ROPES & GRAY

SUMMARY TABLES

Value-Based Care Final Rules for Stark, Anti-Kickback, and Civil Monetary Penalties Regulations

Detailed Summaries

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Value-Based Care AKS Safe Harbors and Stark Exceptions (the "VBC Chart")

The table below summarizes the new value-based care AKS safe harbors and Stark exceptions, finalized largely in the same form described in the proposed rule. We provide key definitions in a glossary beginning on page 15.

	No-Risk Arrangements AKS: Care-Coordination Arrangements 42 C.F.R. § 1001.952(ee) Stark: Value-Based Arrangements 42 C.F.R. § 411.357(aa)(3)	**Partial-Risk Arrangements** AKS: Substantial Downside Risk 42 C.F.R. § 1001.952(ff) Stark: Meaningful Downside Risk 42 C.F.R. § 411.357(aa)(2)	**Full-Risk Arrangements** AKS: Full Financial Risk 42 C.F.R. § 1001.952(gg) Stark: Full Financial Risk 42 C.F.R. § 411.357(aa)(3)
Assumption of Risk	Neither **AKS** safe harbor nor **Stark** exception requires a value-based enterprise ("**VBE**") or eligible value-based enterprise participants ("**VBE Participants**") to assume risk.	To qualify for the **AKS** safe harbor • for a period of at least one year, the VBE (directly or indirectly through VBE Participants) must assume (or enter into a written contract or a value-based arrangement to assume in the next six months) risk as follows: o 30% of any loss of all items and services covered by the payor and furnished to the target patient population (compared to a bona fide benchmark); o 20% of any loss furnished to a target patient population pursuant to a defined clinical episode of care, where the parties design the clinical episode of care to cover items and services furnished in more than one care setting (compared to a bona fide benchmark); or o Receiving prospective, per-patient payment from a payor that is designed to produce material savings for a predefined set of items and services furnished to the target	The **AKS** safe harbor requires that a VBE is prospectively financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population for at least one year. 42 C.F.R. § 1001.952(gg)(10)(i).[1] The **Stark** exception requires a VBE to assume full financial risk from a payor for patient care services for a target patient population for the full term of the arrangement (following a ramp-up period of up to one year). 42 C.F.R. § 411.357(aa)(1)(i).

[1] OIG notes that it expects any stop-loss or other risk adjustment arrangements to act as protection for the VBE against catastrophic losses and not as a means to shift material financial risk back to the payor.

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
		patient population and that is paid on a monthly, quarterly, or annual basis. 42 C.F.R. § 1001.952(ff)(2). • The VBE Participant must be at risk for a meaningful share by: o Assuming two-sided risk for at least 5% of the losses and savings realized by the VBE pursuant to its assumption of substantial downside financial risk; or o Receiving from the VBE a prospective, per-patient payment for a predefined set of items and services furnished to the target patient population. 42 C.F.R. § 1001.952(ff)(3). To fit under the **Stark** exception, a physician must be at meaningful downside financial risk for failure to achieve the value-based purposes of the VBE, for entire term of the value-based arrangement, where the physician: • is responsible to repay or forgo the entity no less than 10% of the total value of the remuneration the physician receives under the value-based arrangement; or • 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 population for a specified period of time. 42 C.F.R. §411.357(aa)(2)(i).	
Ineligible Participants	**AKS** requires that remuneration is <u>not</u> provided by (or received by) the following	**AKS** prohibits Ineligible Participants from exchanging remuneration.	Same as for partial-risk arrangements (at left).

