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

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Introduction

As part of HHS' Regulatory Sprint to Coordinated Care, CMS recently published a proposed rule that, if finalized, would fundamentally change and alleviate the manner in which the Stark Law regulatory framework has traditionally been applied. CMS' proposals come over a decade after the last significant Stark Law rulemaking, and purport to be responsive 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. According to CMS, this environment differs radically from the reimbursement environment in place 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, Medicare's volume-based reimbursement environment generated a concern that entities providing certain services might enter into financial relationships with referring physicians to induce volumes of referrals of the services for which they would be paid, again on a volume-basis. 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. Most of CMS' proposals recognize and attempt to accommodate this fundamental shift.

Many of CMS' proposed changes would have critical operational and structural implications for arrangements between entities and referring physicians. These changes would 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 the proliferation of a great variety of new and restructured relationships between entities and physicians collaborating to improve patient care. CMS also proposes to provide 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; CMS' proposed rule would significantly restore this flexibility. Additional revisions to CMS' regulatory compensation exceptions would offer further operational flexibility. For instance, CMS proposes a new, broad exception for arrangements that are not related to "patient care services", and another for up to \$3,500 of annual, undocumented remuneration to physicians - both of which signal the forthcoming narrowing of the scope of the Stark Law, generally, and concomitant operational and administrative relief for the regulated industry. Stated simply, CMS' proposed regulatory changes (if finalized) would significantly alter the scope of the Stark Law and ease compliance.

This document contains our analysis of the proposed changes and suggestions for operational considerations that could help entities and physicians harness the utility of the rules (if finalized). It is ordered by the proposed rules' potential codification in the Code of Federal Regulations, *i.e.*, from 42 C.F.R. 411.351 through 411.357, and not in any order of importance, except that our discussion of the proposed exception for "value-based arrangements" (to be 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 proposed rules.

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

Current Regulatory Text: None

Proposed New Regulatory Definitions: CMS proposes to codify, at 42 CFR §411.357(aa), a new regulatory exception potentially applicable to “value-based arrangements” that satisfy the following proposed new regulatory definitions, which would be codified at 42 CFR §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).”

Proposed New Exception: CMS proposes 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.”

Effect: The proposed new exception, if finalized, would offer Stark Law protection to a tremendous number of financial arrangements inherent to the health care industry – if they are structured (or restructured) correctly – and would do so 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 a physician’s referrals to (or other business generated for) the entity.

Analysis: Consistent with CMS’ focus on eliminating barriers to providing coordinated, high-quality, value-based care, the proposed exception would apply to a vastly broad variety of “value-based arrangements” (“VBAs”) aimed at care coordination, quality improvement, cost reduction, and/or transition away from a fee-for-service reimbursement environment. The ease with which an arrangement could qualify as a VBA and the associated proposed definitions – and thus be eligible for the proposed exception’s protections – is analyzed in the first subsection, below, entitled “Nuts and Bolts of the ‘Value-Based Arrangement’”. The proposed exception itself would protect only those VBAs meeting its requirements, to include VBAs that pose no downside financial risk to the physician. An arrangement’s ability to satisfy the exception for VBAs is discussed in the second subsection, below, entitled “Satisfying the Exception for ‘Value-Based Arrangements’”.

Nuts and Bolts of the “Value-Based Arrangement”

CMS’ proposed 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 proposed definitions as much as possible, an arrangement between an entity and a physician would 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 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 would not need to be wholly dedicated to 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, another may take the form of an employment agreement, a medical directorship agreement, a co-management agreement, a call coverage agreement, etc. While neither the proposed regulatory text nor rulemaking commentary specifies the degree to which one of the four value-based purposes must be the basis for a VBA, CMS stated that one of those purposes must “anchor” the arrangement. The authors of this Critical Analysis predict that much ink will be spilled on whether and when an arrangement is “anchored” by a value-based purpose – and how that anchoring can be demonstrated.

Equally as important is CMS' proposed definition of a "value-based entity" ("VBE"), which effectively constitutes two or more providers collaborating to achieve a value-based purpose. The proposed definition of a VBE is broad enough that it would encompass 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.

Accordingly, while the proposed regulations would 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' proposed 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 they do not include cherry-picking or lemon-dropping on the basis of health status, or characteristics driven by profit motive or pure financial concerns.

Satisfying the Exception for "Value-Based Arrangements"

To enjoy Stark Law protection, it would be insufficient for an arrangement to merely qualify as a VBA; rather, a VBA would have to satisfy certain requirements in order to satisfy the proposed Stark Law exception for VBAs. However, the proposed exception's requirements would differ and grow more stringent, depending on whether the VBA would (1) occur in the context of a VBE that carries 'full financial risk', (2) impose meaningful downside financial risk on the physician, or (3) impose less than meaningful (or no) downside financial risk on the physician. Thus, the proposed 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 arrangements between a designated health services ("DHS") entity and a physician.

Regardless of the type of VBA, the proposed exception's requirements would not be numerous and would be significantly less stringent than more traditional Stark Law exceptions' requirements. CMS designed the exception in this manner, stating that it believes that in a value-based (and decreasingly volume-based) care delivery and reimbursement system, Stark Law "exceptions need fewer 'traditional' requirements". Most importantly, to satisfy any component of the proposed exception for VBAs, the VBA would neither (a) require fair market value compensation, nor (b) prohibit compensation from taking into account the volume or value of referrals or other business generated. The absence of these substantive requirements is significant, considering that employment arrangements and independent contractor arrangements are or can be structured to have a value-based purpose and qualify as a VBA.

Full Financial Risk

The proposed exception for a VBA associated with a VBE at full financial risk for the cost of a target patient population's care would apply only if the VBE is either (1) 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 six months of the commencement of the VBA. However, as long as the VBE carries full financial risk, 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 proposed 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 employer 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 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 acknowledges this truism, 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."

Accordingly, if the VBE is at full financial risk, it would be relatively easy for the VBA to satisfy the proposed exception. In particular, the proposed exception would require only that (1) the compensation paid via the VBA be "for" or "result from"¹ 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; (4) if compensation would be conditioned on the physician's referrals, the VBA satisfy 42 CFR §411.354(d)(4)(iv); 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 proposed Stark Law exception – 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 and/or takes into account the volume or value of that physician's referrals to or other business generated for the DHS entity.

