The Sprint to Modernize and Clarify the Stark Law—Part II

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The Centers for Medicare & Medicaid Services (CMS) published its much-anticipated proposed Stark rule in the October 17, 2019 *Federal Register*, proposing the most substantive changes to Stark regulations since the final Stark II rulemaking in the 2000s (Proposed Rule).[1] The comment period ended on December 31, 2019. Due to the length and detail of the Proposed Rule, this is the second article of a two-part series and, even then, does not discuss every proposal. Part I was published in the December 2019 issue of *AHLA Connections*.

Part II focuses on CMS' proposals for:

- new value-based exceptions including a number of new and interrelated definitions that support these new exceptions;
- a new exception for limited remuneration to a physician and revision to the isolated transaction exception; and
- revisions to the electronic health record (EHR) exception and a new cybersecurity exception.

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The Proposed Rule attempts to provide relief for parties to value-based arrangements not currently protected by the fraud and abuse waivers and makes great strides in fulfilling CMS' longstanding goal of giving stakeholders "bright-line" rules. However, many of these new exceptions are complicated and compliance may be difficult. Further, they may present new opportunities for "technical violations" of the Stark law. Finally, while CMS has gone a long way to provide regulatory clarity and a pathway for value-based arrangements, the complimentary Department of Health and Human Services (HHS) Office of Inspector General (OIG) proposed regulations to modify the Anti-Kickback Statute and the Beneficiary Inducement Civil Monetary Penalty do not go nearly as far. The OIG attempted to propose a similar set of value-based safe harbors under its authority, but by adding a number of safeguards that are not present in the Stark proposed regulatory changes, CMS' offer of regulatory relief may be undermined by the OIG.

Value-Based Exceptions

CMS proposes three regulatory value-based exceptions combined into one new subsection of the Stark law compensation exceptions at 42 C.F.R. § 411.357. CMS also proposes to protect indirect value-based arrangements under a new exception for indirect compensation arrangements with physicians. These exceptions are in response to industry concerns that it is not as clear as it should be that common and beneficial arrangements, such as gainsharing, pay-for-quality arrangements, and clinically integrated networks, fit within a Stark compensation exception. Under these four proposed exceptions, the number of regulatory requirements and safeguards increases as the level of financial risk accepted by the parties to the arrangements decreases. The value-based exceptions only protect compensation arrangements. Any ownership arrangement that parties claim is a value-based arrangement will not be protected under these proposed exceptions.

CMS explained the challenge of crafting a regulation that was broad enough to allow for innovative value-based arrangements in an evolving environment. While many commenters to CMS' Request for Information sought a one-size-fits-all approach, CMS was concerned that providing one regulatory solution would not be adequate. CMS was driven by multiple goals: lowering regulatory barriers while also encouraging entities to take on greater levels of financial risk. While CMS is definitely moving parties to greater levels of risk, it is uncertain whether the agency accomplished its goal of reducing regulatory complexity. CMS eliminated the typical safeguards of fair market value, prohibiting payment based on the volume and value of referrals, and requiring arrangements to be commercially reasonable. In their place CMS substituted the requirements of financial risk and additional contracting requirements. Value-based arrangement participants will need to evaluate whether these trade-offs will allow innovative payment arrangements to flourish.

Framework/Definitions

All three value-based exceptions focus on a core entity called a "value-based enterprise" or "VBE." The VBE is made up of two or more participants, called VBE Participants. The VBE Participants need to collaborate to achieve at least one value-based purpose. Each of those Participants needs to be a party to a value-based arrangement with at least one other VBE Participant in the VBE. The VBE needs to have a body or person that is accountable for the financial and operational oversight of the VBE. Finally, the VBE needs a governing document that describes the VBE and how the VBE Participants intend to achieve their value based purpose.