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	entities (collectively, the "**Ineligible Participants**"): • A pharmaceutical manufacturer, distributor, or wholesaler; • A pharmacy benefit manager; • A laboratory company; • A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs; • A manufacturer of a device or medical supply; • An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services) ("**DMEPOS**"); or • A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies. 42 C.F.R. § 1001.952(ee)(13). For purposes of the **AKS** only, a manufacturer of a device or medical supply or DMEPOS entity or individual may be eligible for participation in a VBE arrangement if they meet the requirements of a "limited technology participant." The AKS safe harbor protects "limited technology participants" by permitting them to participate in certain exchanges of digital health technology[2] with other VBE participants. 42 C.F.R.	For **Stark**, please refer to commentary under no-risk arrangements (at left).	

[2] Digital Health Technology includes hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	1001.952(ee)(12)(v) and (vi). These VBE arrangements may not condition exchange of the digital health technology on recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant. 42 C.F.R. § 1001.952(ee)(8). The value-based care risk arrangements that are protected under **Stark** do not have a parallel concept of Ineligible Participants.		
Limitations on Remuneration			
Protected Remuneration	**AKS** expressly permits in-kind remuneration only (excludes gift cards). 42 C.F.R. § 1001.952(ee)(1)(i). **Stark** permits in-kind and monetary remuneration. 42 C.F.R. § 411.351.	**AKS:** • Can protect monetary remuneration. • Does not protect ownership or investment interests (or distributions therefrom). 42 C.F.R. § 1001.952(ff)(4)(iii). **Stark** permits in-kind and monetary remuneration. 42 C.F.R. § 411.351.	Same as for partial-risk arrangements (at left).

Required Use	**AKS** requires remuneration to:
	• be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population;
	• not result in more than incidental benefits to persons outside of the target patient population; *and*
	• not be exchanged or used:
	  o more than incidentally, for the recipient's billing or financial management services; or
	  o for the purpose of marketing items or services furnished by the VBE or
		Except when remuneration is exchanged pursuant to a methodology for the assumption of risk**, AKS** requires remuneration to be used predominantly to engage (e.g., ancillary use must be minimal) in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume in the next six months) substantial downside financial risk investment interests (or distributions therefrom). 42 C.F.R. § 1001.952(ff)(4)(ii). When remuneration effectuates the assumption of risk required by the safe harbor, OIG exempts this remuneration from the requirement for	**AKS** requires remuneration to be directly connected to one or more of the VBE's value-based purposes, but does not require the use to be predominant.[3] 42 C.F.R. § 1001.952(gg)(5)(i).
			
			The **Stark** rule is the same as for partial-risk arrangements (at left).

[3] OIG provides more flexibility for a VBE assuming full financial risk to determine the value-based purpose(s) to which the exchange of remuneration is directly connected.

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	a VBE Participant to patients or for patient recruitment activities. 42 C.F.R. § 1001.952(ee)(2). **Stark** requires the remuneration to be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. 42 C.F.R. § 411.357(aa)(3)(ii).	remuneration to be used predominantly to engage in value-based activities. **Stark** requires the remuneration to be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. 42 C.F.R. § 411.357(aa)(2)(4)(ii).	
Impact on Medically Unnecessary/Necessary Items or Services	**AKS** requires that the value-based arrangement not induce parties to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient. 42 C.F.R. § 1001.952 (ee)((7)(iii). **Stark** requires that remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. 42 C.F.R. §411.357(aa)(3)(v).	Same as for no-risk arrangements (at left)	Same as for no-risk arrangements (at left)
Value-Based Arrangement Requirements			
Direct Connection to the Value-Based Purpose	**AKS** requires that the remuneration be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care. 42 C.F.R. § 1001.952(ee)(1)(ii). For **Stark**, CMS declined to limit the universe of compensation arrangements that will qualify as VBAs to those arrangements specifically for the coordination and management of patient care for any of the value-based exceptions.	**AKS** requires that the remuneration be directly connected to at least one of the following permitted value-based purposes: • coordinating and managing the care of a target patient population; • improving the quality of care for a target patient population; or • appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population. 42 C.F.R. § 1001.952(ff)(4). For **Stark**, please refer to commentary under no-risk arrangements (at left).	**AKS** broadly requires that remuneration be directly connected to one or more of any one of the VBE's value-based purposes. 42 C.F.R. § 1001.952(gg)(5)(i). For **Stark**, please refer to commentary under no-risk arrangements (at left).

