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Critical Analysis and Practical Implications of CMS' Changes to the Stark Law's Implementing Regulations

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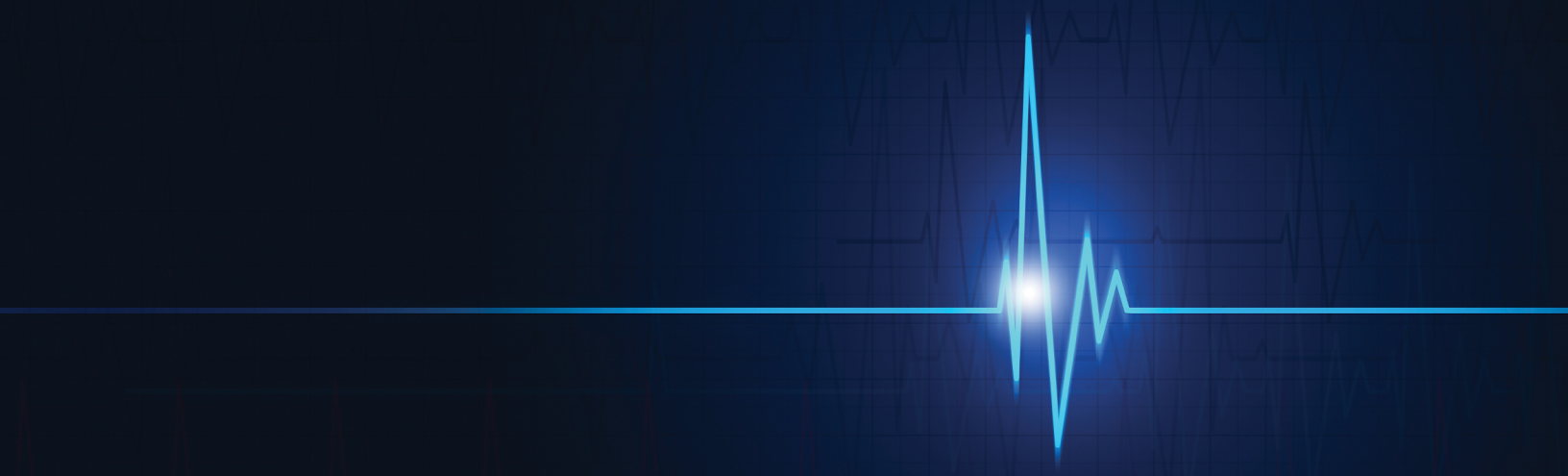

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Introduction

As part of the U.S. Department of Health and Human Services' ("HHS") Regulatory Sprint to Coordinated Care, the Centers for Medicare and Medicaid ("CMS") recently promulgated final rules that fundamentally change and alleviate the manner in which the Stark Law regulatory framework has traditionally been applied. *See* 85 Fed. Reg. 77492 (Dec. 2, 2020) (the "Final Rule"). The Final Rule, coming over a decade after the last significant Stark Law rulemaking, adopts many of the proposals CMS put forward in October 2019, purportedly in response to a shifting reimbursement environment in which health care providers are increasingly reimbursed for the value of their services rather than the volume of their services, and to a corollary need to decrease traditional legal burden on health care providers. According to CMS, this reimbursement environment differs radically from when the Stark Law was enacted and, as economic incentives have shifted, so must the Stark Law. When the first three phases of the Stark Law's (second) Final Rule were promulgated, *i.e.*, between 2001 and 2007, Medicare's volume-based reimbursement environment generated a concern that entities providing certain services might enter into financial relationships with referring physicians to increase the volume of referrals for the services for which they would be paid. This concern, which fundamentally shaped the Stark Law and its implementing regulations, is being rapidly alleviated by both Federal health care program and commercial reimbursement structures that no longer reward quantity, but rather the value and outcome of health services. The Final Rule is an important step in recognizing and responding to this fundamental shift.

Many of the Final Rule's changes have critical operational and structural implications for arrangements between entities and referring physicians. These changes include a new, broad and flexible exception for value-based arrangements of nearly any shape and size. Discussed in detail in Section I herein, this new exception has tremendous potential to allow for the proliferation of a great variety of new and restructured relationships between entities and physicians collaborating to improve patient care. CMS also provides important and overdue definitions of "commercially reasonable" and when compensation "takes into account" the volume or value of referrals. To date, aggressive interpretations of these terms have limited entities' flexibility in contemplating and structuring their relationships with referring physicians; the Final Rule will significantly restore this flexibility. New additions to the definition of "indirect compensation arrangement" will operate to further narrow the scope of the Stark Law, even as the terms of the revised definition are now confusing, ponderous to apply in many cases, and operate to make superfluous the entire exception for "indirect compensation arrangements". Additional revisions to the Stark Law's compensation arrangement exceptions offer further operational flexibility. For instance, CMS adopts a new, broad exception for arrangements that are not related to "patient care services," and another for up to $5,000 of annual, undocumented remuneration to physicians – both of which provide operational and administrative relief for the regulated industry. Stated simply, the Final Rule significantly alters the scope of the Stark Law and eases compliance.

This document contains our analysis of the entirety of the Final Rule and suggestions that may help entities and physicians operationalize and harness the utility of the rule. Our analysis of the Final Rule is ordered consistent with the Final Rule's order of codification in the Code of Federal Regulations, *i.e.*, from 42 C.F.R. § 411.351 through § 411.357, and is not in any order of importance, except that our discussion of the new exception for "value-based arrangements" (codified at 42 C.F.R. § 411.357(aa)) appears in Section I, as it is central to both the purpose and effect of the Final Rule. Each section of our analysis contains the proposed regulatory text, the final regulatory text (showing changes from the proposed text), our analysis, practical implications, and remaining open issues.

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I. New Exception for Arrangements That Facilitate Value-Based Health Care Delivery and Payment

Prior Regulatory Text: None

Proposed New Regulatory Definitions: CMS proposed to codify, at 42 C.F.R. § 411.357(aa), a new regulatory exception applicable to "value-based arrangements" ("VBAs") that satisfy the following proposed new regulatory definitions, which would be codified at 42 C.F.R. § 411.351:

"Value-based arrangement means an arrangement for the provision of at least one 'value-based activity' for a 'target patient population' between or among—

(1) The 'value-based enterprise' and one or more of its 'VBE participants'; or

(2) VBE participants in the same value-based enterprise.

Value-based activity—

(1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one 'value-based purpose' of the value-based enterprise:

(i) The provision of an item or service;

(ii) The taking of an action; or

(iii) The refraining from taking an action.

(2) The making of a referral is not a value-based activity.

Value-based 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 and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

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

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s)."

Final New Regulatory Definitions: CMS finalized the regulatory definitions as proposed, with mostly minor revisions (restated below, noting revisions from the proposed definitions in strikethrough and bold). Most notable among the revisions is CMS'

removal from the definition of "value-based activity" of the phrase "[t]he making of a referral is not a value-based activity". In removing the proposed phrase from the final definition, CMS explained that establishing a plan of care is both a value-based activity and an express part of the regulatory definition of "referral".

"Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

Value-based activity—~~(1) M~~means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(i) The provision of an item or service;

(ii) The taking of an action; or

(iii) The refraining from taking an action.

~~(2) The making of a referral is not a value-based activity.~~

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population **to which the only parties are** ~~between or among~~—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

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 and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means ~~an individual~~ **a person** or entity that engages in at least one value-based activity as part of a value-based enterprise.

Proposed New Exception: CMS proposed to promulgate one new regulatory exception that would have three subparts designed for value-based arrangements that either (1) carry full financial risk, (2) carry meaningful financial downside risk, or (3) carry less than meaningful (or no) financial risk.

"(1) Full financial risk—Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or

(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

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

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The performance or quality standards against which the recipient will be measured, if any.

(ii) The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.

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

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

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

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

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

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

Final New Exception: CMS largely finalized the new exception as proposed, offering Stark Law protection to a tremendous number of financial arrangements inherent to the health care industry – if they are structured (or restructured) correctly. The text of the final exception is restated below, reflecting revisions from the proposed exception in strikethrough and bold. CMS finalized a lower threshold of financial risk to which the physician must be subject as part of a VBA, *i.e.*, 10% instead of 25% as proposed, in order for the VBA to satisfy the component of the exception for VBAs imposing 'meaningful downside financial risk'. Most notably, CMS finalized a requirement – applicable to the component of the exception for VBAs imposing less than meaningful (or no) financial risk – that the parties monitor whether their value-based activities continue to further their goals and make progress towards outcome measures (if any) and, in certain situations, terminate or amend their VBAs accordingly.

"(1) Full financial risk—Remuneration paid under a value-based arrangement, as defined in § 411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the ~~**6**~~ **12** months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

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

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

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

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement ~~**satisfies the requirements of § 411.354(d)(4)(iv).**~~ **complies with both of the following conditions:**

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

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

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

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

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

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

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

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

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

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

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

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

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

(ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician ~~—(A) I~~ is responsible to **re**pay **or forgo** ~~the entity~~ no less than ~~25~~ **10** percent of the **total** value of the remuneration the physician receives under the value-based arrangement.~~; or~~

~~(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.~~

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

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The ~~performance or quality standards~~ **outcome measures** against which the recipient ~~will be measured~~ **is assessed**, if any.

(ii) The ~~performance or quality standards~~ **outcome measures** against which the recipient **of the remuneration** ~~will be measured~~ **is assessed**, if any, are objective and measurable, and **selected based on clinical evidence or credible medical support** ~~any changes to the performance or quality standards must be made prospectively and set forth in writing~~.

(iii) Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

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

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

(vi) The arrangement is commercially reasonable.

(vii) (A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor:

(1) Whether the parties have furnished the value-based activities required under the arrangement;

(2) Whether and how the continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and

(3) Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise –

(1) For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or

(2) For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

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

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

(x) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement ~~satisfies the requirements of § 411.354(d)(4)(iv).~~ **complies with both of the following conditions:**

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

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

(xii) For purposes of this paragraph (aa)(3), "outcome measure" means a benchmark that quantifies:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

Analysis: Consistent with CMS' focus on eliminating barriers to providing coordinated, high-quality, value-based care, the final exception applies to a vastly broad variety of "value-based arrangements" aimed at care coordination, quality improvement, cost reduction, and/or the transition away from a fee-for-service reimbursement environment. The ease with which an arrangement could qualify as a VBA and the associated definitions – and thus be eligible for the exception's protections – is analyzed in the first subsection, below, entitled "Nuts and Bolts of the 'Value-Based Arrangement'". The exception itself protects only those VBAs meeting its requirements, to include VBAs that pose no downside financial risk to the physician. While broad, the new exception seeks to protect patients and the Medicare program from risks inherent to a value-based reimbursement system, namely stinting on care, cherry-picking, lemon-dropping, and manipulation or falsification of data used to verify outcomes. An arrangement's ability to satisfy the requirements of the new exception for VBAs is discussed in the second subsection below, entitled "Satisfying the Exception for 'Value-Based Arrangements'". Most notably, a properly structured VBA can satisfy the new exception regardless of whether the compensation to be paid under the arrangement is consistent with fair market value or takes into account the volume or value of the physician's referrals to (or other business generated for) the DHS entity.

Nuts and Bolts of the "Value-Based Arrangement"

CMS' definitions work together to set distant and nearly all-encompassing boundaries for the types of arrangements that could qualify as VBAs and thus be eligible for the exception's protections (discussed below). In short, and to distill the interrelation of the definitions as much as possible, an arrangement between an entity and a physician will qualify as a VBA (and thus potentially be eligible for the exception's protections) as long as it:

> With respect to the care of a patient population identified on the basis of legitimate and verifiable criteria determined in advance of the arrangement, is reasonably designed for the parties to collaborate (directly and perhaps with others) to either (1) coordinate and manage that care, (2) improve the quality of that care, (3) appropriately reduce the costs to, or growth in expenditures of, payors without reducing the quality of that care, or (4) transition from a volume-based care delivery and payment system to a quality-based system for that care (*e.g.*, through team-based coordinated care models, infrastructure to provide patient-centered coordinated care, and accepting (or preparing to accept) financial risk).

Importantly, a VBA need not be wholly dedicated to any one of these purposes; in fact, the VBA could certainly have other designs and purposes in addition to one or more of the four purposes listed above. For example, while one VBA may take the form of a shared savings distribution agreement between a DHS entity and a physician, another may take the form of an employment agreement, a medical directorship agreement, a co-management agreement, or a call coverage agreement, etc. While none of the proposed regulatory text, final regulatory text, or rulemaking commentary specifies the degree to which one of the four value-based purposes must be the basis for a VBA[1], CMS stated that one of those purposes must "anchor" the arrangement. In the absence of further clarification of that term, whether and when an arrangement is "anchored" by a value-based purpose will likely remain a subjective, elusive, and fact-specific determination.

Equally as important is CMS' definition of a "value-based entity" ("VBE"), which effectively constitutes two or more providers collaborating to achieve a value-based purpose. The definition of a VBE is broad enough that it encompasses not just large, MSSP-participating ACOs, and not just a network of participants in a commercial insurer's quality-based product and payment system – both of which CMS certainly had in mind – but also two independent physicians collaborating with each other and only each other to better coordinate care. A VBE does not need to adhere to any particular legal or structural requirement; indeed, CMS stated that "the final regulations accommodate both formal and informal" VBEs. 85 Fed. Reg. at 77502.

Accordingly, while the regulations require the VBE to have a "governing document" and an "accountable body or person" responsible for the "financial and operational oversight of the enterprise", the written VBA itself could constitute the requisite "governing document", and the "accountable person" could be an individual party to the arrangement (as designated in the arrangement). In other words, by design, CMS' regulations are broad enough to encompass a wide spectrum of VBEs and VBAs – large and small.

Value-based collaborators must use "legitimate and verifiable criteria" to form the basis for identifying the target patient population on whose care they will focus, but CMS explained that the criteria for the selection of a patient population could include medical or health characteristics, geographic characteristics, payor status, or any other characteristic – as long as cherry-picking or lemon-dropping on the basis of health status, or characteristics driven by profit motive or pure financial concerns, is not the sole criterion. Regardless of the breadth of possible criteria, CMS has stressed that the criteria must be documented in advance of the commencement of the VBA and that it "is not sufficient…to merely state that the selection criteria will be determined by another party", *e.g.*, a payor. 85 Fed. Reg. at 77505.

