



SPECIAL REPORT

Untangling VBEs, ACOs and CINs

What to Know about CMS and OIG's Proposed Regulations

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INTRODUCTION

The Centers for Medicare & Medicaid Services and the Office of Inspector General recently released notices of proposed rulemaking relating to the Stark Law and the Anti-Kickback Statute. We break down the new proposed value-based care arrangement exceptions and safe harbors, and implications for provider contracting networks such as accountable care organizations and clinically integrated networks.

On October 9, 2019, in conjunction with the US Department of Health and Human Services (HHS) Regulatory Sprint to Coordinated Care initiative, the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of Inspector General (OIG) both released notices of proposed rulemaking relating to the federal physician self-referral statute (42 USC § 1395nn) and its associated regulations (42 CFR § 411.350 et seq.) (collectively, the Stark Law), and relating to the safe harbors under the federal Anti-Kickback Statute (42 USC § 1320a-7b(b)) and its associated regulations (42 CFR § 1001.952 et seq.) (collectively, AKS).

CMS proposes new Stark Law exceptions, and OIG proposes new AKS safe harbors for certain value-based care arrangements. Conceptually, value-based care arrangements are those that reward improvements in the quality and efficiency of care. They may take the form of shared savings, pay for performance, care management, gainsharing or efficiency arrangements. OIG and CMS state that the agencies worked together closely in developing the proposals to advance the transition to a value-based healthcare delivery and payment system that improves the coordination of care among physicians and other healthcare providers. Both agencies indicated that their focus is on value-based care models that improve health outcomes, lower costs or reduce growth of costs for patients and payors, and improve efficiencies in the delivery of care through care coordination.

LET'S BACK UP: HOW DO THE STARK LAW AND AKS CURRENTLY AFFECT ACO AND CIN ARRANGEMENTS?

Accountable care organizations (ACOs) and clinically integrated networks (CINs) are forms of provider contracting networks. Typically, provider contracting networks contract with healthcare providers to form a network of participating providers, and contract with third-party payors for the network's participating providers to render services to the payors' insureds.

The Stark Law prohibits referrals of Medicare patients to entities that perform designated health services (DHS) if the referring physician or her immediate family member has a financial relationship with that entity, unless an exception applies. AKS prohibits payment or receipt of remuneration for referrals of federal healthcare program beneficiaries. Typically, the ACO/CIN itself is not a licensed healthcare provider and is therefore not a DHS provider. However, often the owner capitalizing and funding the initial operations of the network is a DHS provider (*e.g.*, a hospital), and the participating providers in the network include both DHS entities and physicians. Accordingly, all financial arrangements by and among the network, its owners and participating providers must be scrutinized to ensure that they comply with the Stark Law and do not run afoul of AKS.

Typical ACO/CIN financial arrangements include the capitalization and funding of the network, including its infrastructure, and the opportunities created through

operation of the network—namely, third-party payor contracts negotiated by the ACO/CIN. Many hospital- and health-system-financed ACOs/CINs (where the ACO/CIN is not a DHS provider) have looked to the indirect compensation exception under the Stark Law to address network capitalization and funding of operations, at least until the ACO/CIN is self-sustaining through its operations. Specifically, the health system or hospital establishing the ACO/CIN typically provides initial and ongoing funding, which can create an indirect compensation arrangement with ACO/CIN physicians. The Stark Law indirect compensation exception requires that compensation be within the range of fair market value and not determined in any manner that takes into account the volume or value of referrals¹ or other business generated by the referring physician to the DHS entity.

For distribution of revenues received by third-party payors, many CINs/ACOs have looked to the Stark Law risk-sharing exception.² That exception protects compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses and risk pools) between a managed care organization or provider contracting network and a physician (either directly or indirectly through a subcontractor) for services provided to health plan enrollees (provided that the arrangement does not violate the AKS or any federal or state law or regulation governing billing or claims submission).

A facts-and-circumstances analysis applies to these arrangements under the AKS to ensure that the

¹ Subject to certain exceptions, a "referral" for Stark Law purposes means: (i) the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any DHS for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician; or (ii) a request by a physician that includes the provision of any DHS for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of DHS, or the certifying or recertifying of the

need for DHS. A referral excludes any DHS personally performed or provided by the referring physician.