<table>
<tr><th></th><th>NO-RISK ARRANGEMENTS</th><th>PARTIAL-RISK ARRANGEMENTS</th><th>FULL-RISK ARRANGEMENTS</th></tr>
<tr><td>No Limitation on Decision-making; Restrictions on Directing/Restricting Referrals</td><td>AKS prohibits a value-based arrangement from:
• limiting the VBE Participant’s ability to make decisions in the best interests of its patients;
• directing or restricting referrals to a particular provider, practitioner, or supplier if:
o a patient expresses a preference for a different practitioner, provider, or supplier;
o the patient’s payor determines the provider, practitioner, or supplier; or
o such direction or restriction is contrary to applicable laws under Medicare and Medicaid.
42 C.F.R. § 1001.952(ee)(7).

Stark requires that if remuneration paid to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the value-based arrangement must:
• set out the referral requirement in writing and signed by the parties; and
• not apply the referral requirement if:
o the patient expresses a preference for a different provider, practitioner, or supplier;
o the patient's insurer determines the provider, practitioner, or supplier; or
o the referral is not in the patient's best medical interests in the physician's judgment.
42 C.F.R. § 411.357(aa)(3)(x).</td><td>Same as for no-risk arrangements (at left).</td><td>The AKS is silent on any limitation or restriction of any VBE Participant’s ability to:
• make decisions in the best interests of its patients; or
• direct or restrict referrals to a particular provider, practitioner, or supplier.

The commentary indicates that with respect to both proposals, OIG believes the other protections in the full-risk safe harbors will be sufficient to protect against harm to patients or inappropriately influence referrals.

The Stark rule is the same as for no-risk arrangements (at left).</td></tr>
<tr><td>Marketing/Patient Recruitment</td><td>AKS requires that remuneration is not exchanged or used for the purpose of marketing items or services furnished by the</td><td>Same standards as the no-risk arrangement (left).</td><td>Same standards as the no risk arrangement (left).</td></tr>
</table>

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	VBE or a VBE Participant to patients or for patient recruitment activities. **Stark** is silent on marketing and patient recruitment terms.		
Commercial Reasonableness	Under **AKS** and **Stark**, the value-based arrangement must be commercially reasonable. However, **AKS** further requires consideration of commercial reasonableness on both the arrangement itself and all value-based arrangements within the VBE. 42 C.F.R. § 1001.952(ee)(2); 42 C.F.R. § 411.357(aa)(3)(x) (vi).	Not required for both **Stark** and **AKS**.	Same standards as the partial risk arrangement (left).

Documentation Requirements (in writing/form of agreement)	**AKS:**
	• Governing Document. Governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). 42 C.F.R. § 1001.952(ee)(14)(viii)(D).
	• Target patient population. Identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that are documented in advance of the commencement of the value-based arrangement. 42 C.F.R. § 1001.952(ee)(14)(v).
	• Description of Arrangement (signed by parties). 42 C.F.R. § 1001.952(ee)(3). Must include descriptions of:
	  o value-based purpose(s) of the value-based activities provided for in the value-based arrangement;
	  o value-based activities to be undertaken by the parties to the value-based arrangement;
		AKS:
		• Governing Document. Requires the same standards as no-risk arrangement.
		• Target patient population. Requires the same standards as no-risk arrangement.
		• Description of Arrangement (signed by parties). 42 C.F.R. § 1001.952(ff)(5). Must include descriptions of:
		  o Terms evidencing VBE is at substantial downside financial risk or will assume such risk in the next six months for the Target Patient Population;
		  o Manner in which VBE Participant (except payor whose risk is being assumed from) has a meaningful share of the VBE's substantial downside financial risk;
		  o Value-based activities, Target Patient Population, and type of remuneration exchanged.
		• VBE contract. If not provided in Description of Arrangement,
			AKS:
			• Governing Document. Requires the same standards as no-risk arrangement.
			• Target patient population. Requires the same standards as no-risk arrangement.
			• Description of Arrangement (signed by parties). 42 C.F.R. § 1001.952(gg)(3). Must include descriptions of:
			  o Value-based activities; and
			  o Term of arrangement.
			• VBE contract. Requires the same standards as partial risk arrangement.
			