¹ CMS' examples of compensation that would not be "for" or "result from" value-based efforts include payments for referrals and payments for business unrelated to the target patient population (such as for general marketing or sales).

Meaningful Downside Financial Risk for Physician

With respect to VBEs that are not at full financial risk, CMS proposes to except 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” would mean that the “physician is responsible to pay the entity no less than 25% of the value of the remuneration the physician receives under the VBA”, *i.e.*, to include both monetary compensation and in-kind services.

In the absence of some of the value-based incentives created by full financial risk, CMS would make this component of the proposed exception more difficult to satisfy. Thus, in addition to the requirements listed above (in the “full financial risk” exception), CMS proposes that VBAs imposing meaningful downside financial risk on the physician satisfy three additional requirements: (1) the physician would have to be at downside risk for the entirety of the arrangement; (2) the nature and extent of the financial risk would have to be set forth in writing; and (3) the methodology to be used to determine the amount of the remuneration would have to be set in advance.

CMS declined to propose more onerous requirements because of the incentives created by the physician’s adoption 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 proposed Stark Law exception – 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, CMS proposes to except certain VBAs even if neither the physician, the DHS entity, or 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, CMS proposes to additionally require that the VBA (1) be set forth in writing, (2) be signed by the parties, (3) include a writing that describes (i) the value-based activities to be undertaken by the arrangement, (ii) how they are expected to further value-based purposes, (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 performance of quality standards against which the recipient of the remuneration will be measured, if any.

In addition, CMS would require that (4) if the VBA would impose performance or quality standards against which the recipient of the remuneration would be measured, those standards be objective, measurable, set forth in writing, and apply prospectively. CMS specifically states that such standards must not be applied retroactively, and must not “simply reflect the status quo.” However, the adoption of such performance or quality standards is not in and of itself a requirement for the VBA to satisfy the exception. Stated more simply, a VBA could satisfy the proposed exception even if it does not measure a physician’s performance against performance or quality standards.

CMS would also require that (5) the remuneration subject to the VBA not be conditioned on the volume or value of referrals (of any patients) or other business generated for the entity. 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; CMS would only prohibit 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 proposed requirement could impact VBAs that take the form of employment agreements, for example, that could otherwise permissibly require referrals consistent with 42 CFR §411.354(d)(iv).

Finally, CMS makes clear that physicians and entities would be required to constantly monitor their VBAs to ensure that they continue to satisfy the VBA exception’s requirements – including as to whether the value-based activities taken under the VBA are found to be outdated or incapable of achieving value-based goals and objectives. In such a case, the VBA would no longer satisfy the exception and – given the few requirements of the exception – may need to be either restructured or abandoned. While CMS has proposed this exception to cover both monetary and non-monetary remuneration, CMS is considering restricting the scope of the exception to only non-monetary remuneration. Narrowing the scope of the proposed exception to only non-monetary remuneration would greatly diminish its utility.

Once again, an arrangement between a DHS entity and a referring physician – if structured (or restructured) correctly – could quite easily satisfy this proposed Stark Law exception. 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 performance of quality standards – if any – against which the physician would be measured, the arrangement would satisfy the proposed exception, regardless of whether the compensation paid to the physician would exceed the fair market value of that physician’s services and/or take 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.

Practical Implications: If CMS finalizes this exception as proposed, an entity should be careful to comply (and document its 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 would 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 shelter value-based efforts engaged in by and between two solo practitioners, proper structuring of an arrangement would 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 and 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); and
- The aspirational quality standards – if any – against which the physician's performance would be measured.

CMS Is Considering and Seeking Comments On: CMS is seeking comments on nearly every aspect of the proposed definitions and exception. Set forth below are some, but not all of the concepts that CMS is considering:

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.
- Whether the definition of “transitioning from a volume-based care delivery and payment system to a quality-based system for that care”, *i.e.*, to include team-based coordinated care models, infrastructure to provide patient-centered coordinated care, and accepting (or preparing to accept) financial risk, is appropriate.

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, including pharmaceutical managers, DMEPOS manufacturers and distributors, PBMs, wholesalers, and distributors.

The Proposed Exception

- Whether the safeguards in the proposed exception are 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, in satisfying the exception for VBAs imposing “meaningful downside financial risk” on a physician, the 25% “at risk” threshold is sufficient.
- Whether to require, as part of the VBA exception when less than meaningful (or no) downside financial risk is imposed, that the parties not only monitor whether the VBA is furthering value-based purposes, but do so at specified intervals. CMS is also considering a rule whereby a VBA would no longer satisfy this exception if, after three years, its value-based purposes have not been achieved.
- Whether, similar to the EHR donations exception, a physician should have to contribute 15% of any non-monetary remuneration otherwise satisfying the VBA exception, if less than meaningful (or no) downside financial risk is imposed upon the physician.

Open Questions: Most open questions flow directly from the items that CMS is still considering and upon which it is seeking comment. However, clarity may be needed with respect to (1) the degree to which a value-based purpose must “anchor” the VBA, and (2) the degree to which the physician’s compensation must be “for” or “result from” (and not just relate to) the value-based efforts. For instance, to the extent an employed physician is required to render all of his or her professional medical services in aspiration of measurable quality and performance standards, it would seem reasonable to conclude that all of the physician’s services would be in furtherance of value-based efforts – and thus that all of the physician’s compensation would be “for” or “result from” value-based efforts.

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

1. Proposed New Definition of “Commercially Reasonable”

Current Definition: Currently, the phrase “commercially reasonable” is not defined in regulatory text, although parties typically refer 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 Definition: CMS proposes to amend 42 CFR §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.”

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

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

Analysis: The current 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. CMS’ proposed definition would clarify 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.

Practical Implications: The proposed definition would allow DHS entities (in particular hospitals) to proceed with much greater confidence in entering into arrangements that further legitimate operational and patient care goals, even if they may result in a net financial loss to the entity. In rulemaking commentary, 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), 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 the aforementioned and other legitimate business goals.