² The current risk-sharing exception is presumably available to indirect compensation arrangements, such as distributions to physicians by hospital-owned provider networks. The proposed rule fails to include the risk-sharing exception in a newly proposed list of exceptions applicable to indirect compensation arrangements. This would be a significant departure from longstanding interpretation of this exception, which by its terms applies to indirect arrangements.

structure does not induce referrals of federal healthcare program beneficiaries.

CMS and OIG have issued waivers in connection with more than a dozen government programs, such as the Medicare Shared Savings Program (MSSP). These waivers generally waive application of the Stark Law, AKS and civil monetary penalties law provisions addressing inducements to beneficiaries to certain arrangements of an ACO if the ACO satisfies the requirements of the waiver. The waivers are specific to participation in the named government program and are not available to networks that do not participate in those programs. The waivers have been helpful to ACOs participating in programs such as MSSP. MSSP involves Medicare fee-for-service patients, and therefore the ACOs cannot rely on the risk-sharing exception.

PROPOSED RULES

For value-based arrangements, OIG proposes three new safe harbors (full financial risk, substantial downside financial risk and care coordination), and CMS proposes three new Stark Law exceptions (full financial risk, meaningful downside financial risk and other value-based arrangements). The safe harbors and exceptions vary by the types of remuneration protected (in-kind or in-kind and monetary), the level of financial risk assumed by the parties, and specific conditions. The safe harbors and exceptions follow a tiered structure and offer greater flexibility where the parties assume more downside risk for the cost and quality of care. OIG intended for the value-based safe harbors to be stricter than CMS's correlating exceptions, and thus each AKS safe harbor has more

requirements and compliance elements than the corresponding Stark Law exception.

The proposed new exceptions and safe harbors protect remuneration under a qualified value-based arrangement (VBA). A VBA is an arrangement for the provision of at least one value-based activity for a target patient population between a value-based enterprise (VBE) and one or more of its participants, or among participants in the VBE. A value-based activity means providing an item or service, taking an action or refraining from taking an action, so long as the activity is reasonably designed to achieve at least one value-based purpose of the VBE and as long as the activity is not simply making a referral.

A value-based purpose is:

- Coordinating and managing the care of a target patient population³
- Improving the quality of care for a target patient population
- Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population
- Transitioning from healthcare 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.

A VBE is a collaboration between two or more VBE participants to achieve at least one value-based purpose. The VBE must have an accountable body or person responsible for financial and operational oversight of the VBE, and a governing document that

³ In the OIG proposal, the coordination and management of care is a "mandatory" purpose that must be present in any VBA. CMS does not have a mandatory purpose. Under the CMS proposal, a

protected VBA can engage in any one of the four enumerated value-based purposes.

describes the VBE and how its participants intend to achieve the VBE's value-based purposes. Other than the foregoing, there are no structural or governance requirements for a VBE.

Both agencies define a VBE participant as an individual or entity that engages in at least one value-based activity through a VBE. OIG provides that the following may not be VBE participants:

- A pharmaceutical manufacturer
- A manufacturer, distributor or supplier of durable medical equipment, prosthetics, orthotics or supplies
- A laboratory

STARK LAW EXCEPTIONS

All three Stark Law exceptions have common core requirements but differ in the amount of risk the VBE or physician must assume, and in other respects. Under the proposed full financial risk exception, the VBE must be at full financial risk (or contractually obligated to assume full financial risk within six months of entering into the arrangement). Remuneration need not be set in advance, and the arrangement need not be in writing.

The meaningful downside financial risk exception would require the physician to have meaningful downside financial risk in the event the physician fails to satisfy the purposes of the VBE for the duration of the agreement. In this context, meaningful downside financial risk means that the physician is responsible to pay no less than 25% of the remuneration received under the arrangement, or is financially responsible to the entity on a prospective basis for the cost of all or a defined set of items and services covered by the applicable payor for a target patient population for a specified period. The physician's downside risk must

be set forth in writing, and the methodology for determining the remuneration must be set in advance.