			Stark:
			• Governing Document. Requires the same standards as no-risk arrangement.
			• Documentation of any required referral arrangement. Requires the same standards as no-risk arrangement.

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	o term of the value-based arrangement; o target patient population; o description of the remuneration; o either the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration; o the percentage and amount contributed by the recipient; o if applicable, the frequency of the recipient's contribution payments for ongoing costs; and o the outcome or process measure(s) against which the recipient will be measured. **Stark:** • Governing Document. Governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). 42 C.F.R. § 411.351. • Description of Arrangement (signed by parties). 42 C.F.R. § 411.357(aa)(3)(i). Must include descriptions of: o value-based activities to be undertaken under the arrangement; o how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; o target patient population for the arrangement; o type or nature of the remuneration;	documentation of the VBE's assumption of risk. **Stark:** • Governing Document. Requires the same standards as no-risk arrangement. • Description of Arrangement. Must include only a description of the nature and extent of the physician's downside financial risk. • Documentation of any required referral arrangement. Requires the same standards as no-risk arrangement.	

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	o methodology used to determine the remuneration; and o outcome measures against which the recipient of the remuneration is assessed, if any. ▪ Changes to Outcome Measures. Prospective changes to the outcome measures against which the recipient of the remuneration will be assessed. • Documentation of any required referral arrangement (signed by parties). If applicable, any requirement to make referrals to a particular provider, practitioner, or supplier. 42 C.F.R. § 411.357(aa)(1)(v)(A).		
Volume or Value of Referrals/Referrals Generally	Under **AKS**, the offeror must not take into account the volume or value of, or condition an offer of remuneration on: • referrals of patients who are not part of the target patient population; or • business not covered under the value-based arrangement. 42 C.F.R. § 1001.952(ee)(5). CMS did not finalize any requirement that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity for any of the value-based **Stark** exceptions.	**AKS** requires the same standards as the CCA (left).	**AKS** requires the same standards as the CCA (left).

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
Contribution Requirement	Under **AKS**, the recipient must pay at least 15% of the offeror's cost for in kind remuneration. • If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. • If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals. 42 C.F.R. § 1001.952(ee)(6). Under **Stark**, a contribution is not required for a VBC arrangement. Please refer to the "Donor Contribution" section in the EHR Chart for more detail on the required contribution under the EHR Stark exception.	None.[4] For both **AKS** safe harbor and **Stark** exception, it is possible for a value-based arrangement that does not require a contribution amount to protect a donation of EHR items and services so long as all relevant conditions under the partial risk or full risk safe harbors or exceptions are met.	Same as for partial risk arrangements (left).
Monitoring and Assessment	Under both **AKS** safe harbor and **Stark** exception, the VBE (or a representative) must monitor and assess, annually or at least once during the term of the value-based arrangement. **AKS** requires a report to be submitted to the VBE by its representative conducting the assessment. There are slight distinctions between the characteristics monitored under the safe harbor versus the exception. **AKS** requires the following must be monitored and assessed: • the coordination and management of care for the target patient population in the value-based arrangement;	No monitoring standard prescribed under **AKS** safe harbor or **Stark** exception.	**AKS** requires the VBE to provide or arrange for a quality assurance program that protects against underutilization and assesses the quality of care furnished to the target patient population. 42 C.F.R. § 1001.952(gg)(8). **Stark** requires the same as for partial risk arrangements (left)..