CMS defines a VBE Participant as an individual or entity that engages in one value-based activity as part of a VBE. Many different entities can be a VBE Participant including hospitals,

physician groups, and physicians. CMS recognizes that within the definition of VBE Participant, it uses the word "entity" to describe VBE Participants. CMS makes clear that the word "entity"[2] within the VBE Participant definition is distinct from the narrower Stark law defined term "Entity." CMS recognizes the potential for confusion in using the same word in two different ways within the same regulation, but is trying to align its definitions with the OIG proposed definitions in the value-based safe harbors. CMS may want to revise the existing definition of entity or use a different word within the VBE Participant definition to avoid predictable confusion in the future.

CMS is contemplating whether any entities should be excluded from the definition of VBE Participant. For example, CMS is considering following the OIG's lead by excluding laboratories; pharmaceutical manufacturers; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, and supplies; pharmacy benefit managers; wholesalers; and distributors from the definition of VBE Participant due to program integrity concerns. CMS specially calls out laboratories and durable medical equipment suppliers as entities that do not appear to directly connect with patients and have less justification to enter into value-based arrangements. CMS notes that these entities would not be prohibited from contracting with VBEs and VBE Participants, but they would not be protected by the value-based exceptions. If CMS and the OIG narrow the list of potential VBE Participants, they will make a policy choice that these entities will not be able to engage in value-based arrangements. This potential change will curtail the movement of the entire health care industry towards value-based arrangements, which is one of the stated goals of both CMS and OIG. In turn, the true utility of these exceptions would be greatly diminished. Instead, CMS (and OIG) could consider adding additional regulatory safeguards for certain VBE Participants rather than simply excluding them from participation.

By protecting a value-based enterprise, CMS is attempting to create a universal definition that can cover different permutations of value-based arrangements and the umbrella organizations in which some value-based arrangements operate. For example, the VBE definition appears to protect value-based entities, like accountable care organizations (ACOs) or clinically integrated networks, where a group of providers collaborate to coordinate care. It also likely applies to contract-based value-based arrangements between two parties, like a bundled payment arrangement between a hospital and a physician group practice. This universal definition gives parties flexibility to enter into different types of arrangements without the government prescribing the form and structure of those arrangements.

To qualify as a value-based arrangement, the arrangement must be reasonably designed to achieve at least one value-based purpose. A value-based purpose is defined as one of four goals related to a target patient population: (1) coordinating and managing the care of a target patient population;[3] (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payers without reducing the quality of care for a target patient population; and (4) transitioning from health

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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. This value-based purpose test seems to be a further refined list of goals that first appeared in the Medicare Shared Savings Program (MSSP) fraud and abuse waivers. Specifically, under the pre-participation and participation waivers, CMS and OIG said that the protected financial arrangement needed to be "reasonably related to the purposes of the Shared Savings Program."[4] If you compare the "purposes of the Shared Savings Program" test with the "value-based purpose" test, there are many similarities between the two.

VBEs must carefully consider each activity that they engage in that may violate the Stark law, and if they plan to use these value-based exceptions, they must determine how they will be working towards one of these value-based purposes. Yet, the four value-based purposes seem vague as written. It is clear that the value-based purpose test will have teeth. In preamble discussion, CMS provided some specific examples of what would not satisfy the value-based purpose test. For example, if the value-based purpose of a VBE is to improve quality while reducing costs, and the VBE is providing patient care services but not monitoring utilization, it would seem that they are not meeting the value-based purpose test.[5] So, while the standard itself is vague, CMS clearly has a specific idea of what would and would not qualify as a value-based purpose. Because health care entities like certainty and "bright-line" rules under the Stark law, this vague value-based purpose test may lead many entities to forgo using these exceptions without more guidance from CMS as to what is and what is not a value-based purpose.

These three exceptions protect value-based arrangements between the VBE and a VBE Participant or between or among VBE Participants in the same VBE. For example, a value-based arrangement can be between an ACO and participating group practices, or between different group practices that are within the same ACO. In all cases, the value-based arrangement must be reasonably designed to achieve at least one value-based activity.

CMS defines a value-based activity as the provision of an item or service, taking an action, or refraining from an action. The value-based activity needs to be designed to achieve at least one value-based purpose. In other words, each VBE Participant

who desires Stark law protection for remuneration received under these exceptions will need to meaningfully work towards achieving one of the VBE's goals. No free-riders will be tolerated, as each participant will need to fulfill their responsibilities to achieve the goals of the enterprise.