Satisfying the Exception for "Value-Based Arrangements"

To enjoy Stark Law protection, it is insufficient for an arrangement to merely qualify as a VBA; rather, in order to satisfy the Stark Law exception for VBAs, a VBA must satisfy certain requirements. However, the exception's requirements differ and grow more stringent, depending on whether the VBA (1) occurs in the context of a VBE that carries 'full financial risk', (2) imposes meaningful downside financial risk on the physician, or (3) imposes less than meaningful (or no) downside financial risk on the physician. Thus, the exception is designed to provide protection to nearly the entire waterfront of qualifying VBAs – from shared savings distribution agreements in the context of an MSSP ACO, to similar arrangements made in the context of participating in a commercial insurer's value-based program, to hospital-physician employment, medical directorship, service line management, and other service-based arrangements, to even much smaller direct compensation arrangements between a DHS entity and a physician.

Regardless of the type of VBA, the exception's requirements are not numerous and are significantly less stringent than the requirements of more traditional Stark Law exceptions. CMS admittedly designed the exception in this manner, as it believes that a value-based (and decreasingly volume-based) care delivery and reimbursement system provides inherent safeguards

[1] With respect to the fourth value-based purpose identified above, CMS likened "transitioning" from a volume-based system to a quality-based system to the purpose underlying many of the various start-up arrangements that qualify for protection under the MSSP pre-participation waiver (*see* 80 Fed. Reg. 66733).

importantly, to satisfy any component of the new exception for VBAs, the VBA need not arrange for compensation that (a) is consistent with fair market value, (b) is set in advance, or (c) does not take into account the volume or value of referrals or other business generated – traditional Stark Law requirements that CMS believes "may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures)". 85 Fed. Reg. 77507. The absence of these substantive requirements is significant, considering that employment arrangements and independent contractor arrangements are just two examples of a panoply of arrangements that can be structured (or restructured) to have a value-based purpose, qualify as a VBA, and satisfy the new exception.

Full Financial Risk

The exception for a VBA associated with a VBE at full financial risk for the cost of a target patient population's care applies only if the VBE either (1) is financially responsible, prospectively, for the cost of all patient care items and services covered by the applicable payor, for each patient in the target patient population, for a specified period of time; or (2) would be so within twelve (12) months of the commencement of the VBA. CMS stated in rulemaking commentary that, if Medicare is the payor, the VBE should be responsible for all items and services covered under Parts A and B. However, as long as the VBE carries full financial risk (*e.g.*, capitation, global budget, or similar approaches to payment) for *all* patient care items and services (not just items and services required to treat patients with specific disease states or conditions) for the entire duration of the VBA, the physician himself or herself need not be at full (or even meaningful) financial risk as part of the VBA, in order for the VBA to satisfy the exception. Accordingly, and as an example, if a physician's employer is a DHS entity that is a participant in a VBE that is at full financial risk, the DHS entity can enter into an employment arrangement with that physician (who is also participating in the VBE) and that employment arrangement could qualify as a VBA and be eligible for this component of the exception for VBAs, even if no part of the physician's overall compensation would be at risk of loss (*e.g.*, for failing to achieve certain quality benchmarks). CMS explicitly acknowledges and accepts this, stating that "[e]ven when downstream contractors are paid on something other than a full-risk basis, the [VBE] itself is incented to monitor for appropriate utilization, referral patterns, and quality performance, which we believe helps to reduce the risk of program or patient abuse." 85 Fed. Reg. at 77511.

Accordingly, if a VBE is at full financial risk, it would be relatively easy to structure a VBA to satisfy this component of the exception. In particular, the exception requires only that (1) the compensation paid via the VBA be "for" or "result from"[2] the recipient's efforts to satisfy one of the four purposes identified above; (2) the compensation not be an inducement to reduce or limit medically necessary items or services; (3) the compensation not be conditioned on referrals of patients who are not part of the target patient population or business not covered under the VBA[3]; (4) if compensation *would* be conditioned on the physician's referrals, the VBA satisfy directed referral requirements (*e.g.*, to put the requirement in writing and not to apply the requirement in cases where it would violate patient preference, payor requirements, or the patient's clinical best interest); and (5) records of compensation paid under the VBA be maintained for at least 6 years.

Essentially, an arrangement between a DHS entity and a referring physician, if downstream from a VBE at full financial risk, could easily satisfy this component of the new Stark Law exception for VBAs – as long as some "anchor" purpose of the arrangement is one of the four aforementioned purposes – regardless of whether the compensation paid to the physician exceeds the fair market value of that physician's services, is set in advance, takes into account the volume or value of that physician's referrals to or other business generated for the DHS entity, or is memorialized in any writing, formal or informal, signed or unsigned.

Meaningful Downside Financial Risk for Physician

With respect to VBEs that are not at full financial risk, a second component of the new exception applies to certain associated VBAs that place the physician at "meaningful downside financial risk" for failure to achieve the value-based purposes of the VBE. "Meaningful downside financial risk" is defined to mean that the physician is responsible to repay to the entity (or forego) no less than 10% of the value of the remuneration the physician receives from the entity under the VBA, *i.e.*, to include both monetary compensation and in-kind services. (In the proposed rule, CMS had proposed a 25% threshold.) CMS believes that this responsibility "will likely affect [a physician's] practice and referral patterns in a way that curbs the influence of traditional FFS, volume-based payment." 85 Fed. Reg. at 77515.

[2] CMS' examples of compensation that would not be "for" or "result from" value-based efforts include payments for referrals, payments for business unrelated to the target patient population (such as for general marketing or sales), and non-monetary compensation that is unnecessary and duplicative of technology or other infrastructure that the recipient already has.

[3] For example, if a VBA between a hospital and a physician relates to knee replacement surgeries furnished to Medicare beneficiaries, the VBA will not satisfy the new exception if it requires the physician to perform all of his or her other orthopedic surgeries at the hospital.

However, because of the absence of some of the value-based incentives created by *full* financial risk, this component of the exception is more difficult to satisfy. In addition to the requirements listed above (with respect to "full financial risk"), VBAs imposing meaningful downside financial risk on the physician must satisfy three other requirements: (1) the physician must be at downside risk for the entirety of the arrangement; (2) the nature and extent of the financial risk must be set forth in writing; and (3) the methodology to be used to determine the amount of the remuneration must be set in advance.

CMS declined to impose more onerous requirements because of the incentives created by the physician's assumption of meaningful downside financial risk. Thus, an arrangement between a DHS entity and a referring physician, if imposing such risk on a physician, could easily satisfy this component of the new exception for VBAs – as long as some "anchor" purpose of the arrangement is one of the four aforementioned purposes – and regardless of whether the compensation paid to the physician exceeds the fair market value of that physician's services and/or takes into account the volume or value of that physician's referrals to or other business generated for the DHS entity.

Less than Meaningful (or No) Downside Financial Risk for Physician

Finally, certain VBAs can satisfy the exception for VBAs even if neither the physician, the DHS entity, nor any VBE participant would adopt any degree of financial risk. In addition to meeting some of the requirements from the "full financial risk" and "meaningful downside financial risk" exceptions, this component of the exception requires that the VBA (1) be set forth in writing, (2) be signed by the parties, and (3) include a writing that describes (i) the value-based activities to be undertaken by the arrangement, (ii) how they are expected to further the value-based purposes of the VBE, (iii) the target patient population, (iv) the type or nature of the remuneration, (v) the methodology used to determine the amount of the remuneration, and (vi) the outcome measures[4] against which the recipient of the remuneration will be measured, if any.

In addition, the exception requires that (4) if the VBA would impose outcome measures against which the recipient of the remuneration would be measured, those measures be objective, measurable, selected based on clinical evidence or credible medical support, and determined in advance of their implementation. CMS specifically states that such standards must not be applied retroactively. In the proposed rule, CMS stated that the measures must not "simply reflect the status quo"; in the final rule, CMS declined to include a requirement that the measures "must be designed to drive meaningful improvement in physician performance, quality, health outcomes, or efficiencies in care delivery." *See* 85 Fed. Reg. at 77519-20. However, the adoption of any outcome measure is not in and of itself a requirement for the VBA to satisfy the exception. Stated more simply, a VBA can satisfy the exception even if it does not measure a physician's performance against any outcome measure.

The exception also requires that (5) the remuneration subject to the VBA not be conditioned on the volume or value of referrals (of patients other than those in the target patient population) or business generated for the entity and not covered under the VBA. CMS stresses that compensation subject to the VBA could still be calculated in a manner that "takes into account" the volume or value of the physician's referrals; the exception only prohibits the conditioning of the release of such compensation upon satisfaction of a requirement that the physician refer patients to or generate business for the entity. This last requirement could impact VBAs that take the form of employment agreements, for example, that could otherwise permissibly require referrals if they satisfy the directed referral requirements (*e.g.*, to put the requirement in writing, and not to apply the requirement in cases where it would violate patient preference, payor requirements, or the patient's clinical best interest).

Finally, to satisfy this component of the new exception, physicians and entities must monitor their VBAs (at least annually or, for VBAs of shorter duration, at least once during the term) to ensure that the parties have furnished the required value-based activities and to determine whether the value-based activities taken (and any outcome measures, if any) are expected to further the value-based purposes of the VBE. In the event the activities (and/or outcome measures) are no longer expected to further such purposes, the VBA would no longer satisfy the exception and – given the few requirements of the exception

– may need to be either restructured or abandoned. In such a case, for the VBA to continue to satisfy this component of the exception, either (1) the VBA must be terminated within 30 calendar days of the completion of the monitoring, (2) the ineffective value-based activity must be terminated within 90 days of the completion of the monitoring, and/or (3) the unattainable outcome measure must be terminated or replaced within 90 days of the completion of the monitoring. If such termination or replacement is not achieved within these timeframes, the VBA would be deemed to not satisfy the exception as of the date the activity or measure was determined to no longer further the purposes of the VBE. Accordingly, parties to such a VBA must be not only vigilant, but also confident at the inception of the VBA that they will be able to timely react to (*e.g.*, amend their arrangement to accommodate) any activity or measure later determined to be ineffective. Accordingly,

[4] An "outcome measure" is defined to mean a benchmark that quantifies (A) improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

parties to such a VBA should structure formal termination and amendment provisions to facilitate such vigilance and timely responsiveness.

While CMS had considered restricting the scope of the exception to only non-monetary remuneration, or requiring a recipient of such remuneration to contribute at least 15% of the donor's cost of such remuneration, it ultimately chose not to do so, thus avoiding a narrowing of the scope of the exception that would have greatly diminished its utility.

Once again, an arrangement between a DHS entity and a referring physician – if structured (or restructured) correctly and, if necessary, monitored sufficiently – could quite easily satisfy the new Stark Law exception for VBAs. Effectively, as long as some "anchor" purpose of the arrangement is one of the four value-based purposes, and as long as a writing associated with the VBA describes (i) the value-based activities to be undertaken by the arrangement, (ii) how the activities are expected to further value-based purposes, (iii) the target patient population, (iv) the compensation, (v) the methodology used to determine the amount of the compensation, and (vi) the attainment of outcome measures – if any – against which the physician would be measured, the arrangement would satisfy the exception, regardless of whether the compensation paid to the physician exceeds the fair market value of that physician's services and/or takes into account the volume or value of that physician's referrals to or other business generated for the DHS entity. Thus, integrating and memorializing the integration of value-based purposes and efforts into compensation arrangements could be a panacea for Stark Law compliance.

Applicability to Indirect Compensation Arrangements: A VBA may effectuate an "indirect compensation arrangement" ("ICA") between a DHS entity and a referring physician, in which case the only potentially applicable exception would be the exception for indirect compensation arrangements, 42 C.F.R. 411.357(p). However, most ICAs inclusive of a VBA would not be likely to satisfy that exception, as compensation paid to the physician under a VBA is likely to take into account the volume or value of that physician's referrals to the DHS entity. Accordingly, CMS finalized a rule that makes the VBA exception available to those ICAs that are inclusive of a VBA *if* the physician (or the physician organization in whose shoes the physician stands) is a party to the VBA. Specifically, if the VBA to which the physician is a party satisfies the VBA exception, the physician may make referrals to the entity with which he or she has an ICA.

Practical Implications: DHS entities should be careful to comply (and document their compliance) with each definitional requirement in every stage of developing a VBA with a physician – in particular how the arrangement would enhance care coordination and management, improve the quality of care, appropriately reduce the costs of care (or the growth in expenditures of care without reducing quality), and/or help transition from a volume-based care delivery and payment system to a quality-based system, with respect to an identified patient population.

Given that this exception does not require participation in any particular alternative payment model (such as the MSSP), or even a commercial insurer's value-based program, but rather would apply to value-based efforts engaged in by and between two solo practitioners, let alone a hospital and a physician, proper structuring or restructuring of an arrangement will allow entities and physicians who seek to coordinate and improve patient care to avoid the need to satisfy traditional Stark Law exception requirements – including that compensation be consistent with fair market value, be set in advance, and/or not be determined in a manner that takes into account the volume or value of the physician's referrals. In particular, collaborators should make efforts to ensure that the writings associated with their VBAs describe:

- That some "anchor" purpose of the arrangement is one of the four value-based purposes;
- The value-based activities to be undertaken;
- How those activities are expected to further the value-based purpose(s);
- The target patient population, and the criteria used to identify it;
- The compensation;
- The methodology used to determine the amount of the compensation;
- How that compensation would be "for" or "result from" the activities that would further the value-based purpose(s);
- The outcome measures – if any – against which the physician's performance would be measured;
- The flexibility (if not formal terms) that the parties will need, in the absence of any meaningful financial risk, to monitor and ensure that the parties' value-based activities and any outcome measures continue to further the VBE's value-based purposes and remain attainable, respectively, and if not, to terminate or replace the activities or measures, respectively, within requisite timeframes.

CMS Considered and Sought Comments On: In its proposed rule, CMS sought comments on nearly every aspect of the proposed definitions and exception. Set forth below are some but not all of the concepts that CMS considered but *declined* to implement or finalize in the final regulatory text.

Value-Based Purposes

- Whether an arrangement must purport to promote care coordination and management in order to qualify as a VBA.
- Whether CMS should define "coordinating and managing care" to mean "the deliberate organization of patient care activities and sharing of information… tailored to improve… health outcomes…, in order to achieve safer and more effective care for the target patient population."
- Whether CMS should bolster the third value-based purpose to require reducing costs or growth in costs while not just avoiding the reduction in quality of care, but actually and demonstrably improving or maintaining the improved quality of care.
- Whether and how CMS could determine that the value-based purposes have been actually achieved.