[4] CMS notes that donations of EHR items and services may be permissible under value-based care Stark exceptions. There is no requirement for recipients of donated EHRs items or services to contribute to the donor's cost for the items or services. A party seeking to protect an arrangement involving the donation of cybersecurity software and services only needs to comply with the requirements of an applicable exception, and a contribution may not be required. According to OIG, donations of EHR by VBEs to VBE Participants can be protected by compliance with a value-based safe harbor.

	No-Risk Arrangements	Partial-Risk Arrangements	Full-Risk Arrangements
	• any deficiencies in the delivery of quality care under the value-based arrangement; and • progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement. **Stark** requires the following must be monitored and assessed: • whether the value-based activities are met under the arrangement; • whether and how value-based activities continues to further the value-based purpose(s) of the VBE; and • progress towards outcome measure(s), if any, against which the recipient of the remuneration is assessed. For any negative findings, both **AKS** and **Stark** require timely action or termination within a required time frame.		
No Diversion, Resell, or Use for Unlawful Purpose	Under **AKS**, remuneration would not be protected if the offeror knows or should know that the remuneration is likely to be diverted, resold or used by the recipient for an unlawful purpose.[5] 42 C.F.R. § 1001.952(ee)(11). There are no provisions discussing diversion, resell, or use under any of the **Stark** exceptions.	None for **AKS** or **Stark**.	Same as for partial risk arrangements (left).
Materials and Records	Under **AKS**, the VBE must maintain for at least six years and make available to the HHS Secretary all materials and records sufficient to	Same as for no-risk arrangements (left).	Same as for no-risk arrangements (left).

[5] For purposes of diversion, resell, or use for unlawful purpose, the test is whether the nature or scope of the remuneration offered to the recipient is (1) far in excess of what could reasonably be needed for the recipient to undertake the value-based activity for which the remuneration is intended and (2) the remuneration is transferable in nature, such that the offeror should have known that diversion or resale is likely.

	NO-RISK ARRANGEMENTS	PARTIAL-RISK ARRANGEMENTS	FULL-RISK ARRANGEMENTS
	establish compliance with the conditions of the safe harbor. 42 C.F.R. § 1001.952(ee)(12). Under **Stark**, records of the methodology for determining the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years. 42 C.F.R. § 411.357(aa)(3)(xi).		

Patient Engagement and Support AKS Safe Harbor

The table below summarizes the new patient engagement and support AKS safe harbor (which, by virtue of the CMPL's protection of arrangements satisfying an AKS safe harbor, also protects arrangements from the CMPL's beneficiary inducements prohibition) and related provisions under the CMPL. OIG commentary clarifies that the beneficiary inducement provisions of the CMPL protect arrangements permitted under this safe harbor. We provide key definitions in a glossary beginning on page 15.

	ARRANGEMENTS FOR PATIENT ENGAGEMENT AND SUPPORT TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY *(“**Patient Engagement Safe Harbor**”)* *42 C.F.R. § 1001.952 (hh)*
Protected Remuneration	Protects patient engagement tools and supports furnished by a VBE Participant to a patient in the target patient population of a value-based arrangement to which the VBE Participant is a party. The patient engagement tool or support must be furnished directly to the patient (or the patient's caregiver, family member, or other individual acting on the patient's behalf)[6] by a VBE Participant or eligible agent.[7]
Ineligible Entities	This safe harbor excludes the following: • A pharmaceutical manufacturer, distributor, or wholesaler; • A pharmacy benefit manager; • A laboratory company; • A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs; • A manufacturer of a device or medical supply, but includes a pathway for manufacturers of devices or medical supplies to provide digital health technology; • An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services) (“DMEPOS”);[8] and • A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies. The final rule does not prohibit an entity that is a corporate affiliate or under shared ownership with an Ineligible Participant from offering protected tools and supports.
Patient Engagement Tool	The patient engagement tool or support must: • be an in-kind item, good, or service; • have a direct connection to the coordination and management of care of the target patient population; • not be a gift card, cash, or cash equivalent; and • be recommended by the patient's licensed health care professional.