The definition of "value-based activity" explicitly excludes "the making of a referral."[6] It is understandable that CMS would not want to protect payments for referrals under these new exceptions. After all, the purpose of the statute is to prohibit physician *self-referral,* and CMS clearly feels that approving these types of payments is a bridge too far. However, "taking of an action" and "refraining from taking an action," both "value-based activities," certainly appear intended to protect financial incentives to order or not order a service or item consistent with evidence-based clinical protocols designed to improve quality or lower costs without diminishing the quality of the care. Additionally, coordination and management of care, one of the value-based purposes, is unattainable without financial incentives for physicians to refer patients to a particular provider, supplier, or practitioner, incentives expressly contemplated by all three value-based exceptions. CMS should clarify precisely what it means by a "referral" not being a "value-based activity" because remuneration needing the protection of the value-based exceptions will in certain cases most definitely be contingent on and arguably for "[t]he making of a referral," as "referral" is defined by the Stark regulations.

Each VBE needs to have a governing body or an individual that is responsible for financial and operational oversight of the VBE. This requirement is consistent with existing fraud and abuse waivers that require managing board responsibility and oversight for a value-based entity participating in the MSSP or a Center for Medicare & Medicaid Innovation model. Yet here CMS provides more flexibility, recognizing that some contractual arrangements will not have a separate legal entity nor a governing board that is created for the VBE. As an alternative to a governing board, VBEs can identify an individual who will have oversight responsibility without the need to create an unnecessary layer of governance.

Finally, the VBE will need to create a document that describes the VBE and how the participants intend to achieve its value-based purpose. This requirement does not appear to be burdensome or controversial in that all value-based entities or parties entering into value-based arrangements will generally document that arrangement in writing either through a contract or operating agreement. While certain value-based exceptions have more writing requirements than others, they all require the VBE to create and keep records of all compensation methodologies used for at least six years. There are some value-based arrangements between parties that are not always documented, such as the granting of data analytics tools within a network. Assuming these regulations are finalized as proposed, while not particularly onerous, the writing requirements will increase the risk of inadvertent noncompliance.

Three Exceptions

Full Financial Risk

The first value-based arrangement exception offers protection for remuneration between VBE Participants or between a VBE Participant and the VBE (if a distinct entity) within a VBE that is at full financial risk during the entire duration of the value-based arrangement. "Full financial risk" means the VBE is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payer for each patient in the target patient population for a specified period of time. For example, if a clinically integrated network agrees to manage the delivery of care to a payer's enrollees for a set capitated amount of money, that would satisfy the "full financial risk" requirement. Being at full financial risk for only a portion of patient care does not appear to satisfy this requirement.

Assuming that the VBE can satisfy this challenging requirement, the VBE Participants can enter into value-based arrangements with each other without significant restrictions. They will need to set the arrangement in advance of execution and determine how the arrangement will meet the VBE's value-based goals, but there are no additional restrictions such as a fair market value or volume and value of referrals requirement. Given that the existing Stark risk-sharing exception is interpreted broadly by CMS, and, thus, will in most cases apply to remuneration to a physician participating in a VBE taking full financial risk, it will in many cases be unnecessary for a VBE at full financial risk to assume the burdens of the full financial risk exception.

Meaningful Downside Financial Risk to the Physician

The main difference between the meaningful downside risk exception and the full financial risk exception is the level of risk that the physician needs to take. Under this exception, the physician needs to be at meaningful downside risk with an "entity." Meaningful downside financial risk means that a physician is responsible for paying "the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement" or the physician "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 specific period of time."[7] Because this exception directly requires physicians to take on financial risk, and to date many physicians have been unwilling or unable to accept substantial downside risk, it is possible that this particular exception will see limited use.