Value-Based Arrangements

- Whether physicians' arrangements with DMEPOS suppliers and laboratories should be ineligible as VBAs, given the lack of direct patient contact those entities have.
- Whether physicians' arrangements with other entities should be similarly ineligible as VBAs, including those with pharmaceutical managers, DMEPOS manufacturers and distributors, PBMs, wholesalers, and distributors.

The Exception for VBAs

- Whether the safeguards in the proposed exception were sufficient, *i.e.*, whether CMS should require either fair market value compensation or that compensation not "take into account" the volume or value of referrals or other business generated.
- Whether to allow a VBE to be considered at "full financial risk" if the VBE is financially responsible, prospectively, for the cost of a defined set of patient care items and services (as opposed to all items and services), for each patient in the target patient population, and whether such risk should endure for a minimum period of time of at least one year.
- Whether, in satisfying the exception for VBEs that are at full financial risk, the compensation paid via the VBA should be "for", "result from", or be "related to" the recipient's efforts to satisfy one of the four purposes identified above.
- Whether to require, as part of the VBA exception when less than meaningful (or no) downside financial risk is imposed upon the physician, that the parties not only monitor whether the VBA is furthering value-based purposes, but do so at specified intervals. CMS also considered a rule whereby a VBA would no longer satisfy this exception if, after three years, its value-based purposes had not been achieved.

Open Questions: CMS largely finalized the new definitions and exception as they were proposed and, in rulemaking commentary, largely addressed (and declined to implement) the items upon which CMS sought public comment. However, the regulated industry will likely seek clarity with respect to the degree to which a value-based purpose must "anchor" the VBA.

II. New and Amended Definitions of Key Regulatory Terms and Phrases

1. New Definition of "Commercially Reasonable"

Prior to the Final Rule, the phrase "commercially reasonable" was not defined in regulatory text, although parties had typically referred to CMS' Phase II rulemaking commentary explaining that "an arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals". 69 Fed. Reg. 16053, 16093 (Mar. 26, 2004).

Proposed New Definition: CMS proposed to amend 42 C.F.R. § 411.351 to define "commercially reasonable" to mean that "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

Final New Definition: In the Final Rule, CMS promulgated a slightly revised definition of "commercially reasonable" at 42 C.F.R. § 411.351 to mean 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."

Effect: The definition brings clarity to the meaning of the phrase, which is an element of numerous exceptions, and eases the ability to satisfy it. Exceptions impacted would include the exceptions for:

- Rental of office space
- Rental of equipment
- *Bona fide* employment relationships
- Isolated transactions
- Fair market value compensation
- Indirect compensation arrangements
- Timeshare arrangements

Analysis: The lack of a definition of the phrase "commercially reasonable" – an element of many Stark Law exceptions – has left room for aggressive litigation positions by the DOJ and *qui tam* whistleblowers in False Claims Act actions, *e.g.*, that hiring a physician is *per se* commercially unreasonable if the compensation to be paid to the physician would exceed anticipated revenues from the physician's professional services. Courts have adopted some of these positions, and the resulting ambiguity has both impacted settlement negotiations and inflated settlement amounts. Furthermore, prior rulemaking commentary had left doubt as to whether any test of "commercial reasonableness" should be objective, subjective, or a mix of both. The text of the proposed definition indicated that the test would have been a mix of both objective and subjective tests.

The Final Rule establishes that (1) the determination of "commercial reasonableness" should be made from the perspective of the particular parties to the arrangement, and (2) commercial reasonableness does not hinge on profit, thus making it easier for parties to establish the commercial reasonableness of their arrangements. Although CMS explains in commentary that it is "not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to a determination of commercial reasonableness", it maintains its position that profitability need not be the lynchpin of commercial reasonableness. 85 Fed. Reg. at 77534. CMS' changes to the text of the definition contained in its proposed rule were based on its recognition that "a definition requiring a compensation arrangement to be on similar terms as like arrangements in order to be commercially reasonable…could increase the burden on parties that must seek the expertise of outside organizations" and desire to refocus on the requirement to "appropriately consider[] the characteristics of the parties to the actual arrangement…." 85 Fed. Reg. at 77531-32. Effectively, the test of an arrangement's 'commercial reasonableness' is now entirely subjective and focused on the parties to the arrangement, and no longer needs to include a hunt for similar terms in similar arrangements entered into by similar parties.

CMS also clarifies that it was "retracting [its] statement from the proposed rule that the requirement [under the personal services arrangement exception that aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s)] equates to a requirement that the personal service arrangement is commercially reasonable", instead interpreting this requirement merely as "a protection against sham arrangements for the services of a physician for which the entity has no genuine or reasonable use." 85 Fed. Reg. at 77535. Based on this clarification, the personal services arrangement exception does not (and never did) include a broader commercial reasonableness criterion.

Practical Implications: CMS' newly adopted definition allows DHS entities (in particular non-profit hospitals) to proceed with much greater confidence in entering into arrangements that further their own legitimate operational and patient care goals, even if they may result in a net financial loss to the entity. As in the proposed rule, CMS acknowledged that "commercially reasonable" justifications for entering into an arrangement at an expected loss may include community need, timely access to services, fulfillment of licensure and regulatory obligations, charity care, and improvements to quality and health outcomes. CMS indicated that commercially unreasonable arrangements would include "duplicative" arrangements (*e.g.*, engaging two medical directors when only one is necessary), arrangements to garner business from physicians, and violations of criminal law.

Therefore, entities should consider implementing or amending physician contracting policies and procedures to require, at salient stages of the development of the arrangement, written explanations of how the arrangement would fulfill their own aforementioned and other legitimate business goals. Although rulemaking commentary states that such documentation would not be determinative of an arrangement's commercial reasonableness, its creation and preservation would nevertheless provide an important procedural protection to ensure attention to this criterion, and useful evidence should an arrangement be scrutinized by a third party.

CMS Considered and Sought Comments On: CMS had sought comments on whether it should define the phrase, alternatively, to mean "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty", but ultimately adopted its proposed definition with only minor revisions.

Open Questions: The final definition eliminates the proposed definition's ambiguous and potentially demanding reference to "similar terms and conditions as like arrangements", which may have required parties to search for, identify, and memorialize the fact that similar agreements entered into by similarly situated third parties contained similar terms and conditions. Nevertheless, it remains to be seen what arrangements CMS will consider "sensible."

2. Revision of the Definition of "Fair Market Value"

Prior Definition: Prior to the Final Rule, 42 C.F.R. § 411.351 defined "fair market value" to mean "the value in arm's-length transactions, consistent with the general market value." "General market value" was defined to mean "the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), 'fair market value' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, 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."

Proposed Revised Definition: CMS proposed to amend 42 C.F.R. § 411.351 to define "fair market value" as:

> "(1) General. The value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.
>
> (2) Rental of equipment. With respect to the rental of equipment, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.
>
> (3) Rental of office space. With respect to the rental of office space, the value in an arm's length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

'General market value' means—

> (1) General. The price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.
>
> (2) Rental of equipment or office space. The price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement."

Final Revised Definition: CMS adopted its proposal with minor changes (highlighted in bold and strikethrough below), amending 42 C.F.R. § 411.351 to define "fair market value" as:

> "(1) *General*. The value in an arm's-length transaction, **~~with like parties and under like circumstances, of like assets or services,~~** consistent with the general market value of the subject transaction.
>
> (2) *Rental of equipment*. With respect to the rental of equipment, the value in an arm's-length transaction, **~~with like parties and under like circumstances,~~** of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.
>
> (3) *Rental of office space*. With respect to the rental of office space, the value in an arm's length transaction, **~~with like parties and under like circumstances,~~** of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

~~**(1) General. The price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.**~~

(1) ***Assets*. With respect to the purchase of an asset, 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.**

(2) ***Compensation*. With respect to compensation for services, 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.**

(3) *Rental of equipment or office space*. **With respect to the rental of equipment or the rental of office space,** 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 ~~**the**~~ **a well-informed** lessor and ~~**the**~~ lessee ~~**in the subject transaction at the time the parties enter into the rental arrangement**~~ **that are not otherwise in a position to generate business for each other**."

Effect: The final revised definition largely (and most importantly) serves to bifurcate the concept of "fair market value" from the separate concept of compensation that "takes into account" the volume or value of referrals and other business generated, which are and should remain distinct concepts and elements of many Stark Law exceptions.

Analysis: The revisions to the definition are analytically helpful, in that they more clearly delineate the fair market value requirement and eliminate its conflation with other Stark Law concepts – in particular, the final definition undermines the notion adopted by DOJ in litigation, *qui tam* whistleblowers, and some courts that compensation cannot be consistent with fair market value if it 'takes into account' the volume or value of referrals or other business generated. The revised definition should result in less confusion for parties, practitioners, regulators, and courts alike.

CMS' rulemaking commentary also makes clear that, while the concept of discerning "fair market value" is largely objective (*e.g.*, through analysis of market comparables), it can – in "extenuating circumstances" – embrace a degree of subjectivity. 85 Fed. Reg. at 77556. CMS is explicit that "the fair market value of a transaction…may not always align with published valuation data compilations, such as salary surveys." 85 Fed. Reg. at 77554. For instance, CMS expressly recognizes that a top surgeon who is highly sought after might command fair market value compensation greatly in excess of the amount indicated by salary survey data – *i.e.*, consistent with the general market value of "the subject transaction." *Id.* Similarly, physicians seeking to live in low-cost geographic areas proximate to good schools and desirable recreation opportunities may be paid fair market value compensation significantly less than what certain salary survey data may otherwise indicate. *Id.*

Finally, CMS' revisions make clear that the determination of whether compensation is consistent with "fair market value" would continue to be assessed at the inception and only at the inception of an arrangement, *i.e.*, subsequent market changes would not cause a pre-existing and effective arrangement to fail to comply with the fair market value element of a Stark Law exception.

Practical Implications: Generally, the Final Rule is not likely to cause material deviations from the manner in which parties and valuators already assess the fair market value nature of compensation. Accordingly, the manner in which parties address and document fair market value should not be greatly impacted by the Final Rule. However, to the extent an arrangement reflects special or extenuating circumstances, the parties should be sure to document and articulate those circumstances and (if appropriate) any resultant deviation from what a traditional fair market valuation (*e.g.*, reference to salary survey data) may otherwise dictate.

CMS Considered and Sought Comments On: CMS sought comment on whether the restructuring of the definition of "fair market value", *i.e.*, to accommodate the three fundamental scenarios to which it applies – (1) generally, (2) to equipment leases, and (3) to space leases – may cause any undue distinctions from the statutory language at 42 USC §1395nn(h)(3), but ultimately adopted a definition including these distinctions.

3. New Special Rules for Compensation that "Take Into Account" the Volume or Value of Referrals or Other Business Generated, Revision of Special Rule on Directed Referrals, and Revision of the Definition of "Indirect Compensation Arrangement"

Prior Special Rule and Definition of Indirect Compensation Arrangement: Prior to the Final Rule, CMS's special rules on compensation provided at 42 C.F.R. 411.354(d)(4) that:

> "A physician's compensation from a bona fide employer or under a managed care contract or other arrangement for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:
>
> (i) Is set in advance for the term of the arrangement.
>
> (ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals).
>
> (iii) Otherwise complies with an applicable exception under § 411.355 or § 411.357.
>
> (iv) Complies with both of the following conditions:
>
> (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.
>
> (B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.
>
> (v) The required referrals relate solely to the physician's services covered by the scope of the employment, the arrangement for personal services, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment arrangement for personal services or contract."

Prior to the Final Rule, subsections 42 C.F.R. 411.354(d)(5) and (6) did not exist.

Proposed Special Rule: CMS proposed to codify two new special rules at 42 C.F.R. § 411.354(d)(5) and (6), which would state that:

> "(5) (i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if—
>
> (A) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or
>
> (B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.
>
> (ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if—
>
> (A) The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity; or
>
> (B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

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

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

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

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

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

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

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

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

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

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

Final Special Rule: CMS finalized revisions to 42 C.F.R. § 411.354(d)(4), and added new subsections 42 C.F.R. § 411.354(d)(5) and (6). Under the Final Rule, 42 C.F.R. § 411.354(d)(4)-(6) states as follows (with changes from the proposed rule highlighted in bold and strikethrough):

"(4) ***Directed referral requirement.*** **If** a physician's compensation ~~**from**~~ **under** a bona fide ~~**employer**~~ **employment relationship, personal service arrangement,** or ~~**under a**~~ managed care contract ~~**or other arrangement for personal services may be**~~ **is** conditioned on the physician's referrals to a particular provider, practitioner, or supplier, ~~**provided that the compensation arrangement meets**~~ all of the following conditions **must be met**. ~~**The compensation arrangement:**~~

(i) **The compensation, or a formula for determining the compensation,** is set in advance for the ~~**term**~~ **duration** of the arrangement. **Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.**

(ii) **The compensation** is consistent with **the** fair market value **of the physician's services.** ~~**for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals).**~~

(iii) **The compensation arrangement** otherwise **satisfies the requirements of** ~~**complies with**~~ an applicable exception under §411.355 or §411.357.

(iv) **The compensation arrangement** complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, ~~the arrangement for~~ personal services **arrangement**, or ~~the~~ **managed care** contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, ~~the arrangement for~~ personal services **arrangement**, or ~~the~~ **managed care** contract.

(vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, 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. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(5) ***Compensation to a physician.*** (i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if ~~(A)~~ the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity. ~~; or~~

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

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if ~~(A)~~ the formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity. ~~; or~~

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

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

(iv) This paragraph (d)(5) ~~only to section 1877 of the Act~~ **does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at 411.357(m), (s), (u), (v), (w), and (bb).**

(6) ***Compensation from a physician.*** (i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if ~~(A)~~ the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity. ~~; or~~

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

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

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

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

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

(iv) This paragraph (d)(5) ~~only to section 1877 of the Act~~ **does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at 411.357(m), (s), (u), (v), (w), and (bb).**

Effect: The new special rules effectively define the phrase "takes into account the volume or value" of referrals and other business generated and, in so doing, (1) greatly reduce industry confusion surrounding the meaning of the phrase, and (2) narrow the scope (and thus significance) of the phrase to contemplate only compensation formulae that cause actual compensation amounts to fluctuate with quantifiable and positively correlated increases or decreases in referral volumes. This clarity and narrowing would greatly ease the ability to satisfy the following Stark Law exceptions:

- Academic medical centers
- Rental of office space
- Rental of equipment
- *Bona fide* employment relationships
- Personal service arrangements
- Physician recruitment
- Isolated transactions
- Certain arrangements with hospitals/Remuneration unrelated to the provision of DHS
- Group practice arrangements with a hospital
- Charitable donations by a physician
- Nonmonetary compensation
- Fair market value compensation
- Indirect compensation arrangements
- Obstetrical malpractice insurance subsidies
- Retention payments in underserved areas
- Assistance to compensate a nonphysician practitioner
- Timeshare arrangements
- Limited remuneration to a physician

Analysis: The new definition of "takes into account" is welcome, overdue, and largely consistent with a definition that the authors of this Critical Analysis proposed in comments submitted in response to CMS' previous request for public input on the meaning of the phrase.