CMS is Considering and Seeking Comments On: CMS seeks 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.” This alternative definition might (1) suffer from circularity, in that for an arrangement to be “commercially reasonable”, it would need to “make commercial sense”, which itself would be an undefined phrase, and (2) burden parties by requiring them to demonstrate that their arrangement actually “is” entered into by similar parties.

Open Questions: The proposed definition would still require parties to demonstrate that their arrangement is on “similar terms and conditions as like arrangements”; it is unclear the degree to which parties must search for, identify, and memorialize the fact that similar agreements have been entered into by third parties.

In rulemaking commentary, CMS indicated numerous times that its proposed definition seeks to provide “clarification” of the meaning of the phrase, and offer the “clarity that will benefit the regulated industry, CMS, and [CMS] law enforcement partners.” Unlike “changes” to regulations, the “clarification” of regulatory text connotes retroactive effect. It is unclear whether CMS intends for the commercial reasonableness of historic and current arrangements to be assessed with respect to the proposed definition – or leave them subject to the same types of attack exacerbated by the current ambiguity of the meaning of the phrase, and which led to the proposed definition itself.

2. Proposed Revised Definition of “Fair Market Value”

Current Definition: Currently, 42 CFR §411.351 defines “Fair market value” to mean “the value in arm’s-length transactions, consistent with the general market value.” “General market value” is 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 Definition: CMS proposes to amend 42 CFR §411.351 to state:

“(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.”

Effect: CMS’ proposed revisions would largely (and most importantly) serve 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 proposed revisions would be analytically helpful, in that they would more clearly delineate the fair market value requirement and eliminate its conflation with other requirements – in particular, the revisions would undermine the notion adopted by DOJ, *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. CMS’ proposed delineation 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. 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.” 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 salary survey data may otherwise indicate.

Finally, CMS commentary (and the text of the proposed definition) 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, CMS’ proposed revisions should not cause material deviations from the manner in which valuers 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 CMS’ proposal. 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 Is Considering and Seeking Comments On: CMS seeks 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).

3. Proposed New Special Rules for Compensation that “Takes Into Account” the Volume or Value of Referrals or Other Business Generated

Current Special Rule: None

Proposed Special Rule: CMS proposes to codify two new special rules at 42 CFR §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.”

Effect: The proposed special rules would 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
- Medical staff incidental benefits
- Indirect compensation arrangements
- Obstetrical malpractice insurance subsidies
- Retention payments in underserved areas
- Community-wide health information systems
- Electronic prescribing items and services
- Electronic health records items and services
- Assistance to compensate a nonphysician practitioner
- Timeshare arrangements
- Limited remuneration to a physician (as proposed)
- Cybersecurity technology and related services (as proposed)

Analysis: The proposed 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 that the proposed definition would 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 great value on the resolution of Stark Law-based FCA litigation involving the uncertain (but potentially catastrophic) application of this phrase.

The proposed special rules – by providing “objective tests” for determining whether compensation takes into account referrals – would go a long way towards eliminating the unnecessary costs and expenditures caused by the current ambiguity. By stating that compensation would only “take 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, CMS would appear to restrict the scope of the inquiry and analysis to the compensation formula contained in the four corners of a writing – and not to extend to the hearts and minds of physicians and those who lead DHS entities.

CMS proposes that, in “narrowly-defined circumstances”, fixed-rate compensation could be determined in a manner that “takes into account” referral volume – in particular, when parties “utilize a predetermined tiered approach to compensation under which the volume or value of a physician’s prior referrals is the basis for determining the unvarying rate of compensation... over the entire duration of the arrangement.” However, in so doing, CMS makes clear that the basis for the compensation must be “prior referrals (or other business previously generated by the physician for the entity)” – specifically stating that “[m]erely hoping for or anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or the other business generated by the physician for the entity” (emphases added). Thus, CMS 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 CMS’ proposed rule, such a situation would appear to not implicate the meaning of “takes into account” the volume or value of referrals, as the situation would not contemplate “prior referrals” as a determinative basis for the compensation.

Furthermore, CMS' rulemaking commentary 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 "a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services... are billed each time the employed physician personally performs a service." 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 have 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, CMS' proposed definition would provide substantial comfort, but potentially little operational change. For other entities that have 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 may open opportunities for new and revised processes for considering the viability of potential arrangements and determining subject compensation amounts and methodologies.

In particular, should the proposed rules be finalized, 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 proposed 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, make prudent business decisions consistent with organizational fiduciary duties.

CMS Is Considering and Seeking Comments On: CMS is specifically seeking comment on its proposal to identify when fixed compensation may take into account the volume or value of referrals or other business generated. Furthermore, CMS is seeking comment on whether the new special rules would cause confusion with respect to those specific regulatory instances wherein providers are permitted to base compensation "indirectly" on the volume or value of referrals (e.g., in the exception for donation of EHR items and services, or with respect to a group practice's distribution of profit shares and productivity bonuses).

Open Questions: In rulemaking commentary, CMS states that the proposed rules would "supersede our previous guidance, including guidance with which [the proposed rules] may be (or appear to be) inconsistent." It is not clear what CMS is driving at with this sentence – as any new regulatory text typically "supersedes" previous guidance. While such language may smack of a "change" in regulatory position, CMS may instead be signaling that the proposed rule would apply to not just compensation determinations made after the date that the rule is finalized, but also to prior determinations of compensation amounts subject to arrangements that are no longer effective.

Although CMS stated that its proposed rule is “consistent with the position [CMS] articulated in [2001]” – which would support a position that the special rules (if finalized) should apply to all currently effective compensation arrangements – further clarity from CMS on whether this rule would be a “change” or a “clarification” would be welcome. Given that many existing financial relationships between physicians and DHS entities will continue to exist on and after the date the Final Rule will be effective, it would be analytically difficult to consider subject compensation at risk of improperly “taking into account” the volume or value of referrals before the date of finalization (*i.e.*, because of the current ambiguity), but to consider the exact same compensation as undoubtedly not “taking into account” the volume or value of referrals on and after the date of finalization (*i.e.*, because of the new rule).

