Decoupling Stark from the AKS." CMS also did not remove the requirement that the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a federal or state law. CMS explained that this requirement applies to service arrangements and is carried over from the statutory exception for personal service arrangements. CMS expressed concern that, if it removed this requirement, it would need to include additional safeguards to substitute for the statutory requirements to ensure that arrangements covered by this exception do not pose a risk of program or patient abuse.

The fair market value compensation exception contains a provision whereby an arrangement can be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space or equipment do not change. CMS confirmed that there is no substantive difference between this renewal provision and the indefinite holdover provision in the exceptions for rental of office space, rental of equipment and personal services. Further, CMS stated that neither require the holdover arrangement or renewal arrangement to be documented in a formal writing, so renewals through course of conduct or by verbal agreement are permitted (but parties retain the burden of proof to establish that the terms of the arrangement and the compensation for the same items, office space or services did not change during the renewal arrangement).

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

CMS finalized, with some slight modifications and clarifications, the proposed modifications to the electronic health records ("EHR") software exception in order to build in consistency with the 21st Century Cures Act. First, the proposed revisions to the provision of this exception regarding when software is deemed to be interoperable have been finalized. CMS finalized modification of this language to require a showing that such software *is* certified (rather than *has been* certified). In other words, the certification must 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.

The proposed revisions to the "information blocking" condition have not been finalized; instead, this condition has been removed from the exception. The specific condition being removed prohibited 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 donated EHR items or services. CMS initially proposed changes that would better align this condition with the 21st Century Cures Act by, for example, updating definitions for consistency. While commenters were supportive of updating the exception, they also raised questions and concerns regarding how such a provision would work in an exception, particularly when such revisions would rely on other regulations that have not yet been finalized. CMS concluded that there are now other enforcement authorities that are better suited than an exception condition to deter information blocking and penalize individuals and entities that engage in information blocking.

CMS also finalized language to clarify that certain cybersecurity software and services can be protected under this exception. Furthermore, the proposal to eliminate the sunset provision of this exception, under which this exception would have sunset in 2021, was finalized. CMS also decided to retain the fifteen percent (15%) recipient contribution requirement but removed the requirement that payment of such contribution be made in advance for updates to existing EHR systems. Lastly, CMS finalized its proposals to allow replacement technology and expand the scope of donors protected by this exception.

The corresponding AKS safe harbor for EHR items and services is found at 42 C.F.R. § 1001.952(y). The OIG finalized similar changes to the AKS safe harbor for EHR items and services as those described above for the Stark exception for EHR items and services.

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

CMS finalized, without modification, its proposed changes to 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. CMS did not receive any comments objecting to these finalized changes.

CMS received several inquiries from commenters 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 the term "patient care services" for purposes of this exception, CMS changed this term to "**NPP** patient care services." CMS also added a new definition of the term "NPP patient care services." Under this definition, 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 exception. 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 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 finalized its proposals to further clarify the terms "referral" and "practiced" for purposes of this exception in order to remove ambiguity.

#### ***UPDATING AND ELIMINATING OUT-OF-DATE REFERENCES; NONSUBSTANTIVE CHANGES***

CMS finalized two updates that eliminate out-of-date references. First, in 2003, the Medicare+Choice program was renamed Medicare Advantage. As such, CMS finalized a revision to change any reference in the Stark regulations from Medicare+Choice to Medicare Advantage. Second, CMS finalized a revision 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. In the Final Rules, CMS also made a number of nonsubstantive revisions to the regulation text for purposes of clarification, to ensure conformity between the text of similar regulations, and to reflect the agency's current lexicon.

### **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 added two new exceptions to the Stark Law: (1) limited remuneration to a physician; and (2) cybersecurity technology and related services. These new exceptions are in addition to the new exceptions for arrangements that facilitate value-based health care delivery and payment, described in Section I above.

#### ***LIMITED REMUNERATION TO A PHYSICIAN EXCEPTION (42 C.F.R. § 411.357(z))***

CMS added a new Stark exception for remuneration from an entity to a physician, not to exceed an aggregate of \$5,000 per calendar year (as adjusted annually for inflation), for the provision of items or services provided by the physician to the entity, if all of the specified conditions of the exception are met. To meet this exception, the compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, the compensation cannot exceed the fair market value of the items or services, and the arrangement must be commercially reasonable even if no referrals were made between the parties. (See Section II above for a description of CMS's clarifications in the Final Rules to these three fundamental requirements.) This exception is available for the lease of office space or equipment from a

physician and timeshare arrangements with a physician (provided all requirements of the exception are met), but compensation for the lease of office space or equipment and for the use of premises or equipment cannot be determined using a formula based on certain prohibited percentage-based or per-unit-of-service fees. While many of the requirements of this exception are familiar from the traditional Stark exceptions, the exception for limited remuneration to a physician does not include a requirement for the compensation to be set in advance or for there to be a signed writing memorializing the arrangement.