We agree with CMS' comment in its proposed rule commentary that the definition will have "great value." In the absence of a codified definition of "takes into account," the DOJ and *qui tam* whistleblowers have pursued aggressive interpretations of the phrase in FCA litigation, including that if anticipated referrals play any part – *e.g.*, mere consideration – in an entity's decision to hire or engage a physician, much less how much to compensate a physician, the compensation must "take into account" the volume or value of referrals. Regulators have, in the past, taken the position that compensation amounts in excess of fair market value are inherently suspect of "taking into account" the volume or value of referrals. Courts have adopted widely discrepant interpretations of the phrase, sometimes conflating the phrase's meaning with that of "fair market value" or adopting – as CMS has in the past – entirely circular interpretations of the phrase. These phenomena have caused health care providers to place unduly great value on the resolution of Stark Law-based FCA litigation involving the uncertain (but potentially catastrophic) application of this phrase.

Objective Tests for 'Takes Into Account'

The new special rules – by providing "objective tests" for determining whether compensation takes into account referrals – go a long way towards eliminating the unnecessary costs and expenditures caused by the current ambiguity. By stating that compensation only "takes into account" the volume or value of referrals if (1) the mathematical formula used to calculate the amount of the compensation includes as a variable referrals or other business generated, and (2) the amount of the compensation positively correlates with the number or value of the physician's referrals to (or generation of business for) the entity, the new definition appears to restrict the scope of the inquiry and analysis to the compensation formula contained in the four corners of a writing (assuming the parties live within these four corners) – and not to extend to the hearts and minds of physicians and those who lead and manage DHS entities.

In commentary, CMS encourages stakeholders to carefully consider whether compensation formulae include referrals as a variables. For instance, in responding to comments on the topic of outcomes-based compensation, CMS notes that "[a]lthough bonus compensation based on "system success" may not include referrals to or other business generated for the entity as a variable in many instances, the determination of whether the formula (to determine the compensation) includes such variables must be made on a case-by-case basis." 85 Fed. Reg. at 77542. For instance, CMS explains that "if an entity pays a physician one-fifth of a bonus pool that includes all collections from a set of services furnished by an entity, including those from designated health services referred by a physician to the entity, the formula used to calculate the physician's compensation is: (.20 x the value of the physician's referrals of designated health services) + (.20 x the value of the other business generated by the physician for the entity) + (.20 x the value of services furnished by the entity that were not referred or generated by the physician). The value of the physician's referrals to the entity is a variable in this formula, as is the value of the other business generated by the physician." 85 Fed. Reg. at 77540.

Application to Fixed Compensation and the Special Rule for Directed Referrals

CMS did not finalize provisions within the specials rules related to the treatment of fixed compensation, which would have provided that fixed compensation could have been considered to "take into account" the volume or value of referrals if and only if there was a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined. Instead, CMS finalized only those provisions including compensation based on a formula that correlates compensation amount with referrals, effectively excluding fixed compensation arrangements altogether from ever taking into account the volume or value of referrals. CMS instead addresses the policy concern that a DHS entity could pay inflated fixed compensation for anticipated future referrals through its revision to the special rule on directed referrals. Through this revision, CMS does not allow a DHS entity to require a physician to refer to the DHS entity if "the existence of the compensation arrangement" or "the amount of the compensation" is contingent on the physician's volume or value of referrals. 85 Fed. Reg. at 77543.

In other words, while a DHS entity would not be considered to pay compensation that "takes into account" referrals by virtue of paying inflated fixed compensation, it also would be unable to link the receipt of compensation to the value or volume of the DHS entity's future referral stream from the physician. (The arrangement would, of course, also be separately limited by the fair market value criterion of applicable exceptions.) CMS notes, however, that this rule "does not prohibit directed referral requirements based on an established percentage – rather than the number or value – of a physician's referrals. Therefore, if the directed referral requirement…provided for termination of the compensation arrangement if the physician failed to refer 90 percent, for example, of his or her patients to a particular provider, practitioner, or supplier, it would not run afoul of the special rule at § 411.354(d)(4) or jeopardize compliance with the requirement of the applicable exception." 85 Fed. Reg. at 77550. Further, CMS explains that "[a] directed referral requirement under which a physician is paid different stipulated percentages of a bonus pool depending on the percentage of the physician's referrals that are 'in network' (that is, to a particular provider, practitioner, or supplier) would not be categorically prohibited under § 411.354(d)(4)(vi)." *Id.*

The Final Rule also added an explicit criterion to each of several exceptions (for academic medical centers, *bona fide* employment relationships, personal service arrangements, physician incentive plans, group practice arrangements with a hospital, fair market value compensation, and indirect compensation arrangements) that the arrangement comply with the requirements of the special rule on directed referrals, including the requirement that neither the existence of the arrangement nor the amount of compensation be conditioned on the number or value of the physician's referrals, if it provides for directed referrals.

Thus, the Final Rule appears to have addressed situations that the authors of this Critical Analysis occasionally encounter, *i.e.*, wherein an entity, at the outset of or in contemplation of an arrangement with a physician, projects the volume and value of anticipated referrals from that physician and seeks to make or even alter an offer of compensation to that physician in contemplation of that volume and value. Under the Final Rule, such a situation would appear to not implicate the meaning

of "takes into account" the volume or value of referrals. However, the entity would not be able to "lock in" the physician's referrals by combining a directed referral provision and a requirement that the physician's referrals reach a certain value or volume in order for the agreement to remain effective or for the physician to receive any amount of compensation.

Timing and Special Rules on Unit-Based Compensation

In rulemaking commentary, CMS states that the new special rules supersede any of its previous guidance going forward. *See* 85 Fed. Reg. at 77541. However, the special rules and associated policies "are prospective only and represent CMS policy regarding the volume or value standard and the other business generated standard going forward from the effective date of this final rule." *Id.*

CMS also addresses the application of its special rules on unit-based compensation in light of the Final Rule, stating that "[o]n and after the effective date of this final rule, the special rules at § 411.354(d)(2) and (3) will be either unnecessary or inapplicable to deem unit-based compensation not to take into account the volume or value of a physician's referrals or other business generated by a physician. However, it is important to preserve the regulations at § 411.354(d)(2) and (3) to assist parties, CMS, and law enforcement in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance with the physician self-referral law." 85 Fed. Reg. at 77544. In other words, the special rules on unit-based compensation will remain on the books, but have only historical application.

Reaffirmation of Tuomey Rejection

CMS' rulemaking commentary also again squarely addressed the issue litigated in *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, wherein an employed physician's productivity bonus was based entirely on personal productivity but, because the physician's services were provided in a facility, also correlated directly to the amount of facility fees that could be charged. Rejecting the DOJ's and the court's interpretations in *Tuomey*, CMS stated that "an association between personally performed physician services and designated health services furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to the entity or the volume or value of other business generated by the physician for the entity." 85 Fed. Reg. at 77539. This statement should provide additional comfort for DHS entities and physicians that have already arrived at this conclusion.

Practical Implications: Despite the historical uncertainty, many entities and physicians had already adopted a position that the phrase "takes into account" requires a direct quantitative link between the method of determining compensation and the volume or value of that physician's referrals. For these entities, the new definition will provide substantial comfort, but potentially little operational change. For other entities that had been more circumspect in allowing any correlation between the consideration of referrals and the inception of an arrangement, let alone the determination of compensation subject to that arrangement, the new definition opens opportunities for new and revised processes for considering the viability of potential arrangements and determining subject compensation amounts and methodologies.

In particular, all entities may wish to revisit their physician contracting policies and procedures to determine if they remain aligned with the new rules. As one example, the reduced uncertainty afforded by the new special rules may allow entities to revise or develop policies and procedures to allow more freedom to consider and quantify the volume and value of hoped for and anticipated referrals, to document them appropriately, to consider the likely financial impact of engaging a physician at certain compensation amounts in relation to such volumes and values, and, accordingly, to make prudent business decisions consistent with organizational fiduciary duties.

4. Revision of the Definition of "Indirect Compensation Arrangement"

Prior Definition of Indirect Compensation Arrangement: Prior to the Final Rule, CMS defined an "indirect compensation arrangement" at 42 C.F.R. § 411.354(c)(2) to exist if:

> "(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);
>
> (ii) The referring 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, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and
>
> (iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS."

Proposed Rule: CMS' proposed rule did not include any proposal to revise the definition of "indirect compensation arrangement."

Final Rule Definition of Indirect Compensation Arrangement: Under the Final Rule, CMS revised the definition of an "indirect compensation arrangement" at 42 C.F.R. § 411.354(c)(2), such that an indirect compensation arrangement exists only if (changes from the definition effective prior to the Final Rule are highlighted in bold and strikethrough):

> "(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);
>
> (ii) **(A)** The referring 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 referring physician for the entity furnishing the DHS~~**, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section**~~ **and the individual unit of compensation received by the physician (or immediate family member) –**
>
> **(1) Is not fair market value for items or services actually provided;**
>
> **(2) Includes the physician's referrals to the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or**

(3) Includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(B) For purposes of applying paragraph (c)(2)(ii)(A) of this section, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(C) If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)).

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS."

Effect: CMS' revision to the definition of "indirect compensation arrangement" further limits the reach of the Stark Law, taking many arrangements outside the scope of the Stark Law altogether.

Analysis: Although the Final Rule does not apply the new special rules (discussed above) to the test for determining the existence of an "indirect compensation arrangement", it revises and further narrows the definition of "indirect compensation arrangement" in a different way to calibrate the definition with the more limited set of arrangements that CMS believes should be subject to regulatory scrutiny. In particular, the Final Rule adds an additional definitional criterion for arrangements created by an unbroken chain of financial relationships to qualify as "indirect compensation arrangements". Not only must the physician receive *aggregate* compensation that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing DHS, but the *individual unit* of compensation received by the physician must either not accord with fair market value or include the physician's referrals or other business generated as a variable, resulting in a positive correlation between compensation and referrals or other business generated.

Thus, the revised definition requires, for the first time, analysis of the individual unit of compensation – not merely aggregate compensation – at the stage of determining whether an indirect compensation arrangement exists. Prior to this change, correlation between only aggregate compensation and referral or business generation volume could have been sufficient to qualify an arrangement as an "indirect compensation arrangement". Under the Final Rule, an arrangement where aggregate compensation and referral volume are correlated might not constitute an indirect compensation arrangement at all, depending on the compensation methodology and the nature of the individual unit of compensation. Given the volume of chains of financial relationships that exist between physicians and DHS entities, this revision has the potential to profoundly narrow the reach of the Stark Law. In rulemaking commentary, CMS acknowledged this narrowing and stated that its intent in making the revision was to "effectively incorporate and apply the conditions of the special rules on unit-based compensation at the definitional level when determining whether an indirect compensation arrangement exists", rather than to apply them as an element of the exception for indirect compensation arrangements (42 C.F.R. 411.357(p)). 85 Fed. Reg. 77546. By lifting the conditions of the special rules on unit-based compensation to the definitional level, *i.e.*, from the exception level, many innocuous unbroken chains of financial relationships will no longer need to satisfy, for instance, the writings requirement of the exception for indirect compensation arrangements. Focusing on arrangements where the individual unit of compensation is based on time, units of service, or other "per click" formulae, CMS stated that its intent in making this revision (which had not been a part of the proposed rule) was to "simplify the analysis". *Id.*

However, seemingly simple changes can have unforeseen effects. Both the revised regulatory text and CMS' rulemaking commentary leave open fundamental questions about how to apply the revised definition, particularly in relation to arrangements wherein the 'individual unit of compensation' is *not* based on time, units of service, or other "per click" formulae. For instance:

- When determining whether the new additional criterion for indirect compensation arrangement exists, which financial relationship in the unbroken chain should be examined? CMS did *not* revise the text of its provision at 42 C.F.R. § 411.354(c)(2)(ii)(C), which states that "[i]f the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, **the determination whether the aggregate compensation** varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS **will be measured by the nonownership or noninvestment interest closest to the referring physician** (or immediate family member) (emphases added). In other words, in considering the first criterion for the possible existence of an indirect compensation arrangement, we focus on the *compensation* relationship closest to the referring physician in the unbroken chain of financial relationships. For instance, if a physician holds an ownership interest in a management services organization, which in turn has a services contract with a DHS entity, the determination as to whether the relationship meets the aggregate compensation component of the indirect compensation arrangement definition is made based on the compensation paid by the DHS entity to the MSO, and not based on the remuneration paid to the physician by the MSO as a result of the physician's ownership. However, the unrevised text of 42 C.F.R. § 411.354(c)(2)(ii)(C) does not address or tell us where to focus when we consider the new, second criterion of the indirect compensation arrangement definition. As time marches on, the context of the Final Rule's rulemaking history fades, and the canons of regulatory interpretation do not, the silence of subsection (c)(2)(ii)(C) (or, rather, its exclusive focus on the aggregate compensation criterion of the definition) will become more meaningful. When analyzing the nature of the "individual unit of compensation received by the physician", ought we focus on the financial relationship closest to the physician, regardless of whether that relationship is an ownership interest or a compensation arrangement?

- When analyzing the nature of the "individual unit of compensation", how should we analyze compensation that is *not* based on time, units of service, or other "per click" formulae? In many circumstances, the compensation formula at issue may not be unit-based. For instance, in the example above, the MSO might be paid by the DHS entity on the basis of a percentage of the MSO's costs plus a percentage profit margin. Under the prior definition – analyzing only the nature of the aggregate compensation – this compensation methodology would likely have resulted in an indirect compensation arrangement between the referring physician and the DHS entity. However (and assuming that CMS intends that the closest *compensation* relationship to the physician be the subject of focus for the new, second criterion as well as the original, first criterion of the indirect compensation arrangement definition), it is not clear what constitutes an "individual unit of compensation" in arrangements (such as percentage-of-cost plus arrangements) that are not inherently unit-based. Ought we focus on the costs, or the percentage, as the "individual unit of compensation"? If the percentage does not increase (e.g., from 60% to 65%) as referral volumes increase, has the criterion been satisfied? Certainly costs, themselves, will increase as referral volumes increase, as will the resultant amount of the "plus" percentage profit margin. In the absence of guidance, applying this second, new definitional criterion may not always be 'simple', particularly in the context of arrangements with compensation methodologies that are not inherently "unit-based".