4. Proposed Addition to Carve-Out From Definition of “Designated Health Services”

Current Carve-Out: Currently, 42 CFR §411.351 states 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 do 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 Carve-Out: CMS proposes to amend 42 CFR §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).”

Effect: The proposed definition would narrow the scope of DHS subject to the Stark Law’s prohibitions. In particular, many fewer inpatient hospital services would 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 is that virtually all of their services constitute DHS. CMS’ proposed addition to the definitional carve-out would push most inpatient hospital services outside the definition of DHS – specifically, inpatient hospital services that would not affect the IPPS payment received by the furnishing hospital. CMS’ proposal 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.

CMS clarifies its proposed rule through an example: if a physician (“Physician 1”) referred a patient to a hospital for inpatient hospital services, and subsequent to the patient’s admission the patient was cared for by another physician (“Physician 2”) who ordered additional inpatient hospital services, the service for which Physician 2 referred the patient would not constitute DHS so long as the furnishing of that additional service did not affect the amount of reimbursement the hospital could claim under the IPPS. Therefore, even if Physician 2 had an unexcepted financial relationship with the hospital, services provided pursuant to that physician’s referral would not constitute DHS and, so long as Physician 1 did not have an unexcepted financial relationship with the hospital, the hospital would not be prohibited from billing for the inpatient hospital services it furnished to the patient.

CMS is explicit that this proposed rule would only impact inpatient hospital services: “Although outpatient services are also paid on a composite rate, we believe that there is typically only one ordering physician for outpatient services, and it rarely happens that physicians other than the ordering physician refer outpatients for additional outpatient services that would not be compensated separately under the OPSS”. Therefore, CMS does not propose to offer a similar carve-out for outpatient hospital services. Nevertheless, in many instances, the proposed carve-out should have a significant, minimizing impact on a hospital’s quantifiable Stark Law liability.

Practical Implications: The proposal would have little practical effect, outside of *post hoc* Stark Law analyses and quantifications of exposure. Nonetheless, hospitals 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 hospital services after a patient is already admitted may never refer for DHS (that take the form of inpatient hospital services) unless doing so causes an outlier payment.

CMS Is Considering and Seeking Comments On: CMS notes that it is “aware that not all hospitals are paid under the IPPS” and is “soliciting comments as to whether our proposal...should be extended to analogous services provided by hospitals that are not paid under the IPPS, and, if so, how [it] should effectuate this change in [its] regulation text.” Hospitals in Maryland, for example, may wish to pay special attention to this request for comments. CMS is also soliciting comments as to whether it should extend its proposal to outpatient services or other categories of DHS and, if so, how these changes should be effectuated.

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 in the context of other shifting reimbursement systems, such as those for outpatient hospital services and home health services.

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

Current Special Rules: Currently, 42 CFR §411.352(i) lays out CMS' "Special rule for productivity bonuses and profit shares" and states 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 proposes to amend 42 CFR §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.

Effect: The proposed rule would allow 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 proposed rule would also clarify that:

- (1) the proposed, narrow meaning of the phrase "takes into account" (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" would mean "profits derived from all the DHS of the Group";
- (3) no Group Practice could distribute profits from DHS on a service-by-service basis; and
- (4) DHS profit distributions could 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 could not 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: CMS is concerned that the current Group Practice profit distribution rules can be 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, CMS proposes to "deem" as acceptable any distribution of profits from DHS that are directly attributable to a physician's participation in a "value-based enterprise" (as CMS proposes to define that term). However, given the potentially staggering scope of the 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) – the proposed deeming clause, as drafted, 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, CMS' clarifying changes could 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 proposed changes would disallow such a methodology, but rather would require 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 current 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 proposed changes would also disallow such a methodology.

Practical Implications: Should CMS finalize this proposed rule, a Group Practice would have the opportunity to structure its clinical operations and arrangements in order to could qualify as a “value-based enterprise”, which would allow it to distribute DHS profits to its physicians in a manner directly related to their DHS referrals.

Other Group Practices would be wise to revisit their profit distribution methodologies to ensure that they do not run afoul of the proposed rules – 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 billed to Medicare.

CMS Is Considering and Seeking Comments On: CMS seeks comments on its proposal to clarify the methodologies by which “overall profits” can be distributed. In addition, as currently drafted, CMS allows Group Practices to distribute “profits” from DHS; it now seeks comments as to whether it should allow Group Practices to distribute “revenues” from DHS. Finally, CMS proposes to deem as acceptable any productivity bonus based on the receiving physician’s total patient encounters or personally performed RVUs, as described in 42 CFR §414.22, but seeks comments as to whether any personally performed RVUs should be an acceptable basis for calculating a productivity bonus, regardless of whether they are as described in 42 CFR §414.22.

Open Questions: Given the potential need to restructure compensation distribution methodologies, a grace period for revisiting and restructuring current practices and distribution methodologies may be warranted. It remains to be seen, however, whether CMS would allow such a grace period.

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

Current Provision: Currently, 42 CFR §411.353(c) states 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 proposes to amend 42 CFR §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.”

Effect: Although the proposed change would eliminate “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 explains that its proposal is meant to eliminate perceived confusion over whether the dates specified in the current 42 CFR §411.353(c)(1) are the only dates upon which a period of disallowance would expire. CMS emphasizes that it never intended for this section to describe the only way to end a period of disallowance, but rather that it sought to offer certain bright line rules to constitute the outer limits of a period of disallowance.

CMS acknowledges that the frameworks in the current 42 CFR §411.353(c)(1) “are not always as practical or clear as we originally envisioned” and that “[o]ften when there is an allegation of excess or insufficient compensation paid under an arrangement, there is a dispute between the parties as to what the proper amount of compensation should have been under the arrangement”, such that “the parties may need to litigate the matter” and “[i]t is not clear...at what point in the litigation...the period of disallowance should end.” Further, “in some cases, the cost of litigating the matter may far outweigh the amount in dispute, making litigation highly impractical.”