In keeping with changes to many existing exceptions in the Final Rules, CMS included a requirement that if the remuneration is conditioned on the physician's referrals to a particular provider, practitioner, or supplier (*i.e.*, a directed referral requirement), the requirements of the special rule for directed referrals at 42 C.F.R. § 411.354(d) (4) must be met. Notably, if there is a directed referral requirement conditioning the remuneration to be provided under this exception, this would impose a set in advance and signed writing requirement (among other requirements) that are not otherwise present in this exception. Also in keeping with changes to many existing exceptions, CMS did not include a requirement that the arrangement not violate the AKS.

In the Proposed Rules, CMS had proposed including a limit on remuneration provided under this exception of \$3,500 per year (as adjusted annually for inflation). Based on feedback from commenters, CMS was convinced that the \$3,500 limit would not have been "high enough to accommodate the broad range of nonabusive infrequent or temporary arrangements that an entity and a physician might enter into over the course of a year." CMS determined that an annual aggregate limit of \$5,000 for items or services actually provided by a physician, given the other requirements finalized in this exception, does not pose a risk of program or patient abuse. CMS stated that it believes that when remuneration exceeds \$5,000, the additional safeguards of other Stark exceptions (including the signed writing and compensation set in advance requirements) are necessary to protect against program and patient abuse. CMS also confirmed that an entity may rely on this exception up to the point in a calendar year immediately preceding when the annual aggregate compensation limit is exceeded, and the annual aggregate limit resets each calendar year.

CMS explained its policy that, for purposes of calculating whether the annual compensation limit under this exception has been met, it will not count compensation to a physician for items or services provided outside of the arrangement if such other items or services are protected under another Stark exception. For example, if a hospital has a call coverage arrangement with a physician that meets the exception for personal service arrangements at 42 C.F.R. § 411.357(d)(1), and the hospital later engages the physician to provide sporadic supervision services (under an arrangement that is not documented in writing), CMS would not count the compensation provided under the call coverage arrangement in determining whether the supervision arrangement qualifies for the exception for limited remuneration to a physician. Where there are multiple undocumented and unsigned arrangements for a physician to provide items or services to an entity during a given calendar year, however, it is CMS's policy that the parties have a single compensation arrangement for various items and services, and compensation for all of them needs to be counted in determining whether the \$5,000 annual limit is met. So, for example, if the hospital that has the call coverage arrangement and sporadic supervision services arrangement also engages the same physician to provide occasional imaging interpretations (under an arrangement that is not documented in writing), CMS would count the aggregate compensation paid to the physician for both the supervision services and imaging interpretation services (but not the call coverage arrangement) in determining whether the annual limit is met, and neither arrangement would be protected under the limited remuneration to a physician exception if the aggregate compensation exceeds the \$5,000 limit.

CMS explained that this exception can be used in conjunction with other exceptions to protect an ongoing arrangement during the course of a calendar year in certain circumstances. CMS gave the illustration of an entity that engages a physician to provide call coverage services, pursuant to an arrangement that is not documented and with compensation that is not set in advance. The exception for limited remuneration to a physician could be used to protect payments up to the \$5,000 limit (assuming all requirements of the exception are satisfied). If the parties then agree to continue the arrangement and agree to a rate of compensation, the parties could rely on another exception once requirements of that other exception are met, such as the exception

for personal services or fair market value compensation. Further, as explained in Section IV above, the parties have up to 90 consecutive calendar days to document and sign the arrangement. (CMS made changes to the exception for personal service arrangements at 42 C.F.R. § 411.357(d)(1) (related to the requirement that the arrangement cover all services furnished by the physician or immediate family member) and to the exception for fair market value compensation at 42 C.F.R. § 411.357(l) (related to the requirement that the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year) to ensure that those exceptions could be used in addition to this new exception for limited remuneration to a physician.) As this illustration shows, and as CMS stated: "we anticipate that the exception's greatest utility will come during retrospective review of compliance with the physician self-referral law."

This new exception permits the physician to provide the applicable items/services through an employee whom the physician hired for purposes of performing the services (but not an independent contractor), through a wholly-owned entity or through a *locum tenens* physician. Payments for items/services provided through a physician's employee, wholly-owned entity, or *locum tenens* physician are counted towards the annual aggregate compensation limit applicable to the physician; there is not a separate annual aggregate compensation limit for a physician and his/her employees. CMS did not, however, extend the exception to payments to a physician's immediate family member for items or services provided by the family member (except to the extent the family member is an employee of the physician acting at the direction of the physician, where payments would be counted towards the physician's annual aggregate compensation limit).