The other VBA exception (Other VBA Exception) does not require the remuneration for value-based activities to be at any specified level of risk, but does require that specified elements of the arrangement be in a writing signed by the parties. If the recipient will be measured against performance or quality standards, those standards must be objective and measurable, and any changes must be made prospectively. Similarly, the methodology for determining remuneration must be set in advance.

Under all three exceptions, CMS requires that if remuneration is conditioned on the receiving physician's referral to a particular provider, practitioner or supplier, the condition must satisfy 42 CFR §411.354(d)(4)(iv), which permits referral requirements subject to patient, provider and payor choice.

AKS SAFE HARBORS

OIG offers the greatest flexibility in the proposed safe harbor for VBAs that assume full financial risk. OIG defines "full financial risk" as arrangements in which the VBE is financially responsible for the cost of all items and services covered by a payor for the target patient population and is prospectively paid by such payor. This means that the anticipated cost of all items and services to be covered by the payor for the specific target patient population is determined and paid in advance, rather than being billed and retrospectively reconciled and undergoing a retrospective reconciliation after the services are provided. Such arrangements may include upfront, capitated payments for all services covered by Medicare Part A and Part B for a target patient population, or a VBE that contracts with a Medicaid managed care organization that receives a fixed per-

patient per-month amount, so long as such fixed amount covers all Medicaid services furnished to the target patient population.

In contrast, entities that receive partial capitated payments or a mixed of fee-for-service and capitation payments would not be protected under this rule, although such entities may meet another new safe harbor. The definition of “full financial risk” would not prohibit VBEs from entering into global risk adjustments, risk corridors, reinsurance, stop loss agreements or other arrangements to protect against catastrophic loss. However, such arrangements must be genuinely limited to catastrophic loss and cannot be used to shift risk away from the VBE as a means to circumvent the exception.

OIG’s proposed safe harbor for arrangements with substantial downside risk would protect remuneration exchanged between participants of a VBE arrangement that assumes a substantial downside financial risk from a payor for providing items/services for a target patient population. The safe harbor would not protect any remuneration funded by, or otherwise resulting from contributions by, an individual or entity outside of the applicable VBE.

OIG’s proposed safe harbor for care coordination arrangements (i.e., arrangements with no risk assumption requirement) would protect in-kind (i.e., not monetary) remuneration used primarily to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Among other requirements, the remuneration cannot be funded by, or otherwise result from, contributions of any individual or entity outside of the VBE. Recipients also have a 15% cost-sharing obligation.

Appendix 1 contains a summary of the respective requirements of the proposed AKS safe harbors and Stark Law exceptions for VBAs.

IMPLICATIONS

This analysis focuses on the prescriptive Stark Law exceptions, since, if a VBA gives rise to a financial relationship between a DHS entity and a physician, an exception must be met in order for the physician to make DHS referrals to a DHS entity. Meeting an AKS safe harbor is voluntary, and not meeting a safe harbor does not mean that the AKS is violated, but rather that a facts-and-circumstances analysis is required. The AKS safe harbors in their current state are so detailed—and somewhat unclear—that they would be difficult to apply. As a practical matter, unless the safe harbors are revised and streamlined, they may be of most use in the context of a facts-and-circumstances analysis under the AKS, where the safe harbors are used as guidance for relevant factors to consider.

THE GOOD NEWS

The following elements of the Proposed Rules are likely to be helpful to provider networks:

- The existing Stark Law risk-sharing exception only covers remuneration for services provided to enrollees of a “health plan.” It is unclear under the existing Stark Law risk-sharing exception whether payments not directly related to the risk-sharing payments from a plan, such as furnishing case management personnel or data analytics software to physicians, are covered by the exception. The proposed VBA exceptions apply to services for target patient populations and are not limited to services to health plan enrollees or payments from a plan. These types of services may include those under

hospital efficiency, gainsharing and service line co-management agreements.