- How has the definitional stage of the analysis been 'simplified' now that it requires an inquiry into the 'fair market value' nature of the compensation rate? Before the Final Rule, many unbroken chains of financial relationships did not effectuate indirect compensation arrangements because, for instance, the aggregate compensation received by the physician did not vary with the volume or value of referrals – and this methodological determination could be made without analysis of whether the compensation was or was not also consistent with the fair market value of the items or services being arranged for. The revised definition now appears to require – *at the definitional stage* – a fair market value analysis of any and all individual units of compensation to the extent they are associated with aggregate compensation that varies with referral volume. While this analysis would have had to occur as part of compliance with the exception for indirect compensation arrangements (*i.e.*, prior to the Final Rule), lifting the FMV inquiry to the definitional stage does not work to simply, streamline, or shortcut the Stark Law analysis for most innocuous, unbroken chains of financial relationships, which was the intent behind the revisions. As the regulated industry knows too well, fair market valuations can be costly, untimely, resource-intensive, and anything but simple.

- When would the exception for indirect compensation arrangements (42 C.F.R. 411.357(p)) ever apply? After the Final Rule, an unbroken chain of financial relationships would satisfy the definition of 'indirect compensation arrangement'

only if, among other things, (1) the aggregate compensation received by the physician varies with referral volume *and* (2) the individual unit of compensation is either (a) not fair market value or (b) includes referrals or other business generated as a positively correlated variable resulting in increases (or decreases) in compensation, *i.e.*, 'takes into account' the volume or value of referrals or other business generated. However, it is difficult if not impossible to imagine such an arrangement being able to satisfy the exception for indirect compensation arrangements, which requires that the compensation be both fair market value and *not* determined in any manner that takes into account the volume or value of referrals or other business generated. See 42 C.F.R. 411.357(p)(1)(i). In an effort to spare many innocuous, unbroken chains of financial relationships from satisfying the definition of 'indirect compensation arrangement' and thus having to comply with the technical requirements of the exception for indirect compensation arrangements, *e.g.*, the writings requirement, CMS has appeared to ensure that any unbroken chain of financial relationships that *does* satisfy the revised definition will lead to prohibited referrals and claims.

Perhaps these and other questions will be clarified in future rulemakings, and may have been considered and addressed if CMS had proposed the revision to the definition as part of its October 2019 proposed rulemaking.

Practical Implications: Regardless of how the new definitional criterion is applied and interpreted, the revised definition will substantially narrow the scope of the Stark Law, taking many arrangements outside its ambit altogether. Entities may wish to revisit their physician contracting policies and procedures to require an assessment of the compensation methodology's 'individual unit of compensation', *e.g.*, to assess whether a time-based, hourly rate, or other 'per-click' rate is consistent with fair market value and does not include, as a positively correlated variable, the volume or value of any physician's referrals or other business generated. Assessing such factors at the outset of an arrangement will help prevent arrangements from unintentionally effectuating indirect compensation arrangements that cannot satisfy a Stark Law exception.

5. Addition to Carve-Out From Definition of "Designated Health Services"

Prior Carve-Out: Prior to the Final Rule, 42 C.F.R. § 411.351 stated that "[e]xcept as otherwise noted in this subpart, the term 'designated health services' (or DHS) means only DHS payable, in whole or in part, by Medicare. DHS did not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at § 416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

Proposed New Carve-Out: CMS proposed to amend 42 C.F.R. § 411.351 to add the following to the end of the current section: "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 affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS)."

Final New Carve-Out: The Final Rule revised the carve-out from the definition of DHS, largely as proposed (change from the proposed rule highlighted in bold) 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 ~~affect~~ **increase** the amount of Medicare's payment to the hospital under **any of the following prospective payment systems (PPS): (i)** ~~the~~ Acute Care Hospital Inpatient Prospective Payment System (IPPS)**; (ii) Inpatient Rehabilitation Facility (IRF PPS); (iii) Inpatient Psychiatric Facility (IPF PPS); or (iv) Long-Term Care Hospital (LTCH PPS)**."

Effect: The expansion of the carve-out from the definition of DHS narrow the scope of DHS subject to the Stark Law's prohibitions. In particular, many fewer inpatient hospital services constitute DHS.

Analysis: The Stark Law regulations have long excluded services reimbursed as part of a composite rate from the definition of DHS, except for listed services – such as inpatient hospital services – that are themselves payable through a composite rate. For hospitals, the practical result of this limitation to the Stark Law's composite rate carve-out has been that virtually all of their services have constituted DHS. The expansion of the definitional carve-out pushes most inpatient hospital services outside the definition of DHS – specifically, inpatient hospital services that, when furnished, do not affect payment received under various prospective payment systems by the furnishing inpatient facility or hospital. The change is based on CMS' belief that there is no financial incentive for referring physicians to over-prescribe inpatient hospital services once a patient is already admitted to the hospital.

In the Final Rule, CMS offered the following example to illustrate the operation of the expanded carve-out: after an inpatient has been admitted to a hospital under an established Medicare Severity Diagnosis Related Group (MS–DRG), the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission, and the specialist orders an X-ray. *See* 85 Fed. Reg. at 77570-71. By the time the specialist orders the X-ray, the rate of Medicare payment under the IPPS has already been established by the MS–DRG, and, unless the furnishing of the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the MS–DRG. Moreover, insofar as the provision of the X-ray does not affect the rate of payment, the physician has no financial incentive to overprescribe the service. In such a case, CMS does not believe that the X-ray is DHS that is payable, in whole or part, by Medicare, and the new definition of DHS excludes this service, even though it falls within a category of services that, when billed separately, would be DHS. Thus, assuming the specialist had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception to the Stark Law at the time the X-ray was ordered, the inpatient hospital services would not be tainted by the unexcepted financial relationship and the hospital would not be prohibited from billing Medicare for the admission. On the contrary, if the physician who ordered the inpatient hospital admission had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception, the hospital would be prohibited from billing for the inpatient hospital services.

CMS explicitly declined to extend the policy to apply to hospital services furnished to outpatients. CMS believes that there is typically only one ordering physician for outpatient services and that it would be rare that a physician other than the ordering physician would refer an outpatient for additional outpatient services that would not be paid separately under the OPPS.

Practical Implications: This extension of the carve-out adds great flexibility for hospitals that arrange with certain hospitalists and other hospital-based physicians, particularly those who do not serve as admitting physicians but rather only order services after a patient's inpatient admission. Hospitals and inpatient facilities paid in accordance with the prospective payment systems identified above should consider amending their physician contracting policies and procedures to require

contracting representatives to identify whether the contracting physician(s) have admitting privileges, as physicians who only order inpatient services after a patient is already admitted may never refer for DHS (that take the form of inpatient services), unless the furnishing of such services causes an outlier payment.

Open Questions: CMS' explicit recognition that the connection between a referral and actual reimbursement is in line with CMS' broader focus on adjusting the Stark Law to accommodate the shift from volume-based to value-based reimbursement systems. This recognition may have broader implications for future changes in the context of other shifting reimbursement systems, such as those for home health services.

III. Revisions to Special Rules for Group Practices' Distributions of Profit Shares and Productivity Bonuses

Prior Special Rules: 42 C.F.R. § 411.352(i) contains the Group Practice definition's "Special rule for productivity bonuses and profit shares." Prior to the Final Rule, the special rule stated that:

> "(1) A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).
>
> (2) Overall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:
>
> (i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).
>
> (ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.
>
> (iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.
>
> (3) A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:
>
> (i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)
>
> (ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.
>
> (iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.
>
> (4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request."

Proposed Special Rules: CMS proposed to amend 42 C.F.R. § 411.352 to state the following (emphases added):

> "(1) Overall profits. (i) Notwithstanding paragraph (g) of this section, a physician in the group practice may be paid a share of overall profits of the group that is indirectly related to the volume or value of the physician's referrals.
>
> (ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.
>
> (iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:
>
> (A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) Productivity bonuses. (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is indirectly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services are less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

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

(4) Supporting documentation. Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request."

Final Special Rules: The Final Rule amends 42 C.F.R. § 411.352, effective January 1, 2022, to state the following (changes from the proposed rule in strikethrough and bold):

"(1) Overall profits. (i) Notwithstanding paragraph (g) of this section, a physician in the group practice may be paid a share of overall profits of the group that is indirectly related to the volume or value of the physician's referrals.

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) Productivity bonuses. (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is ~~in~~ **not** directly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. ~~(The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)~~

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services ~~are~~ **constitute** less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) Value-based enterprise participation. **Notwithstanding paragraph (g) of this section,** profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined in § 411.351, are distributed to the participating physician.

(4) Supporting documentation. Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request."

Effect: The Final Rule allows Group Practices to distribute to physicians DHS profits derived from the physicians' participation in a "value-based enterprise", even if the distribution would directly relate to the volume or value of the physicians' DHS referrals.

The Final Rule also clarifies that:

(1) the narrower meaning of the phrase "takes into account" in the Final Rule (see Section II.3, above) would also apply to the manner in which profit shares and productivity bonuses are determined for Group Practice physicians;

(2) for Group Practices of fewer than five physicians, "overall profits" means "profits derived from all the DHS of the Group";

(3) no Group Practice can distribute profits from DHS on a service-by-service basis; and

(4) DHS profit distributions can be based on distributions of profits from services that would not qualify as DHS even if they were paid by Medicare (*e.g.*, personally performed professional services), but cannot be based on distributions of profits for services that would qualify as DHS, but do not qualify as DHS because they are paid only by non-Medicare payors (*e.g.*, clinical laboratory services that are only billed to commercial insurers).

Analysis: In both the proposed rule and the Final Rule, CMS describes its concern that prior Group Practice profit distribution rules could have been interpreted as not allowing groups to compensate their physicians directly for rewards achieved via the physicians' individual participation in alternative payment models ("APMs"), thus discouraging physician participation in such APMs. Accordingly, in the Final Rule, CMS deems as acceptable any distribution of profits from DHS that are directly attributable to a physician's participation in a "value-based enterprise" (as that term is defined by the Final Rule). However, given the broad meaning of the phrase "value-based enterprise" – to include, for example, Group Practices collaborating with their member physicians to further value-based purposes, regardless of Medicare APM participation (see Section I, above) – this deeming clause may afford great leeway to Group Practices that would pursue, on their own, one or more "value-based purposes" and distribute associated DHS profits directly to their member physicians.

On the other hand, to the extent a profit distribution cannot be tied to a value-based effort, the Final Rule's changes will have significant implications for the viability of many Group Practices' current profit-sharing distribution methodologies. Many

Group Practices, particularly multi-specialty group practices, have longstanding profit sharing distribution methodologies that distribute profits from different DHS to different components of member physicians. For example, a Group Practice may distribute profits from diagnostic radiological services to one component of the Group, *e.g.*, orthopedic surgeons, while distributing profits from clinical laboratory services to another component of the Group, *e.g.*, dermatologists. The Final Rule disallows such a methodology, instead requiring the Group Practice to lump all DHS profits together prior to distribution to any component of the Group.

In addition, other Group Practices have interpreted the prior rules to allow the distribution of DHS profits (*e.g.*, from providing x-rays to Medicare patients) on the basis of how the Group distributes profits from providing x-rays to non-Medicare patients. The Final Rule also disallows such a methodology.

Practical Implications: Under the Final Rule, Group Practices have the opportunity to structure their clinical operations and arrangements to qualify as "value-based enterprises", which would allow them to distribute DHS profits to their physicians in a manner directly related to their DHS referrals.

Other Group Practices should revisit their profit distribution methodologies to ensure that they do not run afoul of the Final Rule's new prohibitions – in particular, that DHS profits are not allocated on a service-by-service basis, and that DHS profits are not distributed in a manner that is based on the distribution of profits from services that would constitute DHS if they were billed to Medicare. Recognizing that Group Practices may need to make such revisions, CMS has delayed the effective date of this revision until January 1, 2022; Group Practices should make any required revisions before that date.

CMS Considered and Sought Comments On: CMS sought comments on its proposal to clarify the methodologies by which "overall profits" can be distributed, and as to whether it should allow Group Practices to distribute "revenues" from DHS, as well as whether it should deem as acceptable any productivity bonus based on the receiving physician's total patient encounters or personally performed RVUs and whether any personally performed RVUs should be an acceptable basis for calculating a productivity bonus, regardless of whether they are as described in 42 C.F.R. § 414.22. Ultimately, after reviewing comments, CMS finalized its proposals with virtually no revision.

IV. Elimination of Provision Placing Explicit Outer Limits on Period of Disallowance

Prior Provision: Prior to the Final Rule, 42 C.F.R. § 411.353(c) stated that "[e]xcept as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. For purposes of this section, with respect to the following types of noncompliance, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than—

(i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;

(ii) Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or

(iii) Where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception."

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.353 to state only that, "[e]xcept as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral."

Final Provision: The Final Rule finalized the proposed amendment to 42 C.F.R. § 411.353, as proposed.

Effect: Although the change eliminates "bright line" dates on which a period of disallowance could be considered closed, CMS' rulemaking commentary may afford the most clarity, as it appears to indicate that any termination of a financial relationship would close a period of disallowance.

Analysis: CMS makes clear that the period of disallowance was not intended to extend the period of disallowance beyond the end of a financial relationship, but to give parties clear guidance on steps that could be taken to ensure that the period of disallowance had ended. CMS explains that, although the rules were "initially intended merely to establish an outside, bright-line limit for the period of disallowance, in application, they appear to be overly prescriptive and impractical." 85 Fed. Reg. at 77581.