While accurately pointing out the difficulty in pinpointing the close of a period of disallowance in situations such as those described, CMS’ proposed regulatory text would not add any clarity to such situations. However, in commentary, CMS states that the general principle would be that “the period of disallowance... begin[s] on

the dates when a financial relationship fails to satisfy all requirements of any applicable exception and end[s] on the date that the financial relationship ends or satisfies all requirements of an applicable exception.” This commentary is helpful in that it indicates that the termination of a financial relationship would effectively close a period of disallowance. In previous rulemakings, CMS had suggested that a period of disallowance could continue subsequent to the termination of a financial relationship, e.g., if a physician had not made a final rent payment.

CMS’ 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 our 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. While CMS opines that it “was never our intent” that these types of errors create excess or insufficient compensation for the purposes of 42 CFR §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.” 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 proposed regulatory change would have little practical effect. The proposed 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.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

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

Current Definition: Currently, 42 CFR § 411.353(g) states 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 proposes to delete 42 CFR §411.353(g) in its entirety and instead codify a new provision at 42 CFR §411.354(e)(3), which would state 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.”

Effect: The proposed change would expand 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.

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.” In those cases, CMS does not believe “the arrangement poses a risk of program or patient abuse.”

In rulemaking commentary related to this proposal, CMS also took the opportunity to address 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). Noting that the proposed 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”, CMS “reiterate[d] that the special rule [at §411.354(d)(1) on compensation considered to be set in advance] is merely a deeming provision”

(emphasis added). In other words, “while compensation is considered to be set in advance...if the compensation is ‘set out in writing before the furnishing of items or services’ and the other requirements...are met...it is not necessary that the parties reduce the compensation to writing before the furnishing of items or services.” Instead, CMS describes 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, and notes that compensation under such circumstances 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.²

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.” 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 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...”

Practical Implications: The proposed expansion of the 90-day grace period (from missing signature to missing writings) would 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, which the new grace period would substantially ease. Contracting policies and procedures could 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.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

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.

² Although such a writing would no longer be necessary, the burden of proof of compliance with a Stark Law exception would remain with the DHS entity, making such a writing at least prudent.

VI. Proposed Additional Exceptions to Ownership and Investment Interests

Current Exclusions: Currently, 42 CFR §411.354(b)(3) states 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 proposes to amend 42 CFR § 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).”

Effect: The proposed change would effectively narrow the scope of the Stark Law’s prohibitions by excluding additional types of ownership and investment interests from constituting financial relationships.

Analysis: CMS’ rulemaking commentary informally defines titular ownership to mean “an interest that excludes the ability or right to receive the financial benefit of ownership..., including the distribution of profits, dividends, proceeds of sale, or similar returns on investment.” It is not clear how helpful the proposed exclusion for titular ownership would 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. The proposal to provide explicit protection for entities that both employ physicians and offer an ESOP would bring a modicum of needed clarity.

Practical Implications: CMS’ proposed 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.

CMS Is Considering and Seeking Comments On: CMS seeks comments on whether the safeguards on ESOPs imposed by ERISA are sufficient for the purposes of the Stark Law and, if not, what additional safeguards should be included. For instance, CMS seeks comment as to whether it is necessary to restrict the number or scope of entities owned by an ESOP that would not be considered an ownership or investment interest of its physician employees. CMS also seeks comment as to whether its ESOP exclusion should apply only to an interest in an entity arising from an interest in “qualifying employer securities” offered to a physician as part of an ESOP. Finally, CMS seeks comments as to whether the ESOP exclusion is necessary, or whether the current 42 CFR §411.354(b)(3)(i) is sufficiently flexible to include non-abusive ESOPs and similar plans.

Open Questions: CMS’ proposals 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. Proposed New Provision Pertaining to Exceptions Applicable to Indirect Compensation Arrangements

Current Provision: None

Proposed Provision: CMS proposes to codify a new provision at 42 CFR §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.”

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

Analysis: CMS’ proposed provision would clarify 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 proposed provision would also allow indirect compensation arrangements to satisfy the new exception (discussed in Section I) for arrangements that facilitate value-based health care delivery and payment. The latter proposal 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 proposal, value-based arrangements that are indirect compensation arrangements (which could be many) might have 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: CMS’ proposal would be unlikely to have substantial operational impact, although properly structured indirect compensation arrangements might be able to satisfy the new (proposed) exception for value-based arrangements, which offers more flexibility than the exception for indirect compensation arrangements.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

VIII. Proposed Changes Applicable Throughout the Regulatory Framework

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

Current Provisions: Many Stark Law exceptions currently require 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 proposes 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. The anti-kickback statute safe harbor compliance requirements for referral services and obstetrical malpractice subsidies exceptions would remain in place.

Effect: The following exceptions would no longer require that an arrangement not violate the anti-kickback statute or state or Federal regulations:

- 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: CMS' basis for including this language in the regulations at the outset was its concern that unscrupulous physicians and other entities would potentially seek to protect intentional unlawful conduct by complying with the minimal requirements of a Stark Law regulatory exception. 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.” 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. Removal of these requirements from many Stark Law exceptions would simplify analysis of Stark Law compliance, and avoid confusion as to applicable legal standards.

Practical Implications: The proposal has little to no practical implications.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

2. Proposed Provisions Pertaining to Required Referrals

Current Provisions: Currently, 42 CFR §411.354(d)(4) allows 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 proposes to preserve the provision at 42 CFR §411.354(d)(4), but to add subparagraphs to specific regulatory exceptions that would expressly require compliance with 42 CFR §411.354(d)(4).

Effect: The following exceptions would expressly require compliance with 42 CFR §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

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 would require referrals as part of an arrangement with a physician, it would remain important for the entity to ensure that the requirement accommodates patient choice, insurer requirements, and physician judgment.

CMS Is Considering and Seeking Comments On: CMS is considering whether an express reference to 42 CFR §411.354(d)(4) is necessary within the exception for academic medical centers, given the nature of academic medical centers. CMS is also seeking comments as to whether the text of 42 CFR §411.354(d)(4) should be relocated to §411.354(e).

IX. Proposed Changes to Exceptions for Direct Compensation Arrangements

1. Proposed Changes to Office Space and Equipment Rental Exceptions

Current Provisions: Currently, 42 CFR §411.357(a)(3) and (b)(2) require 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 proposes to amend 42 CFR §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 means 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).