Under both definitions of "meaningful downside financial risk," the physician will be responsible for payment to "the entity." As noted above, CMS already identified the potential confusion with referring to "entities" in value-based arrangements. Although the "entity" is apparently the business entity or individual who is conveying remuneration directly to the physician (or medical practice in which the physician "stands in the shoes") for her value-based activity, it is unclear in the regulatory text whether "entity" means a health plan, managed

care organization, the VBE, another VBE Participant, an "entity" as defined at 42 C.F.R. § 411.351 (a "DHS entity"), or all of the above when conveying remuneration for a value-based activity to a physician taking meaningful downside financial risk.[8] A VBE Participant is defined in the regulation as an individual or entity, and it is possible that CMS intended for the financial responsibility to be payable to an entity that is also a VBE Participant, but not an individual that is a VBE. CMS will need to provide greater clarity in the final regulation as to what entity the physician must enter into this risk-based arrangement with. As discussed more fully below, this will be especially important in an indirect value-based arrangement. And again, given that the existing Stark risk-sharing exception is interpreted broadly by CMS and, thus, will in most cases apply to remuneration to a physician taking "meaningful downside financial risk," it will in many cases be unnecessary for the entity and the physician to assume the burdens of this exception. We recognize that some meaningful downside risk arrangements between a hospital and a physician may not apply to specific enrollees and therefore, the risk-sharing exception may not be available in all cases. Yet, we still believe that the risk-sharing exception may be available in many cases.

Under the second, alternative definition of "meaningful downside financial risk," the physician must be financially responsible on "a prospective basis" for the cost of all or a defined set of patient care services. The term "prospective basis" is a defined term under the regulation, meaning that a *VBE* has assumed financial responsibility for the cost of all patient care items or services covered by the applicable payer prior to providing items or services.[9] CMS has created confusion by using this defined term "prospective basis" under both risk-based exceptions. Under the full risk exception, CMS intended that the VBE is at financial risk, but under the downside risk exception, it intended for the physician to be at financial risk. But because the term "prospective basis" only refers to financial risk of the VBE, and not the physician, CMS should refine the regulatory language in the final rule to clearly articulate its intent.

As CMS promised, this second exception would have additional regulatory requirements commensurate with the lower level of financial risk. Specifically, under this exception, the description of the nature and extent of the downside risk must be set forth in writing, and "the methodology used to determine the amount of remuneration is set in advance of the undertaking of the value based activity for which the remuneration is paid." In contrast, the full financial risk exception does not have the writing and set in advance requirements. As noted above, given that the existing Stark risk-sharing exception is interpreted broadly by CMS and, thus, will in most cases apply to remuneration to a physician taking "meaningful downside financial risk," it will in many cases be unnecessary for the entity and the physician to assume the burdens of this exception.

Value-Based Arrangements

The third value-based arrangement exception, suitable for gainsharing, pay-for-quality, and other no-risk arrangements, requires no physician or VBE financial risk, but adds additional regulatory requirements that must be satisfied. CMS not only required that these arrangements be put in writing, but it also inserted the "signed by the parties" requirement. Further, CMS was quite prescriptive regarding what needed to be included in the writing, mandating that the value-based activities must be described, explaining how the value-based activities will further the value-based purpose of the enterprise and identifying the target patient population, the type or nature of the remuneration, the methodology to determine the remuneration, and the performance or quality standards that will be measured, if any. Further, if any performance or quality measure is used, that it be objective and measurable and that any change in methodology must be prospective. This last requirement is notable in that CMS is not mandating that there be any measurable performance or quality measures, but only that if one is used, that it be in writing, objective, and measurable.

These additional requirements will significantly increase transaction costs as well as make it more likely that parties will be subject to technical violations. Further, CMS provides a lengthy example in its preamble on the implicit need to monitor the value-based arrangement protected under this exception.[10] If the value-based arrangement ultimately proves to not meet a value-based goal, the arrangement would no longer be protected under the exception. This implicit ongoing monitoring requirement adds a layer of ambiguity to the exception, where parties may not know the exact point in time where the exception no longer applies. And parties may be reluctant to invest in a care intervention where it may abruptly need to stop a particular protocol when it no longer meets the vague point in time when the exception no longer applies. While CMS is clearly trying to limit the complexity of certain Stark regulations and avoid common pitfalls that lead to faultless Stark law violations, this value-based exception seems to move in the opposite direction.