While accurately pointing out the difficulty in pinpointing the close of a period of disallowance in situations such as those described, the Final Rule does not add any clarity to such situations. In commentary, CMS offers that "*one* way to establish that the period of disallowance has ended… is to recover any excess compensation and bring the financial relationship back into compliance with the requirements of an applicable exception." 85 Fed. Reg. at 77581 (emphasis added). But CMS makes clear it is not the only way, and the Final Rule removes the period of disallowance regulations "to ensure that what was intended as an elective 'safe harbor' is not mistaken for a compulsory action required to ensure that the period of disallowance has ended." *Id.*

CMS' rulemaking commentary also explains that, during the life of a financial relationship, compensation errors may be detected and corrected in accordance with the terms of the arrangements, thus avoiding a period of disallowance altogether. CMS asserts that correction of errors after a financial relationship has ended, however, cannot avoid a period of disallowance associated with the time that the financial relationship existed. Oddly, in discussing "questions regarding whether administrative errors, such as invoicing for the wrong amount of rental charges…or the payment of compensation above what is called for under a personal service arrangement due to a typographical error entered into an accounting system, create[s] the type of 'excess compensation' or 'insufficient compensation' described in" CMS preamble guidance and the period of disallowance rules, CMS' rulemaking commentary did not note the longstanding carve-out from the definition of "remuneration" for forgiveness of amounts due to minor billing errors. 85 Fed. Reg. at 77581. While CMS opines that it "was never our intent" that these types of errors create excess or insufficient compensation for the purposes of 42 C.F.R. § 411.353(c)(1), it also states that "the failure to remedy such operational inconsistencies could result in a distinct basis for noncompliance with the physician self-referral law." *Id.* It is not clear from this commentary when forgiveness of amounts due to such errors would be treated as permissible forgiveness of amounts owed, due to a minor billing error or, if not, why not.

Practical Implications: This regulatory change will have little practical effect. The change might also have little analytical impact, as the determination of the end date of a period of disallowance has always demanded a fact-specific analysis and is usually relevant only when calculating a refund or fashioning a submission into CMS' Self-Referral Disclosure Protocol.

V. New Special Rule on Grace Periods for Temporary Noncompliance with Writing and Signature Requirements

Previous Definition: Prior to the Final Rule, 42 C.F.R. § 411.353(g) stated as follows:

> "Special rule for certain arrangements involving temporary noncompliance with signature requirements. (1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—
>
> (i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and
>
> (ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception."

Proposed Definition: CMS proposed to delete 42 C.F.R. § 411.353(g) in its entirety and instead codify a new provision at 42 C.F.R. § 411.354(e)(3), which would have stated as follows:

> "(3) Special rule on writing and signature requirements. In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—
>
> (i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and
>
> (ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception."

Final Definition: CMS finalized the proposed definition at 42 C.F.R. § 411.354(e)(3), and also added a new rule on electronic signatures at 42 C.F.R. § 411.354(e)(3). Further, CMS revised the text of its provision at 42 C.F.R. § 411.354(d)(1) on when compensation may be considered 'set in advance.' As amended, these provisions now state as follows (with changes from the proposed rule highlighted in bold and strikethrough):

42 C.F.R. § 411.354(d)(1): "***Set in advance.*** ~~**(1)**~~ Compensation is ~~**considered**~~ **deemed to be** "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating 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. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified.

> **(ii) Notwithstanding paragraph (d)(1)(i) of this section, compensation (or a formula for determining the 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 conditions are met:**
>
> **(A) All requirements of an applicable exception in §§ 411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation).**
>
> **(B) The modified compensation (or the 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.**
>
> **(C) 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. Paragraph (e)(4) of this section does not apply for purposes of this paragraph (d)(1)(ii)(C).**

42 C.F.R. § 411.354(e): "(e) *Special rule on compensation arrangements* – (1) *Application*. This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement*. In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(3) *Signature requirement*. In the case of any signature requirement in this subpart, such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law.

(4) *Special rule on writing and signature requirements*. In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception."

Effect: The Final Rule expands the current 90-day grace period (for missing signatures) to also apply to failures to document an arrangement in writing at the outset of an arrangement. It also makes clear that electronic signatures are sufficient for the Stark Law's signature requirements.

Analysis: CMS explains that it has "reviewed numerous compensation arrangements that fully satisfied all the requirements of an applicable exception…except for the writing or signature requirements" and that "[i]n many cases, there are short periods of noncompliance with the physician self-referral law at the outset of a compensation arrangement, because the parties begin performance under the arrangement before reducing the key terms and conditions of the arrangement to writing." 85 Fed. Reg. at 77590. In those cases, CMS does not believe "the arrangement poses a risk of program or patient abuse." *Id.*

In rulemaking commentary associated with the proposed rule, CMS addressed its interpretation of the special rule for when compensation is deemed to be "set in advance," currently codified at 42 C.F.R. § 411.354(d)(1). CMS noted that, while the expansion of the 90-day grace period would "not amend, nor does it affect, the requirement under various exceptions in § 411.357 that compensation be set in advance…the special rule [at § 411.354(d)(1) on compensation considered to be set in advance] is merely a deeming provision" (emphasis added). 85 Fed. Reg. at 77591. The Final Rule goes a step further in emphasizing this view, changing the special rule to replace the phrase "is considered 'set in advance'" with "is deemed to be 'set in advance'". *Id.* Additionally, CMS added a provision to the rule addressing scenarios in which compensation is modified, and providing that compensation may be set advance even if modified during the course of an arrangement, under certain conditions, and in particular where modifications are only applied prospectively.

The Final Rule also deleted the phrase "and may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician," because the requirements for modifying compensation were separately codified in the Final Rule. CMS explains that, in circumstances in which the parties verbally agree to a rate of payment *before the furnishing of items and circumstances*, but do not reduce that agreement to writing, compensation would still be considered set in advance. Relegating the status of § 411.354(d)(1) to a mere "deeming provision" has a meaningful and liberalizing effect for compliance with the "set in advance" element of numerous Stark Law exceptions, as it effectively allows a physician or DHS entity representative to state in writing, well after the fact, that the parties had verbally agreed to a compensation rate or methodology prior to the commencement of the arrangement (or the date on which changes to compensation rates were actually effectuated).[5]

CMS further opines that "records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance." 85 Fed. Reg. at 77592. CMS notes that there are "many ways in which the amount of or a formula for calculating the compensation under an arrangement can be documented before the furnishing of items or services", including "informal communications via email or text, internal

[5] Although such a writing is no longer necessary, the burden of proof of compliance with a Stark Law exception remains with the DHS entity, making such a writing at least prudent.

notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services…" *Id.*

Practical Implications: The Final Rule's expansion of the 90-day grace period (from missing signature to missing writings) will have enormous practical utility. Ensuring that an arrangement is reduced to writing prior to the provision of any items or services is a common and significant operational challenge that the new grace period will substantially ease. Contracting policies and procedures may be amended to utilize the benefit of the grace period, *e.g.*, to require, at a defined period of time after the commencement of an arrangement, that all necessary writings are in fact in place.

CMS' clarification that compensation may be "set in advance" verbally is also likely to be enormously useful, as physicians and DHS entities can now, when necessary, create and rely on *post hoc* declarations and statements from contracting representatives as to prior verbal agreements on compensation amounts and formulae.

Open Questions: CMS' relegation of 42 C.F.R. § 411.354(d)(1) to "deeming provision" status (*i.e.*, where satisfaction of the rule is evidentiary of but not required for compliance) could have enormous implications for the interpretation and application of other Stark Law regulatory provisions that similarly would not appear to be reasonably construed as deeming provisions.

VI. Additional Exceptions to Ownership and Investment Interests

Prior Exclusions: Prior to the Final Rule, 42 C.F.R. § 411.354(b)(3) stated that "Ownership and investment interests do not include, among other things -

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An 'under arrangements' contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS "under arrangements" with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section); or

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section)."

Proposed Exclusions: CMS proposed to amend 42 C.F.R. § 411.354(b)(3) to add the following to the end of the current text:

"(vi) A titular ownership or investment 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 sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a)."

Final Exclusions: CMS finalized the additions to the exception as proposed.

Effect: The Final Rule effectively narrows the scope of the Stark Law's prohibitions by excluding additional types of ownership and investment interests from constituting financial relationships, providing physicians greater flexibility, particularly in states where the corporate practice of medicine is prohibited.

Analysis: The regulation informally defines titular ownership to mean an interest that excludes the ability or right to receive the financial benefit of ownership…, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. It is not clear how helpful this exclusion for titular ownership will be, given that titular ownership – *i.e.*, the inability to receive a financial benefit – would not likely effectuate a "financial relationship" in the first place. However, providing explicit protection for entities that both employ physicians and offer an ESOP brings a modicum of needed clarity.

Practical Implications: CMS' protection for ESOPs may offer new structural opportunities for entities that have an interest in pursuing an ESOP arrangement, but otherwise the proposals would have little practical effect.

Open Questions: The Final Rule's revisions to titular ownership or investment are fairly clear, and rely on concepts that are already well defined. The scope of retirement plans that may be excepted under the final regulation remains to be seen and will have implications for the flexibility afforded to physician employers.

VII. New Provision Pertaining to Exceptions Applicable to "Indirect Compensation Arrangements"

Prior Provision: None

Proposed Provision: CMS proposed to codify a new provision at 42 C.F.R. § 411.354(c)(4), which would state as follows:

"Exceptions applicable to indirect compensation arrangements.

(i) General. Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§ 411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) Special rule for indirect compensation arrangements involving value-based arrangements. When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined in § 411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party, only the exceptions at §§ 411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement."

Final Provision: The Final Rule finalized this new provision as proposed.

Effect: This provision clarifies – finally – that direct compensation exceptions are not available to protect indirect compensation arrangements, absent certain situations involving "value-based arrangements".

Analysis: The new provision clarifies what had previously been implied by the structure of the Stark Law regulations – that to avoid the Stark Law's prohibitions, an indirect compensation arrangement may only rely on those general exceptions applicable to all financial relationships and the compensation arrangement exception for indirect compensation relationships, 42 C.F.R. § 411.357(p).

The provision also allows indirect compensation arrangements to satisfy the new exception (discussed in Section I) for arrangements that facilitate value-based health care delivery and payment. This allowance is necessary because the proposed exception for "value-based arrangements" – unlike the exception for indirect compensation arrangements – does not require compensation to be determined in a manner that does not "take into account" the volume or value referrals. Without this allowance, value-based arrangements that are indirect compensation arrangements (which could be many) would have had great difficulty satisfying the exception for indirect compensation arrangements. For the reasons stated in Section I, parties to indirect compensation arrangements may wish to consider whether their arrangements are or can be structured as "value-based arrangements", in order to harness the flexibility of the exception for such arrangements.

Practical Implications: The additional provision is unlikely to have substantial operational impact, although properly structured indirect compensation arrangements might be able to satisfy the new exception for value-based arrangements, which offers more flexibility than the exception for indirect compensation arrangements.

VIII. Changes Applicable Throughout the Regulatory Framework

1. Removal of Requirement Not to Violate the Anti-Kickback Statute

Prior Provisions: Prior to the Final Rule, many Stark Law exceptions required that an arrangement "not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation...." In addition, the exceptions for obstetrical malpractice subsidies and referral services require that subsidies and referral services, respectively, comply with the corollary anti-kickback statute safe harbors.

Proposed Provisions: CMS proposed to amend Stark Law exceptions to remove the requirement that an arrangement not violate the anti-kickback statute or any state or Federal law or regulation. CMS proposed that the anti-kickback statute safe harbor compliance requirements for referral services and obstetrical malpractice subsidies exceptions would remain in place.

Final Provisions: The Final Rule removes the requirement that arrangements not violate the anti-kickback statute from all regulatory exceptions except the fair market value compensation exception. The Final Rule also removed requirements pertaining to compliance with Federal and State laws or regulations governing billing or claims submissions from all regulatory exceptions.

Effect: The following exceptions no longer require that an arrangement not violate the anti-kickback statute, and no longer require compliance with state or Federal laws or regulations governing billing or claims submission:

- Temporary non-compliance
- In-office ancillary services
- Academic medical centers
- Implants furnished by an ASC
- EPO and other dialysis-related drugs
- Preventive screening tests, immunizations, and vaccines
- Eyeglasses/contact lenses following cataract surgery
- Intra-family rural referrals
- Physician recruitment
- Charitable donations by a physician
- Nonmonetary compensation
- Fair market value compensation
- Medical staff incidental benefits
- Indirect compensation arrangements
- Obstetrical malpractice insurance subsidies
- Professional courtesies
- Retention payments in underserved areas
- Community-wide health information systems
- Electronic health records items and services
- Assistance to compensate a non-physician practitioner
- Timeshare arrangements

Analysis: In rulemaking commentary, CMS explains that it "no longer believe[s] that it is necessary or appropriate to include requirements pertaining to compliance with the anti-kickback statute and Federal and State laws or regulations governing billing or claims submissions as requirements of the exceptions to the physician self-referral law." 85 Fed. Reg. at 77568. CMS has come to this conclusion based on its experience that, when a compensation arrangement violates the intent-based anti-kickback statute, it will likely also fail to meet one or more of the other key requirements of a self-referral law exception. CMS noted that it is unaware of any instances of Stark Law non-compliance that turned solely on an underlying violation of the anti-kickback statute. CMS declined to extend the removal of the anti-kickback statute requirement from the fair market value compensation exception, however, because CMS did not want the regulation to protect arrangements that would not be permitted under the statutory exception for fair market value compensation. Unlike other exceptions, CMS noted that the fair market value compensation exception does not have "substitute requirements or safeguards" against potentially abusive arrangements, and believes requiring compliance with the anti-kickback statute as part of the exception provides such substitute safeguard.

Practical Implications: As with the proposal, the finalization of these changes has little to no practical implications.

2. Provisions Pertaining to Required Referrals

Prior Provisions: Prior to the Final Rule, 42 C.F.R. § 411.354(d)(4) allowed DHS entities to require physicians – as part of certain arrangements – to refer their patients to particular providers, practitioners, or suppliers, but only if certain restrictions are in place and in writing, *e.g.*, patient choice, insurance requirements, or physician judgment.

Proposed Provisions: CMS proposed to preserve the provision at 42 C.F.R. § 411.354(d)(4), but to add subparagraphs to specific regulatory exceptions that would expressly require compliance with 42 C.F.R. § 411.354(d)(4).

Final Provisions: CMS finalized this proposal, as discussed in detail in Section II.3 (above).

Effect: The following exceptions would expressly require compliance with 42 C.F.R. § 411.354(d)(4) (to the extent the subject arrangement would require referrals):

- Academic medical centers
- *Bona fide* employment relationships
- Personal services arrangements
- Group practice arrangements with a hospital
- Fair market value compensation
- Indirect compensation arrangements
- Value-based arrangement exceptions

Analysis: CMS explains that the explicit inclusion of these requirements in the text of applicable regulatory exceptions is necessary, given the proposed meaning of the phrase "takes into account" the volume or value of referrals (see Section II.3, above).