- Hospital-owned ACOs/CINs have historically relied on an indirect compensation analysis, either to take the position that no indirect compensation arrangement exists, or that the indirect compensation exception applies to payments to physicians. The latter requires that compensation be fair market value and not determined in a manner that takes into account the volume or value or other business generated by the referring physician to the DHS entity.⁴ The proposed VBA exceptions eliminate both the volume and value and fair market value requirements. This elimination should benefit networks in several ways. First, eliminating the volume and value requirement reflects the fact that working together to achieve the goals of a VBA necessarily requires referrals among the parties to the arrangement. Second, networks will not have to demonstrate that distributions to physicians are fair market value. Given a lack of readily available public benchmarking data for value-based payments, demonstrating fair market value of such payments has not been a simple or quick exercise. Also, the requirement has presented challenges when a network wishes to reward the performance of a high-performing, already highly compensated physician. Finally, without a fair market value requirement, an ACO/CIN may provide assistance to physicians, such as data analytics software, to help achieve value-based purposes.

- The proposed clarification to when compensation “takes into account the volume or value of referrals or other business generated” is not explicitly aimed at VBEs, but it suggests that many types of value-based payments arguably do not give rise to a direct or indirect (depending on the contract structure) compensation arrangement with DHS entities.⁵ One area that can raise concern is hospital funding of a CIN without commensurate physician funding, and continued subsidization of the CIN. This currently is justified as not being “remuneration” to physicians because it is unrelated to the volume or value of referrals or other business generated, and will be even more strongly justified on this basis if the proposed revision is adopted.

Further good news is that CMS does not propose any prescriptive requirements to qualify as a VBE. It is likely that many ACOs and CINs are already VBEs and so do not have to take any further action to be considered as such, since a VBE is a collaboration of two or more VBE participants.

THE NOT SO GOOD NEWS

While the proposals are certainly helpful to provider networks, elements of the proposals could be barriers to qualifying for an exception. These include the following:

- For two of the three new exceptions, the methodology for determining remuneration must be set in advance. CMS is not requiring

⁴ In circumstances where there is a direct compensation arrangement between a DHS entity and physician, the personal services exception typically is used. That exception also requires that compensation be fair market value and not determined in a

manner that takes into account the volume or value or other business generated by the referring physician to the DHS entity.
⁵ See commentary at 84 Fed. Reg. at 55793–55795, discussing proposed § 411.354(d)(5) and (6).

the actual compensation to be set in advance, just the methodology for determining that compensation. However, metrics and performance criteria often are fine-tuned during performance periods, as best practices and clinical programs designed to achieve those metrics evolve and clinical data becomes available. In many cases it is therefore not feasible to have a concrete distribution plan at the onset of a performance period.

- Often, provider networks look for safeguards against unlimited downside risk, and carve-outs are not atypical. State insurance laws also generally prohibit entities from accepting full risk or even partial risk unless they are licensed as an insurer or are in a downstream arrangement with a plan. Therefore, a plan would be involved in the arrangement, and the parties could avail themselves of the existing risk-sharing exception for most types of distributions. If the Full Risk Exception is not available, then the types of items and services that are not part of the risk-sharing distribution might not be protected. Note,

however, that the Meaningful Physician Risk Exception or Other VBA Exception could be available if all requirements of those exceptions could be met.

- With respect to meaningful physician risk, physicians rarely have the obligation to make a repayment of payments from a CIN. Rather, the CIN makes payment only after the physician's share is determined. This can take the form of a withhold or a bonus, but the end result is that the physician is at risk that he will not receive the full amount of payment unless certain financial and/or quality metrics are met. Therefore, the Meaningful Physician Risk exception may have limited use, unless revised to recognize that forfeiting a potential payment is equivalent to making a repayment.
- The Other VBA Exception requires that both the methodology used to determine the remuneration and the performance standards be set forth in the written agreement. As discussed, this may not be practical for many arrangements.