Assuming providers and physicians can get comfortable with the level of potential technical risk and ambiguous standards, and the transaction costs of putting together a value-based arrangement under this part of the exception are not prohibitively high, this last exception provides the most attractive path towards value-based arrangements. While there are many requirements under this exception, they generally involve contracting and monitoring. Yet, the exception does not require any financial risk, nor does it require that remuneration be fair market value or that it not be based on the volume or value of referrals or other business generated between the parties. It seems that many providers and certainly physicians are not ready for full financial risk or even meaningful downside risk arrangements. Therefore, this last exception provides the most likely path for entities to pursue value-based arrangements.

Indirect Value-Based Arrangements

Finally, CMS has recognized that value-based arrangements will often create indirect compensation arrangements between a physician and another VBE Participant that is a DHS entity. Therefore, CMS is proposing to make the three value-based exceptions at proposed 42 C.F.R. § 411.357(aa) applicable to indirect financial arrangements where the relationship closest to the physician is a value-based arrangement. This is

a welcome addition, in that many problematic value-based arrangements are indirect compensation arrangements that would not otherwise be protected under existing exceptions. However, CMS should add the existing "risk-sharing" exception to its proposed list of exceptions applicable to indirect compensation arrangements (proposed 42 C.F.R. § 411.354(c)(4)). The "risk-sharing exception" expressly references compensation conveyed "directly or indirectly" and this exception has been and should continue to be available to DHS entities, such as hospitals, that have indirect compensation arrangements with physicians resulting from risk-sharing arrangements.

Impact of AKS Proposal for Safe-Harbor

The three Stark law value-based exceptions cannot be reviewed in a vacuum. For many value-based arrangements, parties will need to comply with both the Stark law and the Anti-Kickback Statute. While the two risk-based exceptions are similar to their Anti-Kickback Statute counterparts, the no-risk value-based exception and safe harbor have some important differences that will ultimately lower the utility of the Stark value-based arrangement exception.

There are two important distinctions between both regulatory proposals. First, under the value-based arrangement exception, CMS will allow for monetary and in-kind remuneration to be protected. In contrast, the OIG will only protect in-kind remuneration under the value-based arrangement safe harbor. Next, under the value-based arrangement safe harbor, the OIG requires that the recipient of the in-kind remuneration contribute at least 15% of the value of the item or service. The value-based exception has no contribution requirement. The problem with the disparity in the Stark value-based exceptions and the OIG's value-based safe harbors is that value-based arrangements will by their very nature involve compensation that is contingent on retaining patients within the VBE and, when protocols warrant, referring patients for certain services or items. Unless the existing risk-sharing safe harbors apply to such compensation, and they will most certainly not apply to no-risk value-based arrangements, these compensation arrangements can easily be characterized by regulators and other plaintiffs as inducements to refer patients to particular providers and suppliers for federal health care program-covered services or items. Consequently, it is difficult to see how CMS' proposed value-based exceptions will have utility if the OIG's safe harbors do not mirror them.

"Recalibrating Scope and Application of the Regulations"

Beyond the proposed value-based exceptions, CMS also proposed revisions to existing exceptions and the creation of new exceptions. While the list of revised exceptions is too voluminous to cover in this article, we encourage interested parties to review proposed revisions to the rental of office space and equipment exceptions, remuneration unrelated to the provision of designated health services exception, payments by a physician exception, and the fair market value exception. We touch briefly upon two new exceptions, limited remuneration to a physician and cybersecurity, and revisions to existing exceptions, isolated transaction exception, and the EHR exception.