Practical Implications: None. To the extent that an entity requires referrals as part of an arrangement with a physician, it remains important for the entity to ensure that the requirement accommodates patient choice, insurer requirements, and physician judgment.

IX. Changes to Exceptions for Direct Compensation Arrangements

1. Changes to Office Space and Equipment Rental Exceptions

Prior Provisions: Prior to the Final Rule, 42 C.F.R. § 411.357(a)(3) and (b)(2) required that the space or equipment rented or leased must not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and must be used exclusively by the lessee when being used by the lessee (and not be shared with or used by the lessor or any person or entity related to the lessor).

Proposed Provisions: CMS proposed to amend 42 C.F.R. § 411.357(a)(3) and (b)(2) by adding to the end of the text of each a statement that, for purposes of these exceptions, "exclusive use" would mean that the lessee (and any other lessees of the same office space or equipment) uses the same office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor).

Final Provisions: The Final Rule amended the provisions as proposed.

Effect: The changes clarify the meaning of exclusive use for the purposes of the office space and equipment rental exceptions, which to date has been uncertain.

Analysis: In prior rulemaking commentary, CMS stated its belief that the exclusive use requirement was designed to prevent "paper leases," where payment passes from a lessee to a lessor, even though the lessee is not actually using the office space or equipment. With the addition of this new language, the space or equipment rented still must not exceed that which is reasonable and necessary for the legitimate business purposes of the lessee's lease arrangement. However, the Final Rule clarifies CMS' apparent longstanding interpretation that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment at the same time as the lessee. Most importantly, the Final Rule clarifies that the Stark Law does not prevent multiple lessees from using the rented space or equipment at the same time, so long as the lessor (or related entity) is excluded.

Practical Implications: For entities that have adopted a conservative interpretation of the current provision, this clarification substantially expands the type of lease arrangements possible with referring physicians and will likely decrease the burden associated with monitoring a lessee's use of leased space or equipment.

2. Changes to Physician Recruitment Exception

Prior Provision: Prior to the Final Rule, 42 C.F.R. § 411.357(e)(4) stated that, "In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met: (i) The writing in paragraph (e)(1) of this section is also signed by the physician practice…"

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.357(e)(4)(i) to state that "The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital."

Final Provision: The Final Rule amended 42 C.F.R. § 411.357(e)(4)(i) as proposed.

Effect: The Final Rule eliminates the requirement for a physician practice to sign a recruitment support arrangement between a hospital and a physician joining the physician practice, so long as all remuneration from the hospital passed directly to and/or through to the physician.

Analysis: In rulemaking commentary, CMS explains that, in the Self-Referral Disclosure Program, it has seen arrangements in which a physician practice hires a physician recruited by a hospital but receives no financial benefit from the recruitment arrangement, yet the parties find themselves in non-compliance with the physician recruitment exception because the practice did not sign the recruitment arrangement. CMS states that, when a physician practice retains none of the financial support provided by a hospital to a physician recruited into that practice, there is not "a compensation arrangement between the physician practice and the hospital…of the type against which the statute is intended to protect…." 85 Fed. Reg. at 77599. Eliminating the practice's signature requirement in those instances "would reduce undue burden without posing a risk of program and patient abuse." 85 Fed. Reg. at 77600.

Practical Implications: This small revision to the regulatory text may substantially reduce burden on hospitals that seek to support physician recruitment into community medical practices. The requirement to obtain signatures of both the physician and the physician group on a recruitment agreement has been a substantial and unnecessary operational challenge, and its removal in those frequent instances wherein remuneration is entirely passed through to recruited physicians is a welcome change.

3. Replacement of the Exception for Certain Arrangements with Hospitals

Current Provision: Currently, 42 C.F.R. § 411.357(g) states as follows:

"Certain arrangements with hospitals. Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as 'unrelated', remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician."

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.357(g) to state as follows:

"Remuneration unrelated to the provision of designated health services. Remuneration provided by a hospital to a physician if the remuneration does not relate to the provision of designated health services. Remuneration does not relate to the provision of designated health services if –

(1) The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals; and

(2) The remuneration is for an item or service that is not related to the provision of patient care services.

(3) For purposes of this paragraph (g):

(i) Items that are related to the provision of patient care services include, but are not limited to, any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services.

(ii) A service is deemed to be not related to the provision of patient care services if the service could be provided by a person who is not a licensed medical professional."

Final Provision: CMS declined to finalize the proposed revision in the Final Rule.

Effect: There is no effect as compared to the status quo, while CMS continues to "evaluate the best way to restore utility to the statutory exception." 85 Fed. Reg. at 77603.

Analysis: CMS' proposal would have substantially expanded the potential usefulness of this exception (which, after previous CMS rulemakings, has had virtually no practical application). Given the range of financial arrangements that may exist between physicians and hospitals, both generally but also potentially within the ambit of a hospital's acquisition of a physician's practice, CMS' proposal had the potential to significantly narrow the scope of the Stark Law. Although CMS declined to adopt the proposal now, CMS indicated they may "finalize revisions to the exception for remuneration unrelated to the provision" of DHS in "future rulemaking." *Id.*

Practical Implications: Because there is no change, there are no practical implications relative to the status quo.

Open Questions: It remains an open question when CMS will make changes to increase the utility of this exception.

4. Narrowing of Isolated Transactions Exception

Prior Provision: Prior to the Final Rule, 42 C.F.R. § 411.351 defined "isolated financial transaction" as a "[t]ransaction… involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that –

(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and

(2) The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party."

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.351 to define "isolated financial transaction" as

"(1) a transaction involving a single payment between two or more persons or a transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

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

Final Provision: The Final Rule amended 42 C.F.R. § 411.351 to define "isolated financial transaction" as follows (changes from proposed rule in bold and strikethrough):

"(1) a **one-time** transaction involving a single payment between two or more persons or a one-time transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, **single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute**, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

Effect: The Final Rule narrows the applicability of the isolated transaction exception to exclude one-time payments for multiple or repeated services, but not as much as was contemplated by CMS' proposal. In particular, CMS allowed settlement of a *bona fide* dispute to continue to be treated as an isolated transaction, thus retaining a common tool deployed by many Stark Law practitioners to protect settlement agreements resolving payment disputes.

Analysis: In rulemaking commentary, CMS explains that it does not intend for the isolated transactions exception to apply to single payments that compensate for the prior provision of multiple services because "if a physician provides multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date." 85 Fed. Reg. at 77576. CMS asserts that the provision of remuneration in the form of services commences a compensation arrangement at the time the services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for DHS and the entity wishes to bill Medicare for such services. CMS reiterates that the exception

for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law.

This analysis gives undue emphasis to the definition of "remuneration", which may contemplate that a physician's service to a hospital (for example) confers some benefit or value upon a hospital and thus commences the transfer of "remuneration." However, this analysis gives insufficient consideration to the definition of "compensation arrangement", which requires an "arrangement involving remuneration." 42 C.F.R. § 411.354(c) (emphasis added). Stated simply, if there is no "arrangement", *e.g.*, for the physician to provide services (remuneration) to the hospital in return for compensation (remuneration), then the physician's provision of services to the hospital should not commence a "compensation arrangement" needing the protection of a Stark Law exception – even if the physician's services conferred some value upon the hospital. Accordingly, if an arrangement (to pay the physician for services provided) is first formed at the time of an isolated transaction, then that arrangement should be – analytically and in practice – eligible for the exception for isolated transactions.

Nonetheless, the text of CMS' rule would unquestionably narrow the scope of the isolated transaction exception to exclude protection of such arrangements. CMS' change thus constitutes one of the few restrictive proposals in the Final Rule. While the Final Rule leaves room (that would have been eliminated by CMS' proposal) to protect forgiveness of an amount owed in settlement of a *bona fide* payment dispute, the addition of this passage will lead to some uncertainty. In particular, the concept of "the forgiveness of an amount owed in settlement of a bona fide dispute" (which is protected) is not always exclusive of the concept of "a single payment for multiple or repeated services" (which is explicitly not protectable). Thus, when the *bona fide* dispute pertains to payment for multiple or repeated services, the application and utility of the isolated transactions exception will be uncertain.

Practical Implications: Many DHS entities have appropriately relied on the isolated transactions exception to address non-payment for services that already had been provided, particularly when an arrangement had not yet been formed. CMS' new exception for payments to a physician under $5,000 (discussed further below) protects a subset of such arrangements under some circumstances, and settlement amounts themselves will still be protectable under the isolated transactions exception. However, the clarification of the isolated transactions exception in the Final Rule will likely make it more difficult to resolve disputes or demands for payment for services previously provided, as protection of the settlement amount may not protect the entirety of the financial relationship between the physician and the entity. Therefore, as a best practice, entities should exercise even greater care in ensuring that all physician relationships are identified and appropriately documented and fully meet the requirements of other Stark Law exceptions at the outset of the relationship (*i.e.*, before either the entity or the physician begins to provide remuneration to the other). In any case, settlements should be structured to highlight the forgiveness of an amount (if applicable), as well as the *bona fides* of the dispute.

5. Expansion of Exception for Payments by a Physician

Prior Provision: Prior to the Final Rule, 42 C.F.R. § 411.357(i) stated:

"Payments by a physician. Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically excepted by another provision in §§ 411.355 through 411.357 (including, but not limited to, § 411.357(l)). "Services" in this context means services of any kind (not merely those defined as "services" for purposes of the Medicare program in § 400.202 of this chapter)."

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.357(i)(2) to except payments by a physician "[t]o an entity as compensation for any other items or services (i) [t]hat are furnished at a price that is consistent with fair market value; and (ii) [t]o which the exceptions in paragraphs (a) through (h) of this section are not applicable", and to add 42 C.F.R. § 411.357(i)(3) stating that "[f]or the purposes of this paragraph (i), 'services' means services of any kind (not merely those defined as 'services' for purposes of the Medicare program in § 400.202 of this chapter)."

Final Provision: The Final Rule amended 42 C.F.R. § 411.357(i) as proposed.

Effect: The Final Rule greatly expands the scope of this exception to apply – with hardly any restrictions – to any payment by a physician to an entity, other than for the rental of office space or equipment, for personal services, or in the context of an isolated transaction.

Analysis: Reversing prior rulemakings, CMS explains that the current regulatory exception is too narrow. After revisiting the statutory framework, CMS now views the statutory exception for payments by a physician as "a catch-all to protect certain legitimate arrangements that are not covered by" the preceding seven statutory exceptions. 85 Fed. Reg. at 77604. Therefore, the Final Rule amends the regulatory exception to apply to payments by a physician so long as the exceptions codified at 42 C.F.R. § 411.357(a) through (h) would not apply to the subject payment. Of those exceptions, however, only the exceptions for rental of office space or equipment, for personal services, or for isolated transactions, would feasibly apply to payments made by a physician.

Accordingly, the Final Rule substantially expands the utility of the regulatory 'payments by a physician' exception. While many common physician-hospital relationships would still be excluded from the scope of the exception, it would function to protect many others – for instance, the rental by a physician of residential or storage space from a hospital, or a physician's purchase of equipment or other goods from a hospital.

Practical Implications: Entities should consider revisiting their physician contracting policies and procedures to implement processes whereby determinations are made, sufficiently early in the process of contemplating an arrangement, as to whether payments would be received from a physician and, if so, if the payments would be for something other than the rental of office space or equipment, for personal services, or as an isolated transaction. If so, then the only Stark Law requirement related to such a payment would be the payment's consistency with the fair market value of the item or service at issue – and contracting policies and procedures may be amended to acquire analysis and documentation accordingly.

6. Expansion of Exception for Fair Market Value Compensation

Prior Exception: Prior to the Final Rule, 42 C.F.R. § 411.357(l) stated as follows:

"Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(6) 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" (emphasis added).

Proposed Exception: CMS proposed to amend 42 C.F.R. § 411.357(l) to state as follows (emphases added):

"Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services or for the use of office space or equipment, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items, services, office space, or equipment during the course of a year. An arrangement may 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.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement is commercially reasonable.

(5) [Reserved]

(6) 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.

(7) The arrangement satisfies the requirements of § 411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one of the group's physician's referrals to a particular provider, practitioner, or supplier."

Final Provision: The Final Rule amended 42 C.F.R. § 411.357(l) to state as follows (changes from the proposed rule highlighted in bold and strikethrough):

"Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services or for the use of office space or equipment **by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians**, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment. **The writing specifies—**

(i) The items, services, office space, or equipment covered under the arrangement;

(ii) The compensation that will be provided under the arrangement; and

(iii) The timeframe for the arrangement.

(2) ~~**The writing specifies a timeframe for the arrangement, which can be for**~~ **An arrangement may be for** any period of time and contain a termination clause~~**, provided that the parties enter into only one arrangement for the same items, services, office space, or equipment during the course of a year**~~. An arrangement may 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. **Other than an arrangement that satisfies all of the conditions of paragraph (z) of this section, 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.**

(3) The ~~**writing specifies the**~~ compensation ~~**that will be provided under the arrangement. The compensation**~~ must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement ~~**is**~~ **would be** commercially reasonable **even if no referrals were made between the parties**.

(5) **The arrangement does not violate the anti-kickback statute (section 1128(b) of the Act).**

(6) 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.

(7) The arrangement satisfies the requirements of § 411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier."

Effect: The Final Rule's most significant change is the expansion of the scope of the exception to include arrangements for the rental of office space.

Analysis: CMS has long held the view that "because arrangements for the rental of office space had been subject to abuse, we believed that it could pose a risk of program or patient abuse to permit parties to protect such arrangements relying on the [fair market value compensation exception]." 85 Fed. Reg. at 77605. After reviewing a number of legitimate, non-abusive office space lease arrangements that could not satisfy the requirements of the rental of office space exception because the term of the arrangement was for less than one year, CMS has reconsidered its prior position. CMS explains that it now believes that the fair market value compensation arrangement should be available to protect non-abusive relationships for rental of office space, subject to restrictions on percentage of revenue and per-click arrangements. As with other short-term compensation arrangements permitted under 42 C.F.R. § 411.357(l), parties are permitted to enter into only one arrangement for the rental of the same office space during the course of a year.