Finally, CMS addressed payments under the limited remuneration exception and the "stand in the shoes" rule under Stark. CMS stated that this exception is available to protect a direct compensation arrangement between an entity and a physician as well as a "deemed" direct compensation arrangement between an entity and a physician who stands in the shoes of the physician organization (*i.e.*, a physician owner) to which the entity provides the compensation. This means that compensation received by the physician organization is counted towards the annual aggregate compensation limit of each physician who stands in the shoes of the physician organization. CMS gave an example of an entity that pays a physician organization \$1,000 for the lease of the physician organization's equipment, where the physician organization has two physician owners who stand in the shoes of the physician organization. This \$1,000 would be counted towards the annual remuneration limit for *each* of the two physician owners. (This same rule does not apply to physicians who are not required to stand in the shoes and who are not treated as permissibly standing in the shoes of the physician organization.)

#### ***CYBERSECURITY TECHNOLOGY AND RELATED SERVICES EXCEPTION (42 C.F.R. § 411.357(bb))***

CMS added a new Stark exception for nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the specified conditions of the exception are met. The term "technology" is defined in the regulatory text of this new exception as "any software or other types of information technology." CMS also added a new definition at 42 C.F.R. § 411.351 specifying that the term "cybersecurity" means "the process of protecting information by preventing, detecting, and responding to cyberattacks."

The exception requires that 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. In addition, the exception requires that 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. Finally, the arrangement needs to be documented in writing, but there is not a requirement that the writing is signed. CMS did not specify in regulatory text which terms of the arrangement must be in writing, but stated that it believes that the appropriate standard is that "contemporaneous documents would permit a reasonable person to verify compliance with the exception at the time that a referral is made." A risk assessment is not required prior to the donation, and the recipient does not need to make a financial contribution. CMS stated, however, that "donors are free to require recipients to contribute to the costs of donated cybersecurity technology and services," but cautioned "that the determination of the amount of the

required contribution may not take into account the volume or value of the physician recipient's referrals or other business generated between the parties."

Donated technology could include, for example, 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. Hardware (such as encrypted servers, encrypted drives and network appliances) can be included in the nonmonetary remuneration, but, as with any other nonmonetary remuneration covered under this exception, only if it is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. The exception does not apply to technology or services that are used predominantly in the normal course of the recipient's business, such as IT help desk services. CMS noted that, with respect to technology and services that have multiple uses other than cybersecurity, "[w]hile donated technology and services may include functions other than cybersecurity, the **core functionality** of the technology and services must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate" (emphasis added). CMS highlighted that the exception covers only items and services that qualify as cybersecurity technology and services, not to other types of cybersecurity measures outside of technology or services (such as upgraded wiring, installing high security doors or other infrastructure upgrades). Further, "reestablishing" cybersecurity does not include payment of a ransom on behalf of a physician, or reimbursement of a ransom paid by a physician, in response to a cyberattack (and such payment or reimbursement would not be nonmonetary remuneration).

CMS explained that it understood that the cost of cybersecurity technology and services has increased dramatically, and the risks associated with a cyberattack on a single provider or supplier are borne by every component in the system, *i.e.*, an "organization's cybersecurity posture is only as strong as its weakest link." So, "an entity wishing to protect itself by preventing, detecting, and responding to cyberattacks has a vested interest in ensuring that the physicians with whom the entity exchanges data are also able to prevent, detect, and respond to cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity, which inherently present higher risk than connections that permit physicians 'read-only' access to the entity's data systems." CMS further explained that it believes a primary reason that an entity would provide cybersecurity technology and services to a physician is to protect itself from cyberattacks, but the donated technology and services also may have value for the recipient since the recipient can use its resources for needs other than cybersecurity expenses. For this reason, CMS finalized this exception to provide an avenue for such donations to be protected when they satisfy all of the requirements of this exception.

CMS also noted that, with respect to care coordination, an arrangement for the donation of cybersecurity technology and services may qualify as a value-based arrangement to which the new value-based exceptions (described in Section I above) may be applicable, depending on the facts and circumstances. Further, the exception for EHR items and services now covers certain cybersecurity software and services, provided all the requirements of that exception are met.

The corresponding new AKS safe harbor protecting the donation of cybersecurity technology and related services is found at 42 C.F.R. § 1001.952(jj), and is generally aligned with the Stark exception.

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*Please contact the authors or your regular Dorsey attorney if you would like assistance with understanding how the Stark Final Rules impact your organization.*