[6] A tool or support would not be in violation of the safe harbor requirement if furnished to the patient indirectly through the patient's caregivers or family members, or through another individual acting on behalf of the patient. OIG illustrates this in their example where a minor patient suffers from asthma, and the patient's parent or guardian accepts a new air purifier for the patient's bedroom, on the patient's behalf, without violating this requirement.

[7] A VBE Participant might order or arrange for the delivery of a tool or support from an independent third party that qualifies as an “eligible agent.” An eligible agent (defined as any person or entity that is not identified as an Ineligible Participant) does not need to become a VBE Participant.

[8] For purposes of this safe harbor, companies that sell or rent DMEPOS are ineligible for the safe harbor without exception.

	OIG makes clear that Ineligible Participants are not able to circumvent that restriction by indirectly funding or contributing to tools and support protected under this safe harbor. A protected patient engagement tool or support may not be funded or contributed by: • A VBE Participant that is not a party to the applicable value-based arrangement; or • An Ineligible Participant.
Applicable Target Patient Population	• The patient receiving the patient engagement tool or support must be a member of the target patient population of a value-based arrangement to which the VBE Participant is a party. • The selection criteria for determination of the Target Patient Population, and selection criteria to identify patients likely to benefit from the relevant tools and supports, must be identified in advance. • Parties may modify their target patient population selection criteria prospectively by amending their existing value-based arrangement. VBE Participants can retroactively attribute patients to the target patient population without amending the value-based arrangement if such patients meet the selection criteria established prior to the commencement of the value-based arrangement.
Required Use	The patient engagement tool or support must advance one or more of the following goals: • Adherence to a treatment regimen determined by the patient's licensed health care provider professional; • Adherence to a drug regimen determined by the patient's licensed health care provider professional; • Adherence to a follow-up care plan established by the patient's licensed health care professional; • Prevention or management of a disease or condition as directed by the patient's licensed health care professional; or • Ensuring of patient safety.
Insurance Coverage Status of the Patient	The VBE's decision to make available the tool or support must not take into account the type of insurance coverage of the patient.[9]
Impact on Medically Unnecessary/Necessary Items or Services	The patient engagement tool or support may not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a federal health care program.
Monetary Cap	The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE Participant on an annual basis may not exceed $500.
Marketing/Patient Recruitment	The VBE Participant or any eligible agent does not exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes.
Materials and Records	For a period of at least six years, the VBE Participant makes available to the Secretary of the Department of Health and Human Services, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the conditions of this safe harbor.

[9] OIG confirms that for practicality purposes, this requirement does preclude a VBE from defining a Target Patient Population in a manner that takes into account patients' payor type.

Glossary of Terms for Value-Based Care and Patient Engagement and Support AKS Safe Harbors

and

Value-Based Care Stark Exceptions

*The following definitions are used in the value-based care safe harbors and exceptions. These terms largely align under both the AKS and Stark. We have noted any differences in **bold**.*

TERM	DEFINITION
Value-based arrangement	An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are (A) the value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based enterprise. **Note that for purposes of Stark law (not AKS), a compensation arrangement is an arrangement between a physician (or immediate family member of a physician) and the entity to which the physician makes referrals for designated health services. Therefore, the definition of "value-based arrangement" relates to a compensation arrangement between a physician and an entity that participate in the same value-based enterprise. It does not cover compensation arrangements between a payor and a physician.**
Value-based activity	(A) 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: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action; and (B) **does not include the making of a referral**. [*bolded language is included only in AKS safe harbor*]
Value-based enterprise	Two or more VBE participants (A) collaborating to achieve at least one value-based purpose; (B) 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; (C) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (D) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).
Value-based enterprise participant or VBE participant	An individual or entity that engages in at least one value-based activity as part of a value-based enterprise, **other than a patient acting in his/her capacity as a patient**. [*bolded language is included only in AKS safe harbor*]
Value-based purpose	Means (A) coordinating and managing the care of a target patient population; (B) improving the quality of care for a target patient population; (C) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (D) 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.