Practical Implications: The expansion of this exception to include qualifying office space arrangements affords opportunities for DHS entities and physicians to enter into shorter term rental arrangements with physicians. Additionally, the fair market value compensation exception does not contain an exclusive use requirement, such that the availability of this exception might allow for more flexible leasing arrangements wherein space is shared between hospital lessors and physician lessees. These changes might be particularly helpful to providers in rural areas.

7. Expansion of Exception for Electronic Health Records Items and Services

Prior Provision: Prior to the Final Rule, 42 C.F.R. § 411.357(l) stated, in relevant part, as follows:

"Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met: …

(2) The software is interoperable (as defined in § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 C.F.R. Part 170.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services)….

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met: …"

Further, 42 C.F.R. § 411.351 defined "electronic health record" and "interoperable" as follows:

"Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions."

"Interoperable means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered."

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.357(w) to state, in relevant part, as follows:

"Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including certain cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met: …

(2) The software is interoperable (as defined in § 411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in the then-applicable version of 45 C.F.R. part 170.

(3) The donor (or any person on the donor's behalf) does not engage in a practice constituting information blocking, as defined in section 3022 of the Public Health Service Act, in connection with the donated items or services….

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items 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. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met: …"

In relation to this proposed change, CMS also proposed a change to 42 C.F.R. § 411.351 to define "electronic health record" and "interoperable" as follows:

"*Electronic health record* means a repository that includes electronic health information that—

(1) Is transmitted by or maintained in electronic media; and

(2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual."

"*Interoperable* means—

(1) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user;

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(3) Does not constitute information blocking as defined in section 3022 of the Public Health Service Act."

Final Provision: The Final Rule promulgated some but not all of the proposed revisions to 42 CFR § 411.357(w). The Final Rule amends this exception to state as follows (in relevant part):

"Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, *including cybersecurity software and services*) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:…

(2) The software is interoperable (as defined at §411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then applicable version of 45 CFR part 170.

(3) [Reserved]

(4) (i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services. (ii) Except as provided in paragraph (w)(4)(i) of this section, with respect to items and services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals. (iii) The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

…

(8) [Reserved]"

CMS declined to amend the definition of "electronic health record" as proposed, choosing to maintain the prior definitions as follows: *"Electronic health record* means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions."

CMS declined to adopt the definition of "interoperable" as proposed, choosing to revise the definition but omitting the proposed provision related to information blocking and deleting the phrase "without special effort on the part of the user" such that the final definition reads as follows:

"Interoperable means— (1) Able to securely exchange data with and use data from other health information technology; and (2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law."

Effect: The Final Rules clarifies that donations of cybersecurity software and services are permitted under the electronic health record ("EHR") exception, removes the sunset provision, and maintains the existing definition of "electronic health record" while introducing a slightly modified definition of "interoperable" (which no longer references the concept of "information blocking" from the 21st Century Cures Act). In addition, the Final Rule (i) modifies the 15% physician contribution requirement (by revising §411.357(w)(4) as it pertains to the timing of payments for updates) and (ii) permits certain donations of replacement technology (*i.e.*, by deleting the prior subsection (8), which prohibited donations if the physician "possesses or has obtained items or services equivalent to those provided by the donor.").

Analysis: The Final Rule substantially updates the EHR donation exception and signals CMS' continued commitment to encouraging the continued adoption of these technologies. CMS' decision not to adopt its proposed clarifications to the interoperability provisions and relevant definitions to more closely align with the final ONC rules implementing the 21st

Century Cures Act (relating to information blocking) reflects its belief (and that of many commenters) that newer and separate authorities are better suited than the EHR donation exception to deter information blocking. CMS did, however clarify the circumstances under which EHR technology will be deemed interoperable. In the Final Rule, CMS explained that an EHR is deemed interoperable if "on the date it is provided to the recipient, it is certified by a certifying body authorized by ONC to certification criteria identified in the then-applicable version of 45CFR part 170." 85 Fed. Reg. at 77608-9. While ONC-approved certification is not the only way to meet the interoperability standard, having such certification will provide assurance that software will be deemed interoperable.

The clarifications regarding cybersecurity software and services should provide comfort to those donating or accepting donations of such software and services, as long as the predominant purpose of the software or services is cybersecurity associated with the EHR.

Finally, elimination of the requirement that the 15% contribution be paid in advance for updates to previously donated EHR software and technology and clarification that such contribution must be made "at reasonable intervals" should eliminate a significant barrier to EHR adoption.

Practical Implications: The final changes should open opportunities to engage with community physicians on the adoption of important additional technologies that may offer better protection for patient information, as well as enable donors to more clearly identify and avoid disallowed conduct.

8. Revisions to Exception for Assistance to Compensate a Non-Physician Practitioner

Prior Provision: Prior to the Final Rule, 42 C.F.R. § 411.357(x) protected "[r]emuneration provided by a hospital to a physician to compensate a nonphysician practitioner (NPP) to provide "patient care services", if certain conditions were met.

Proposed Provision: CMS proposed to amend 42 C.F.R. § 411.357(x) to add a requirement that the arrangement between the hospital and the physician "commences before the physician (or the physician organization in whose shoes the physician stands under 411.354(c)) enters into the compensation arrangement [with the NPP]." CMS also proposed to add definitions of "NPP referral" and "NPP patient care services" and implement these terms throughout the exception. "NPP referral" was proposed to be defined as "a request by a [NPP] that includes any [DHS] for which payment may be made under Medicare, the establishment of a plan of care by a [NPP] that includes the provision of such a [DHS], or the certifying or recertifying of the need for such a [DHS], but does not include any [DHS] personally performed or provided by the [NPP]." "NPP patient care services" were proposed to be defined as "direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement."

Final Provision: The Final Rule amended 42 C.F.R. § 411.357(x) as proposed.

Effect: The Final Rule narrows the applicability of the exception by clarifying that the exception is available only for assistance with non-physician practitioners who are not yet employed by or contracted with the physician or physician group.

Analysis: CMS' revisions add clarity to several aspects of the exception for assistance to compensate a NPP. First, the revisions clarify that the hospital/physician compensation arrangement must commence prior to the physician/NPP compensation arrangement. Prior to the Final Rule, there was no express requirement regarding the timing of the compensation arrangement between the NPP and the physician. The current absence of such a requirement adds risk that the hospital could be subsidizing payment for an NPP with whom the physician already has an arrangement, rather than one who is bringing new NPP services to the geographic area, which is a core purpose of the exception.

The Final Rule also addresses issues that have been raised in connection with the requirement that the NPP has not, within one year of the commencement of his/her compensation arrangement with the physician, practiced, been employed to, or otherwise engaged to provide "patient care services" for another physician group located in the geographic area. Recognizing that many NPPs often work as registered nurses or other health care professionals prior to becoming NPPs, the Final Rule limits application of the one year restriction to only those individuals who had furnished "NPP patient care services," as defined above, in the geographic area.

Finally, the term "NPP referral" is uniquely defined in § 411.357(x) to describe certain referrals made by NPPs. CMS believes it is unnecessary to have one definition of "referral" at § 411.351 that is applicable throughout the regulations, and a different definition of the term specific to this exception. Therefore, the Final Rule changes references to "referral" when describing the actions of an NPP in § 411.357(x), to "NPP referrals." Notably, the definition of "NPP referral" is narrower than the definition of "referral", as applicable to physicians.

Practical Implications: These revisions are unlikely to require significant operational changes, although contracting policies and procedures should be revised (if necessary) to ensure that any assistance offered to compensate an NPP must be only for new hires adding new NPP services to the area.

9. New Exception for Limited Remuneration to a Physician

Prior Exception: None

Proposed New Exception: CMS proposed to codify a new exception at 42 C.F.R. § 411.357(z) that would state as follows:

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

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement is commercially reasonable.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(2) The annual remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPIU_Updates.asp."

Final New Exception: The Final Rule codified a new exception at 42 C.F.R. § 411.357(z) that would state as follows (noting differences from the proposed rule in bold and strikethrough):

"Limited remuneration to a physician – (1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of ~~$3,500~~ **$5,000** per calendar year, as adjusted for inflation in accordance with paragraph (z)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement ~~is~~ **would be** commercially reasonable **even if no referrals were made between the parties**.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(vi) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of 411.354(d)(4).

(2) A physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at 411.351, except that the regular physician need not be a member of a group practice).

(3) The annual **aggregate** remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPIU_Updates.asp."

Effect: This new exception protects certain payments to physicians in return for items and services, pursuant to undocumented arrangements, but totaling no more than $5,000 annually.

Analysis: As part of CMS' efforts to offer flexibility for non-abusive business practices, the Final Rule promulgates a new exception for certain annual amounts less than $5,000 paid to physicians as fair market value compensation for items and services, without any requirement that the compensation be set in advance or the associated arrangement be set out in writing or signed. CMS believes that allowing physicians to receive limited remuneration from entities, subject to certain conditions, does not pose a risk of program or patient abuse, even when such an arrangement is not documented. This new exception offers a great amount of flexibility to DHS entities and physicians, as technical forms of Stark Law non-compliance tend to be associated with smaller financial relationships that – operationally and relatively – do not warrant the same attention to detail by the parties.

CMS notes that it is aware of instances of non-abusive, ongoing service arrangements under which services are furnished sporadically, at a low rate (or amount) of compensation, or for a short period of time. For instance, CMS describes circumstances in which a physician has a documented call coverage arrangement with a hospital, but also provides and is compensated for limited supervision services outside the terms of the call coverage arrangement. Because compensation in these instances was paid in cash, the nonmonetary compensation exception would not apply, and because the arrangements were not documented in writing, the fair market value compensation exception would not apply. Under these circumstances, however, and assuming that compensation provided for the supervision services is under the $5,000 annual limit and consistent with fair market value, the new exception would apply. CMS also clarifies in the Final Rule that the new exception is available for arrangements for the physician's employees to provide services to the entity, as well as for services provided through a wholly-owned entity or *locum tenens* physicians, and not only arrangements for the physician's personally performed services. However, the exception does not apply to arrangements for the physician's independent contractor to provide service to the entity.

The $5,000 limit does not count compensation paid to a physician for items and services provided outside the arrangement the parties wish to protect, to the extent that other compensation satisfies another exception. CMS also explains that the new exception can be combined with other exceptions. For instance, if compensation under $5,000 were provided to a physician for services not provided pursuant to a documented arrangement, and the physician also provided services pursuant to a documented arrangement, the requirements of the personal service arrangement exception that all services

provided by the physician to the entity be covered or cross-referenced, or that the parties enter into only one arrangement for the same services in a year, do not apply. In keeping with CMS' decision not to exclude office space from the meaning of items and services, this new exception is available for limited office space use arrangements, subject to prohibitions on percentage-based and per-unit of service compensation. On the other hand, this new exception does not protect the "first" $5,000 of undocumented remuneration. For example, if a hospital provides $4,000 of undocumented remuneration to a physician for call coverage services, and then $3,000 of undocumented remuneration to the same physician for supervision services, the exception would apply to neither arrangement.

The new exception includes the (new) standard directed referral requirement, *e.g.*, any arrangement for limited remuneration that includes a directed referral requirement must be memorialized in writing.

Practical Implications: This new exception will have substantial utility in eliminating Stark Law concerns pertaining to minor, undocumented arrangements with physicians, but should not have significant practical implications for entities that maintain contracting policies and procedures applicable to all physician financial relationships. Of course, if an entity becomes aware of an undocumented arrangement, this exception will substantially reduce the burden associated with gathering documentation and contemplating its support of the arrangement.

CMS Considered and Sought Comments On: CMS sought comments on whether its proposed $3,500 limit would be appropriate, too high, or too low to accommodate non-abusive compensation arrangements, and ultimately settled on a higher $5,000 limit. CMS also sought comments on whether it would be necessary to limit the new exception to services personally performed and items personally provided by the physician, and determined that it was not necessary to do so, providing a wider berth in the Final Rule.

10. New Exception for Cybersecurity Technology and Related Services

Prior Exception: None

Proposed New Exception: CMS proposed to codify a new exception at 42 C.F.R. § 411.357(bb), which would protect "[n] onmonetary remuneration (consisting of certain types of technology and services), if all of the following conditions are met:

(i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

(ii) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

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

(iv) The arrangement is documented in writing.

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

In relation to this proposed change, CMS also proposed amending 42 C.F.R. § 411.351 to define "cybersecurity" as "the process of protecting information by preventing, detecting, and responding to cyberattacks."

Final New Exception: The Final Rule promulgated a new exception for cybersecurity donations and related services at §411.357(bb) with certain modifications (from the proposed rule) related to the types of nonmonetary remuneration permitted under the exception, as well as non-substantive modifications to the text of the regulation. As finalized, the text of the new exception reads as follows (with the revision from the proposed rule highlighted in bold and strikethrough):

"(bb) *Cybersecurity technology and related services*. (1) Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met:

~~**(i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.**~~

(i) 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.

(ii) 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.

(iii) The arrangement is documented in writing."

CMS finalized the definition of "cybersecurity" as proposed, and finalized the definition of "technology" without the phrase "other than hardware." Thus, the cybersecurity exception at final §411.357(bb) is applicable to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

Effect: The new exception offers new, broad protection for arrangements involving the provision of cybersecurity technology and related services, with few requirements. The new cybersecurity exception is broader in scope and does not include the same restrictions contained in the EHR donation exception (which would apply in the case of a cybersecurity donation made pursuant to the EHR exception). For example, unlike the EHR donation exception, the cybersecurity exception permits the donation of hardware in certain circumstances, and there are no contribution requirements for the software, services and hardware that qualify for donation.

Analysis: The new exception reflects CMS' increased awareness of and concern with the cybersecurity of patient health and other information, as well as its desire to promote and encourage wider adoption of effective technologies.

With respect to the exception's requirement that the technology or services be necessary to implement, maintain, or reestablish cybersecurity, CMS considered and sought comment on whether to 'deem' certain arrangements as satisfying this requirement. CMS chose not to adopt the proposed deeming provision. As finalized, the exception protects donations of a broad range of technology and services, including both locally installed cybersecurity software and cloud-based cybersecurity software. The exception also applies to *hardware* that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. In rulemaking commentary, CMS provides multiple examples of items and services to which the new cybersecurity exception would apply. CMS also stated in rulemaking commentary that "cybersecurity as a service" may be protected, including third-party services managing and monitoring the cybersecurity of a recipient.

Practical Implications: The new exception will allow engagement between DHS entities and community physicians to improve the protection of patient health and other information stored by the physicians.