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Limited Remuneration to Physician Exception and Isolated Transaction Exception

Under the new limited remuneration to a physician exception, CMS proposes to protect remuneration from an entity to a physician for the provision of items or services by a physician that does not exceed $3,500 per calendar year, as adjusted for inflation.[11] Under this exception, the remuneration needs to be fair market value, cannot be determined in any manner that takes into account the volume and value of referrals or other business generated by the physician, and must be paid pursuant to an arrangement that is commercially reasonable. Additionally, this exception also protects certain compensation for the lease of office space and equipment.

This exception is notable in that there is no writing, signature, or set in advance requirement. CMS explained that, based upon its experience through the Self-Referral Disclosure Protocol, the agency found a number of situations where parties sporadically fell out of compliance due to these technical errors, but that the physician was still receiving fair market value reimbursement for his provision of items or services. CMS set the aggregate compensation limit within this exception at a low enough level that it believed there was no risk of program or patient abuse. This exception would allow for parties to come into compliance with another existing exception within a reasonable period of time. It seems clear that if finalized, this exception will allow CMS to lower the number of self-disclosures related to minor contract management issues.

Finally, we note that CMS is proposing to "clarify" the isolated transaction exception by providing a new definition of isolated financial transactions at 42 C.F.R. § 411.351. Under the new definition, an isolated transaction only constitutes a single payment or a transaction that involves integrally related installment payments. CMS goes on to say that isolated transactions can include a one-time sale of property or a practice but cannot include a single payment for multiple or repeated services (such as a payment for multiple services previously provided yet not compensated.) While certain health care attorneys have taken the position that the isolated transaction exception protects a one-time catch-up payment for past services rendered without a signed writing, CMS is making clear that the isolated transaction exception is not available for this purpose. It seems that CMS is offering the limited remuneration exception as an alternative pathway to compliance that is not available through the isolated transaction exception.

EHR Exception Revisions and New Cyber Security Exception

CMS is proposing a number of changes and updates to the existing EHR exception as well as proposing a new exception to protect the donation of cybersecurity technology and related services.

CMS is proposing the following changes to its existing EHR exception: updating the interoperability definition to align with current HHS definitions, updating the data lock-in provision to incorporate the prohibition on information blocking, clarifying that the donations of certain cybersecurity software and services is permitted under the EHR exception, removing the sunset provision, and modifying definitions to have them align with the 21st Century Cures Act.[12] While not yet in regulatory text, CMS is contemplating removing the 15% donation contribution requirement or at least modifying the requirement so that it applies in limited circumstances.

Additionally, CMS is proposing a new regulatory exception for the donation of cybersecurity technology and related services.[13] This exception requires that the technology is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. Eligibility for the technology or services, or the amount of the technology or services, cannot directly take into account the volume or value of referrals or other business generated between the parties. In addition, receipt of the technology cannot be a condition of doing business with the donor. Finally, the exception is clear that the donation of cybersecurity hardware is not protected. C

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Views and opinions expressed in this article are those of the authors alone and not the law firms with which the authors are affiliated or AHLA.

Endnotes

1 84 Fed. Reg. 55766 (Oct. 17, 2019).
2 42 C.F.R. § 411.351.
3 CMS proposes to define Target Patient Population in 42 C.F.R. § 411.351 to mean: "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."
4 *See* 80 Fed. Reg. 66726, 66742 (Oct. 29, 2015) where CMS and OIG defined the following purposes: (1) promoting accountability for the quality, cost, and overall care for a Medicare population as described in the Shared Savings Program; (2) managing and coordinating care for Medicare fee-for service beneficiaries through an ACO; and (3) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.
5 *See* 84 Fed. Reg. 55766, 55773 (Oct. 17, 2019).
6 *Id.* at 55773.
7 *See* proposed 42 C.F.R. § 411.357(aa).
8 42 C.F.R. § 411.351 (Definition of entity).
9 *See* proposed 42 C.F.R. § 411.357(aa)(1)(vi).
10 *See* 84 Fed. Reg. 55766, 55784-85 (Oct. 17, 2019).
11 *See* proposed 42 C.F.R. § 411.357(z).
12 Pub. L. No. 114-225 (Dec. 13, 2016).
13 *See* proposed 42 C.F.R. § 411.357(bb).