TERM	DEFINITION
Digital health technology	Hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.
Limited technology participant	A VBE participant that exchanges digital health technology with another VBE participant or a VBE and that is: (A) a manufacturer of a device or medical supply, but not including a manufacturer of a device or medical supply subject to the Sunshine Act reporting requirements set forth under 42 C.F.R. § 403.906 during the preceding calendar year, or reasonably expects to be subject to such requirements during the present calendar year; or (B) an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).
Manufacturer of a device or medical supply	An entity that meets the definition of applicable manufacturer under the Sunshine Act, as set forth under 42 C.F.R. § 403.902, because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or medical supply, but not including entities under common ownership with such entity.
Target patient population	An identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that (A) are set out in writing in advance of the commencement of the value-based arrangement; and (B) further the value-based enterprise's value-based purpose(s).

Electronic Health Record Items and Services AKS Safe Harbor and Stark Exception

*The table below provides a brief summary of the electronic health record ("**EHR**") safe harbor and exception, which were finalized in largely the same form as described in the proposed rules. The table reviews all of the key changes that are relevant to an analysis under the EHR safe harbors and exceptions.*

	Current AKS and Stark Requirements	**Revisions to AKS** Electronic Health Records Items and Services Safe Harbor ("**EHR Safe Harbor**") 42 C.F.R. § 1001.953(y)	**Revisions to Stark** Electronic Health Records Items and Services Exception ("**EHR Exception**") 42 C.F.R. § 411.357(w)
Definitions of Interoperable	**AKS** and **Stark** define "interoperable" to mean 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.	"Interoperable" means: • securely exchange data with and use data from other health information technology; and allow for complete access, exchange, and use of all electronically accessible health information for use under applicable State or Federal law. 42 C.F.R. § 1001.952 (y)(14)(iii)	"Interoperable" means: • able to securely exchange data with and use data from other health information technology; and • allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law. 42 C.F.R. § 411.351
Covered Technology	**AKS** and **Stark** both protect 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.	Clarifies that protected remuneration includes cybersecurity software and services used predominantly to protect electronic health records in its scope in its scope: • nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, <u>including cybersecurity software and services</u>) necessary and used predominantly to create, maintain, transmit, receive, <u>or protect</u> electronic health records. 42 C.F.R. § 1001.952 (y). •	Clarifies that protected remuneration includes cybersecurity software and services used predominantly to protect electronic health records in its scope in its scope: • nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, <u>including cybersecurity software and services</u>) necessary and used predominantly to create, maintain, transmit, receive, <u>or protect</u> electronic health records. 42 C.F.R. § 411.352(w). •
Sunset Provision	**AKS** and **Stark** safe harbor and exception slated to sunset on December 31, 2021.	Eliminates the EHR safe harbor sunset provision in the EHR safe harbor. 42 C.F.R. § 1001.952(y)(13)	Eliminates the EHR safe harbor sunset provision in the EHR safe harbor. 42 C.F.R. § 411.357(w)(13).
Replacement Technology	**AKS** and **Stark** currently prohibit the donation of replacement technology if the	Eliminates the prohibition on replacement technology at 42 C.F.R. § 1001.952(y)(7).	Eliminates the prohibition on replacement technology at 42 C.F.R. § 411.357(w)(8).