WHERE THIS LEAVES THINGS

The following chart lists Stark Law exceptions that could potentially be available for financial arrangements between participating physicians and VBEs (*e.g.*, ACOs/CINs that qualify as VBEs) owned by DHS entities:

TYPE OF FINANCIAL ARRANGEMENTS	POTENTIAL STARK LAW EXCEPTION
VBE is at full risk from a plan. Distributions from the plan payments to the VBE are made to physicians based on a combination of payment for services to plan beneficiaries, achievement of surpluses under the risk-sharing arrangement and achievement of quality metrics with	The current risk-sharing exception would protect the potential financial relationships between the hospital and physicians. In this context, the proposed exceptions are unnecessary.

respect to plan beneficiaries (e.g., some or all surplus payments are made contingent on meeting quality and other value-based metrics).

Same facts as above, except that the VBE pays for telemedicine equipment and software for VBE physicians, so that the physicians can provide telemedicine services to plan beneficiaries.

If the telemedicine equipment and software are not considered “risk-sharing compensation” protected under the risk-sharing exception, the proposed full risk exception could be helpful to replace the current indirect compensation analysis. Note that few arrangements are truly full risk. However, an arrangement that does not fit the “full risk” definition could perhaps fit the Meaningful Physician Risk Exception or Other VBA Exception.

Same facts as above, except that the physician may use the equipment for non-plan beneficiaries as well as plan beneficiaries, including Medicare patients.

Same as above.

The VBE is paid by a plan if the VBE participants achieve certain cost savings and quality metrics, and the VBE distributes the payments to VBE participants, including physicians. There is no downside risk except the risk of not receiving the distribution

The current risk-sharing exception would protect the potential financial relationships between the hospital and physicians. In this context, the proposed exceptions are unnecessary and might not be available. Since the physicians do not have downside risk as defined in the proposed Meaningful Financial Risk exception, only the Other VBA Exception is potentially available. The requirements for measurement of performance and strict set in advance standard may be obstacles.

Same as above, except that the VBE places a nurse navigator in physicians’ offices to help coordinate care to achieve cost savings and quality metrics.

This element of remuneration might not be viewed as a risk-sharing payment under the risk-sharing exception. For the reasons described above, the Meaningful Physician Risk Exception would not apply. The proposed Other VBA Exception would be helpful here, but difficult to meet, as noted above.

Gainsharing arrangement: VBE contracts with hospital to reduce the cost of certain services through the efforts of VBE physicians in areas such as choosing lower cost items where clinically appropriate. Cost savings are paid to the VBE, which distributes savings to the physicians.

Currently, gainsharing arrangements generally are structured to try to address the volume/value and fair market value requirements of existing exceptions. It is not clear if the proposed Other VBA Exception would be available for distributions based only on cost savings. Also, most gainsharing arrangements as currently structured would not meet the standards for the Meaningful Physician Risk Exception unless the “downside” is revised to include forfeiture of potential payments.

Same as above, except that distribution of the cost savings is contingent on meeting certain quality metrics.

This type of arrangement is more clearly eligible for protection under the proposed Other VBA Exception. As noted above, such arrangements could meet the Meaningful Physician Risk Exception if the definition of downside risk included forfeitures as well as repayments.

TAKEAWAYS

Assuming that CMS and OIG will finalize the exceptions and safe harbors in materially the same form, CINs and ACOs may wish to consider taking the following steps:

-
- CINs and ACOs should determine whether it would be possible to document performance and distribution criteria in advance of the performance period. If so, the CIN/ACO can consider whether the Other VBA Exception, if finalized, may be available to them.
-
- CINs and ACOs should identify whether there are other resources—such as nurse navigators, telemedicine or portals—that the networks may have historically been reluctant to provide to CIN/ACO participating providers because of the current regulatory gray area, but that are important for advancing the network’s value-based goals and could be provided under one of the proposed exceptions and safe harbors, to the extent financially feasible.
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APPENDIX 1

SUMMARY OF PROPOSED VBA STARK LAW EXCEPTIONS AND AKS SAFE HARBORS

STARK LAW

FULL FINANCIAL RISK

An exception for full financial risk VBAs would apply when:

1. The VBE is at full financial risk (or is contractually obligated to assume full financial risk within six months of entering into the arrangement).
2. The remuneration is compensation for value-based activities undertaken on behalf of the target patient population by the recipient.
3. The remuneration is not intended to induce the reduction or limitation of medically necessary items or services.
4. The remuneration is not conditioned on referring patients outside of the target patient population or other business outside the VBA.
5. The remuneration, to the extent conditioned on the receiving physician's referral to a particular provider, practitioner or supplier, satisfies 42 CFR § 411.354(d)(4)(iv).
6. Records relating to the arrangement and calculation of the remuneration are maintained for at least six years.