Effect: The proposal would 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 the proposed 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 proposed 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 proposal 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 may substantially expand the type of lease arrangements that would be possible with referring physicians, and could decrease the burden associated with monitoring a lessee’s use of leased space or equipment.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

2. Proposed Changes to Physician Recruitment Exception

Current Provision: Currently, 42 CFR §411.357(e)(4) states 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 proposes to amend 42 CFR §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.”

Effect: This proposal would eliminate 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: 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 opines 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...” Eliminating the practice’s signature requirement in those instances “would reduce undue burden without posing a risk of program and patient abuse.”

Practical Implications: This small proposed 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 would be a welcome change.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

3. Proposed Replacement of The Exception for Certain Arrangements with Hospitals

Current Provision: Currently, 42 CFR §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 proposes to amend 42 CFR §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.”

Effect: The proposed changes would resuscitate and broaden the scope of a currently dormant exception, effectively removing from the scope of the Stark Law’s prohibitions any arrangement wherein a hospital provides remuneration to a physician for items or services not related to the provision of patient care services.

Analysis: CMS’ proposal would substantially expand the potential usefulness of this exception (which, after previous CMS rulemakings, has virtually no practical application). CMS proposes for the exception to protect any remuneration provided by a hospital (but only a hospital) to a physician that is not related to “patient care services.” To satisfy the proposed exception, remuneration unrelated to patient care services would only need to be determined in a manner that does not take into account the volume or value of a physician’s referrals; most notably, the exception would not require compensation to be consistent with fair market value.

Necessarily, much future Stark Law analysis would turn on when and whether an arrangement is sufficiently unrelated to patient care services to warrant protection from this exception. As a “general principle” to guide such analyses, CMS states that “if a service can be provided legally by a person who is not a licensed medical professional and the service is of the type that is typically provided by such persons, then payment for such a service is unrelated to the provision of [DHS]....” (emphasis added).

CMS proceeds to provide examples of arrangements that are related to, or unrelated to, patient care services. First, CMS explains that call coverage services and utilization review services would relate to the provision of patient care services, and therefore would not be eligible for this exception. Likewise, “medical director services typically include, among other things, establishing clinical pathways and overseeing the provision of designated health services in a hospital”, and would therefore likely relate to patient care services and be ineligible for the exception. However, “the administrative services of a physician pertaining solely to the business operations of a hospital” would not relate to patient care services, such that “if a physician is a member of a governing board along with persons who are not licensed medical professionals, and the physician receives stipends or meals that are available to the other board members...this remuneration would not relate to the provision of designated health services....” Certain other financial transactions could also qualify for the exception, for instance “if a physician who joins another practice sells the furniture from his or her medical office to a hospital, and the hospital places the furniture in the hospital’s facilities”, the remuneration would not be related to the provision of designated health services.

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, this proposal has the potential to significantly narrow the scope of the Stark Law.

Practical Implications: Hospitals should consider revisiting their physician contracting policies and procedures with an eye towards early-stage identification, analysis, and documentation of whether a contemplated arrangement is for a service that (1) can be provided legally by a person who is not a licensed medical professional and (2) is of the type that is typically provided by such persons, which would allow hospitals to short-circuit the need for full Stark Law analysis of (and avoid exposure to Stark Law liability from) that arrangement.

Similarly, DHS entities and physicians embarking upon a multi-faceted arrangement should consider the extent to which the arrangement could be comprised of numerous, smaller arrangements – some of which relate to patient care services, and some of which do not.

CMS Is Considering and Seeking Comments On: CMS seeks comments on these proposals, as well as other possible ways for distinguishing between remuneration that is related to the provision of DHS and remuneration that is unrelated to the provision of DHS. Specifically, CMS seeks comment as to whether it should limit what it considers to be remuneration related to DHS to remuneration paid explicitly for a physician’s provision of DHS to a hospital’s patients.

Open Questions: While CMS offers a potential litmus test that seems relatively straightforward – “if the service could be provided by a person who is not a licensed medical professional” – the standard for items is less clear. It remains an open question where CMS will draw the line on which items are related to patient care services and which are not, especially as CMS seeks comment on whether the exception should apply more narrowly than as proposed.

4. Proposed Narrowing of Isolated Transactions Exception

Current Provision: Currently, 42 CFR §411.351 defines “isolated financial transaction” as a “Transaction... 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 proposes to amend 42 CFR §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)

Effect: This proposed provision would narrow the applicability of the isolated transaction exception to exclude one-time payments for multiple or repeated services, thus (potentially) eliminating a common tool deployed by many Stark Law practitioners to shelter an agreement made for the first time to pay for services that had been previously provided.

Analysis: CMS explains that it does not intend for the isolated transactions exception to be used for single payments that compensate for the 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. 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 designated health services and the entity wishes to bill Medicare for such services. 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 CFR §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, then the physician’s provision of services to the hospital does 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’ proposed rule would unquestionably narrow the scope of the isolated transaction exception to exclude protection of such arrangements. CMS’ proposed change thus constitutes one of the few restrictive proposals in this rulemaking.

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. While CMS’ proposed new exception for payments to a physician under \$3,500 (discussed further below) would protect a subset of such arrangements under some circumstances, this proposed clarification of the isolated transactions exception would make it more difficult to resolve disputes or demands for payment of greater sums as consideration for services already provided. Therefore, 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).

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

Open Questions: CMS’ rulemaking commentary implies that the exclusion of a single payment for multiple purposes from the isolated transactions exception is already its policy, stating that “it is our policy that the exception for isolated transactions is *not* available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services.” CMS also justifies its proposed regulatory change in part, however, by referencing other proposed regulations “that will facilitate compliance with the physician self-referral law in general and the writing and signature requirements in particular”, which “if finalized, would afford parties with sufficient flexibility to ensure that personal service arrangements comply with the physician self-referral law”, leaving “no reason to unduly stretch the meaning and applicability of the exception for isolated transactions....” Since those proposed changes are not yet in effect, it is not clear whether CMS would allow the isolated transaction exception to “stretch” in this way with respect to arrangements that occur (or have occurred) before the rule is finalized, or whether its proposed narrowing of the scope of the isolated transactions exception, *i.e.*, to exclude single payments for multiple services, is intended to be retroactive.