MEANINGFUL DOWNSIDE FINANCIAL RISK

The exception for VBAs with meaningful downside financial risk requires that the arrangement satisfy items (2) through (6) above, but adds the following mandates:

1. The physician has a meaningful downside financial risk in the event she fails to satisfy the purposes of the VBE for the duration of the arrangement.
2. The physician's downside financial risk is set forth in writing.
3. The methodology for determining the remuneration is set in advance, prior to the physician undertaking any value-based activities.

In order for the physician to satisfy the meaningful downside financial risk requirement, he must be responsible to pay no less than 25% of the remuneration received under the arrangement, or must be financially responsible to the entity on a prospective basis for the cost of all or a defined set of items and services covered by the applicable payor for a target patient population for a specified period.

OTHER VBA

Compensation exchanged between parties to a VBA qualifies for the proposed other VBA exception under the Stark Law if the arrangement complies with items (2) through (6) of the full financial risk exception, and also meets the following requirements:

1. The arrangement is set forth in a writing signed by the parties and describes the following:
 - a. The value-based activities to be undertaken
 - b. How the activities are expected to further the purposes of the VBE, the target patient population and the type of remuneration
 - c. The methodology used to calculate the remuneration, and the objective and measurable performance standards against which the recipient will be measured, if any.
2. To the extent that the recipient will be measured against any performance standards, such standards must be objective and measurable, and any

changes to such standards must be set forth in writing.

3. The methodology for determining the remuneration is set in advance, prior to the physician undertaking any value-based activities.

AKS

FULL FINANCIAL RISK

The VBAs with full financial risk safe harbor would protect remuneration if:

1. The VBE (either directly or through a VBE participant) has entered into a signed, written agreement to assume full financial risk from a payor for a target patient population for at least one year.
2. Such writing has a minimum one-year term and specifies the material terms of the VBA, including the activities to be undertaken by each party.
3. The VBE participant does not claim any form of payment, whether directly or indirectly, from a payor for items or services covered under the arrangement.
4. The remuneration (whether cash or in-kind) exchanged between the VBE and VBE participant meets the following requirements:
 - a. Is used primarily for the value-based activities of the parties set forth in (2) above
 - b. Is directly connected to the VBE's value-based purposes, which must include the coordination and management of care for the target patient population
 - c. Does not induce the VBE to limit medically necessary items or services
 - d. Does not provide an ownership or investment interest or distributions as a result of any such interests
- e. Is not funded by, or does not result from, contributions from any individual or entity outside of the VBE.

5. The VBE or VBE participant does not take into account the volume or value of referrals of patients outside the target patient population or business not otherwise covered under the VBA.
6. The VBE provides an operational utilization review program and a quality assurance program that protects against underutilization and specifies patient goals and outcomes as appropriate.
7. The VBA does not include marketing to or recruitment of patients.
8. The VBE or VBE participant agrees to make available to HHS, upon request, all records necessary to establish compliance with this exception.

SUBSTANTIAL DOWNSIDE FINANCIAL RISK

The proposed VBAs with substantial downside financial risk safe harbor would protect remuneration exchanged between a VBE and a VBE participant pursuant to a VBA if the following standards are met:

1. The VBE must have assumed, or be contractually obligated to assume, substantial downside financial risk from a payor for providing or arranging for the provision of items and services for a target patient population. The VBE can assume this risk directly if the VBE is an entity, or through a VBE participant acting as an agent of, and accountable to, the VBE.
 - a. OIG defined "substantial downside financial risk" as:
 - i. "Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of

- costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;
 - ii. Repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;
 - iii. Prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or
 - iv. Partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected FFS payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the VBAs.”
2. The terms of the VBA require the VBE participant to meaningfully share in the VBE’s substantial downside financial risk for providing or arranging for items and services for the target patient population.
 - a. This condition is intended to ensure that VBE participants ordering or arranging for items and services for patients closely share the VBE’s goals and share in accountability if those goals are not achieved.
 - b. A VBE participant “meaningfully shares” in the VBE’s substantial downside financial risk if the VBA contains one of the following:
 - i. “Risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor (*e.g.*, an 8-percent withhold, recoupment payment, or shared losses payment);
 - ii. Partial or full capitated payment or similar payment methodology (excluding the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and SNFs or other like payment methodologies); or
 - iii. In the case of a VBE participant that is a physician, a payment that meets the requirements of the Stark Law’s regulatory exception for VBAs with meaningful downside financial risk.”
 3. The VBA is set forth in a writing that contains a description of the nature and extent of the VBE’s substantial downside financial risk for the target patient population and a description of the manner in which the recipient meaningfully shares in the VBE’s substantial downside financial risk.
 4. The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target

patient population or business not covered under the VBA.

5. The VBA does not:
 - a. Place any limitation on VBE participants' ability to make decisions in the best interest of their patients
 - b. Direct or restrict referrals to a particular provider, practitioner or supplier if:
 - i. A patient expresses a preference for a different practitioner, provider or supplier.
 - ii. The patient's payor determines the provider, practitioner or supplier.
 - iii. Such direction or restriction is contrary to applicable law or regulations.
6. The VBA does not include marketing items or services to patients or engaging in patient recruitment activities.
7. The VBE or its VBE participants maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions and make such records available to the Secretary upon request.
8. The remuneration must be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk.
9. The remuneration exchanged must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population.

CARE COORDINATION

OIG's proposed safe harbor for care coordination arrangements would protect in-kind remuneration

exchanged between VBE participants to further care coordination under the following conditions:

- *Commercially Reasonable, Written Agreement:* The VBA must be commercially reasonable and set forth in a written agreement signed by the parties that covers:
 - » The value-based activities to be undertaken by the parties
 - » Term
 - » Target patient population
 - » A description of the remuneration
 - » The offeror's cost for the remuneration
 - » A description of the remuneration
 - » The offeror's cost for the remuneration
 - » The percentage of the offeror's cost contributed by the recipient
 - » If applicable, the frequency of the recipient's contribution payments for ongoing costs
 - » The specific, evidence-based valid outcome measure(s) against which the recipient would be measured.
- *Remuneration Limitations:* The in-kind remuneration:
 - » Must be used primarily to engage in value-based activities that have a direct nexus to the coordination and management of care for the target patient population
 - » Cannot induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items and services furnished to any patient
 - » Cannot be funded by, or otherwise not result from the contributions of, an individual or entity outside of the VBE. The offeror does not, and should not, know that the remuneration is likely to be diverted, resold or used by the recipient for an unlawful purpose.

- *Volume/Value Conditions:* The offeror cannot take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population and business not covered under the VBA.
- *Cost-Sharing:* The recipient of remuneration must pay for at least 15% of the offeror's cost for the in-kind remuneration.
- *VBA Requirements:* The VBA must:
 - » Be directly connected to the coordination and management of care of the target patient population
 - » Not place any limitation on the VBE participants' ability to make decisions in the best interest of their patients
 - » Not direct or restrict referrals if the patient, payor or practitioner determines otherwise
 - » Not include marketing to patients or engage in patient recruiting activities.
- *Monitoring and Assessment:* At least annually, the VBE, or the VBE's accountable body or responsible person, must monitor and assess:
 - » The coordination and management of care of the target patient population
 - » Any deficiencies in the delivery of quality care under the VBA
 - » Progress toward achieving the evidence-based, valid outcome measure(s) in the VBA.
- *Termination:* The parties must terminate the arrangement within 60 days if the VBE's accountable body determines that the VBA is unlikely to further the coordination and management of care for the target patient population, has resulted in material deficiencies in quality of care, or is unlikely to achieve the evidence-based valid outcome measures.
- *Documentation:* At any time upon request, the VBE participants must provide documentation that the parties comply with the safe harbor provisions.

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