5. Proposed Expansion of Exception for Payments By a Physician

Current Provision: Currently, 42 CFR §411.357(i) states:

“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 proposes to amend 42 CFR §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 CFR §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).”

Effect: The proposed changes would greatly expand 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. Therefore, CMS proposes that the regulatory exception apply to payments by a physician so long as the exceptions codified at 42 CFR §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, CMS’ proposal would substantially expand 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, and if the proposed rule is finalized, then the only Stark Law requirement related to such a payment would be its consistency with the fair market value of the item or service at issue – and contracting policies and procedures could be amended to acquire analysis and documentation accordingly.

CMS Is Considering and Seeking Comments On: CMS is not specifically seeking comments on this proposal.

6. Proposed Expansion of Exception for Fair Market Value Compensation

Current Exception: Currently, 42 CFR §411.357(l) states as follows (emphasis 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 (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.”

Proposed Exception: CMS proposes to amend 42 CFR § 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."

Effect: This proposed change would expand the scope of the exception for fair market value compensation 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]." 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 CFR §411.357(l), parties would be permitted to enter into only one arrangement for the rental of the same office space during the course of a year.

Practical Implications: The proposed expansion of this exception to include qualifying office space arrangements would afford 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 proposals might be particularly helpful to providers in rural areas.

CMS Is Considering and Seeking Comments On: The current exception requires that any services to be performed under the arrangement not involve the counseling or promotion of a business activity that violates state or Federal law. CMS is soliciting comments on whether this requirement is necessary to protect against program or patient abuse, or if it should be removed. If removed, CMS queries whether it should be replaced with other safeguards, such as those included in many other statutory or regulatory exceptions.

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

Current Provision: Currently, 42 CFR §411.357(l) states, 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 CFR 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 defines “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 proposes to amend 42 CFR §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 CFR 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 proposes a change to 42 CFR §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.”

Effect: The proposed changes would clarify that donations of cybersecurity software and services are permitted under the electronic health record (“EHR”) exception, would remove the sunset provision, and would modify the definitions of “electronic health record” and “interoperable” to ensure consistency with the 21st Century Cures Act. In addition, the proposed changes would modify the 15% physician contribution requirement and permit certain donations of replacement technology.

Analysis: CMS' proposed revisions would substantially update the EHR exception and signal CMS' continued commitment to encouraging the continued adoption of these technologies. Proposed clarifications to the interoperability provisions and relevant definitions would more closely align the exception with other regulations regarding EHRs, as well as better define the requirements for interoperability and functionality of donated EHR. The proposed clarifications regarding cybersecurity software and services would 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. The other proposed changes, including elimination or extension of the sunset provision and elimination of or modification to the 15% physician contribution requirement, would continue to promote, and would remove a significant barrier to, EHR technology adoption.

Practical Implications: The proposal would 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.

CMS Is Considering and Seeking Comments On: CMS makes a blanket request for comments on its proposals regarding the EHR exception. More specifically, CMS seeks comments on the following:

- Its proposed clarifications to the EHR interoperability provisions, including modifying the deeming provision to clarify that, on the date the software is provided, it “is” certified and removing the reference to “an edition” of certification criteria to align with proposed changes to the Office of the National Coordinator for Health Information Technology’s certification program;
- Aligning the prohibition on the donor engaging in information blocking in connection with the donated items or services with the Public Health Services Act’s definition of information blocking;
- Its approach to both expand the EHR exception and create a cybersecurity exception, requiring a party seeking to protect an arrangement involving the donation of cybersecurity software and services only to comply with the requirements of one applicable exception. In particular, CMS seeks comments on whether, with the addition of a stand-alone cybersecurity exception, it is necessary to modify the EHR exception to expressly include cybersecurity;
- Whether CMS should select a later sunset date, instead of making the EHR exception permanent, and, if so, what that date should be;
- The updated definition of “interoperable”, including specifically that the proposed definition would align the definition of “interoperable” with the statutory definition of “interoperability” (or eliminating “interoperable” to replace with “interoperability”);
- The updated definition of “electronic health record”;
- Whether using terminology identical to the Public Health Service Act and Office of the National Coordinator for Health Information Technology regulations would facilitate compliance with the requirements of the EHR exception and reduce any regulatory burden resulting from the differences in the agencies’ different terminology related to the singular concept of interoperability;
- The impact of reducing or eliminating the EHR exception’s 15% physician contribution requirement on the use and adoption of EHR technology, and any attendant risks of fraud and abuse, including specific examples of any prohibitive costs associated with the 15% physician contribution requirement, both for the initial donation of EHR technology and for subsequent upgrades and updates to the technology;

- The types of situations in which the donation of replacement EHR technology would be appropriate and how to safeguard against situations where donors inappropriately offer, or physician recipients inappropriately solicit, unnecessary technology instead of upgrading their existing technology for legitimate reasons;
- The modification or elimination of the EHR exception's 15% physician contribution requirement for updates to previously donated EHR software or technology; and
- How to define "small or rural physician organization" and "rural physician organization" for purposes of eliminating or reducing the percentage contribution required for small or rural physician organizations only, as well as other subsets of potential physician recipients for which the 15% contribution is a particular burden.

Open Questions: Many of the proposed updates to the interoperability provisions are dependent on the finalization of other regulations. As those regulations are similarly subject to change based on public comments, there is the heightened possibility of the interoperability proposals being modified in the final rule.

With regard to the potential applicability of the EHR exception to cybersecurity software or services, CMS specifies that the "predominant purpose of the software or services must be cybersecurity associated with the EHR" but that "arrangements in which the software package included other functionality related to the care and treatment of individual patients would be protected." As these technologies continue to develop and become more expansive, it may become more difficult to determine the "predominant purpose" of different technologies. As CMS also proposed a less burdensome cybersecurity exception that does not include the "predominant purpose" test, the usefulness of an expanded EHR exception to protect the donation of cybersecurity software and services is subject to question.

Finally, the numerous proposed alternatives for modifications to the 15% physician contribution requirement and CMS' openness to suggestions fosters uncertainty on how any changes may be finalized.

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

Current Provision: Currently, 42 CFR §411.357(x) protects “[r]emuneration provided by a hospital to a physician to compensate a nonphysician practitioner (NPP) to provide “patient care services”, if certain conditions are met.

Proposed Provision: CMS proposes to amend 42 CFR §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 proposes to add definitions of “NPP referrals” and “NPP patient care services” and implement these terms throughout the exception. “NPP patient care services” would 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.”

Effect: The proposed changes would narrow the applicability of the exception by clarifying that the exception would be available only for assistance with non-physician practitioners who are not yet employed by or contracted with the physician or physician group.

Analysis: CMS’ proposed revisions would add clarity to several aspects of the exception for assistance to compensate a NPP. First, the revisions would clarify that the hospital/physician compensation arrangement must commence prior to the physician/NPP compensation arrangement. Currently, there is 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 proposed rule would also address 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, 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 proposed rule would limit 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 “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 proposed rule would change references to “referral” when describing the actions of an NPP in §411.357(x), to “NPP referrals.”

Practical Implications: These proposed revisions are unlikely to require significant operational changes, although any assistance offered to compensate an NPP must be assuredly for new hires adding new NPP services to the area.

CMS Is Considering and Seeking Comments On: CMS did not explicitly request comments on this proposal.

9. Proposed New Exception for Limited Remuneration to a Physician

Current Exception: None

Proposed New Exception: CMS proposes to codify a new exception at 42 CFR §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.”

Effect: This proposed new exception would protect certain payments to physicians for items and services, pursuant to undocumented arrangements, totaling no more than \$3,500 annually.

Analysis: As part of its efforts to offer flexibility for non-abusive business practices, CMS proposes a new exception for certain annual amounts less than \$3,500 paid to physicians as fair market value compensation for items and services, without any requirement that the arrangements be documented in writing. CMS believes that allowing physicians to receive limited remuneration from entities, subject to certain conditions, would not pose a risk of program or patient abuse, even when such an arrangement is not documented. This proposed exception would provide 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 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 \$3,500 annual limit, the proposed exception would apply.

The proposed \$3,500 limit would not count compensation paid to a physician for items and services provided outside the arrangement the parties wish to protect. CMS also explains that the new exception could be combined with other exceptions. For instance, if compensation under \$3,500 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, CMS would not apply the requirement of the personal service arrangement exception (if applicable to the documented arrangement) 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. In keeping with its decision not to exclude office space from the meaning of items and services, this proposed new exception would be available for limited office space use arrangements, subject to prohibitions on percentage-based and per-unit of service compensation.

Practical Implications: This proposed new exception would 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 proposed exception may substantially reduce the burden associated with gathering documentation to support the arrangement.

CMS Is Considering and Seeking Comments On: CMS seeks comments on whether the \$3,500 limit is appropriate, too high, or too low to accommodate non-abusive compensation arrangements. CMS also seeks comments on whether it is necessary to limit the new exception to services personally performed and items personally provided by the physician. Additionally, although CMS has not included a requirement in the proposed exception that the arrangement not violate the anti-kickback statute or other Federal or state law governing billing or claims submission, it seeks comment as to whether such a safeguard is necessary in this particular exception, “in light of the absence of requirements for set in advance compensation and written documentation of the arrangement.” Finally, CMS seeks comments as to whether the text of the personal services arrangements exception should be modified to state that services covered by this proposed exception are not subject to the requirement for cross-reference and the limitation to one agreement for the same services in a year.

10. Proposed New Exception for Cybersecurity Technology and Related Services

Current Exception: None

Proposed New Exception: CMS proposes to codify a new exception at 42 CFR §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 proposes amending 42 CFR §411.351 to define “cybersecurity” as “the process of protecting information by preventing, detecting, and responding to cyberattacks.”

Effect: The proposed exception would offer new, broad protection for arrangements involving the provision of cybersecurity technology and related services, with few requirements.

Analysis: The proposed new exception reflects CMS’ increased awareness of and concern with cybersecurity of patient health and other information, as well as its desire to promote and encourage wider adoption of effective technologies. Donors of technology and services would be able to indirectly take into account the volume and value of a physician’s referrals when considering which physicians to donate technology to, as well as the amount of technology to donate.

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

CMS Is Considering and Seeking Comments On: CMS seeks comments on its approach to both expanding the EHR exception (discussed above) and creating the proposed cybersecurity exception, and its position that a party seeking to protect an arrangement involving the donation of cybersecurity technology services would only need to comply with the requirements of one applicable exception. In particular, CMS seeks comments on whether, with the addition of a stand-alone cybersecurity exception, it is necessary to modify the EHR exception to expressly include cybersecurity.

In addition, CMS seeks comments on the following:

- Whether the proposed exception should require a writing and signatures;
- Whether the limitation of the proposed exception, *i.e.*, to protect only donations of technology and services that are used predominantly to implement, maintain, and reestablish cybersecurity, would prohibit the donation of cybersecurity technology and related services that are vital to improving the cybersecurity posture of the health care industry;
- Whether to deem certain arrangements as satisfying the requirement that the technology or services are necessary to implement, maintain, or reestablish cybersecurity, including the manners in which parties could reliably demonstrate that a donation furthers a recipient’s compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards, (*e.g.*, whether parties could demonstrate that a donation meets the cybersecurity deeming provision through documentation, certifications, or other methods not proscribed by regulation, as well as what qualifies as a widely recognized cybersecurity framework or set of standards);
- Whether certain types of entities should be excluded from donating cybersecurity technology and related services and, if so, why, especially as it relates to historical concerns and other considerations regarding direct and indirect patient care;
- The proposed requirement that neither a potential recipient nor a potential recipient’s practice (including employees or staff members) may make the receipt of cybersecurity technology and related services, or the amount or nature of the technology or services, a condition of continuing to do business with the donor;
- Aligning the proposed definition of “interoperable” (for purposes of the proposed deeming provisions) with the statutory definition of “interoperability”; and
- The proposed definition of “cybersecurity” and “technology”.



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