	CURRENT AKS AND STARK REQUIREMENTS	REVISIONS TO AKS	REVISIONS TO STARK
	recipient already possesses equivalent items or services. 42 C.F.R. § 1001.952(y)(7); 42 C.F.R. § 411.357(w)(8).		
Permitted Donors	**AKS** is limited to (1) an individual or entity, other than a laboratory company, who submits claims or requests for payment, either directly or through reassignment, to the federal health care program or (2) a health plan. 42 C.F.R. § 1001.952(y)(1). **Stark** is limited to (1) a physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS or (2) a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier, with respect to any DHS provided by that supplier. **Stark** specifically excludes (1) a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with 42 C.F.R. § 414.50; and (2) a laboratory company. 42 C.F.R. § 411.357(w)(8).	Expands the scope of protected donors to include certain entities that bear financial risk in patient outcomes, such as accountable care organizations, parent companies of hospitals, and health systems. Donations of interoperable electronic health records software or information technology and training services by these donor entities are now eligible for protection. 42 C.F.R. § 1001.952(y)(1)	• No change in protected donors.
Donor Contribution	Under both **AKS** and **Stark**, before receipt of the items and services, the recipient pays 15% of the donor's cost for the items and services. The donor (or affiliated/related party) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.	• The 15% contribution requirement for EHR donations does not change, but the requirement to make this payment in advance for updates to existing EHR systems is removed. • The AKS Final Rule confirms that contributions for initial and replacement	• The 15% contribution requirement for EHR donations does not change, but revising certain provisions related to timing of payments. • With respect to items or services donated after the initial donation or the replacement donation, the revised EHR

	Current AKS and Stark Requirements	**Revisions to AKS**	**Revisions to Stark**
	42 C.F.R. § 1001.952(y)(11); 42 C.F.R. § 411.357(w)(4).	EHR items and services must be made in advance of the donation but contributions for updates to previously donated EHR item and services need not be paid in advance. 42 C.F.R. § 1001.952(y)(11).	exception finalizes the requirement permitting cost contribution amount to be paid at reasonable intervals. 42 C.F.R. § 411.357(w)(4).

Cybersecurity Technology and Related Services AKS Safe Harbor and Stark Exception

The table below provides a brief summary of the Cybersecurity Technology Safe Harbor and Exception, which were finalized in largely the same form as described in the proposed rules. This table provides a broad overview of all key changes to the AKS revisions, codified at 42 C.F.R. § 1001.952(jj), and the Stark revisions, codified at 42 C.F.R. § 411.357(bb).

	ADDITIONS TO AKS *Cybersecurity Technology and Related Services Safe Harbor* *(“**Cybersecurity Safe Harbor**”)* *42 C.F.R. § 1001.952 (jj)*	**ADDITIONS TO STARK** *Cybersecurity Technology and Related Services Exception* *(“**Cybersecurity Exception**”)* *42 C.F.R. § 411.357(bb)*
Definitions	Under **AKS**, Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks. Technology means any software or other types of information technology. 42 C.F.R. § 1001.952(jj)(5)(i). • “Covered Technology” cybersecurity software may be donated under both the EHR and Cybersecurity Safe Harbors, depending upon the predominant usage.	Under **Stark**, Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks. Technology means any software or other types of information technology. 42 C.F.R. § 411.351. • “Covered Technology”, cybersecurity software may be donated under both the EHR and Cybersecurity Exceptions, depending upon the predominant usage.
Required Elements	The Cybersecurity Safe Harbor is available for exchange of nonmonetary remuneration (consisting of certain technology and services) necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity (“**Cybersecurity Remuneration**”), if all of the following conditions are met: • The donor does not account for the volume or value of referrals or other business generated between the parties. • The donation or the amount or nature of the donation cannot be conditioned upon future referrals. • Neither the recipient nor the recipient’s practice (or any affiliates) makes the donation, or the amount or nature of the donation, a condition of doing business with the donor. • A general description of the technology and services and the amount of the recipient’s contribution, if any, are set forth in writing and signed by the parties. • The donor does not shift the costs of technology or services to any federal health care program. 42 C.F.R. § 1001.952(jj).	The Cybersecurity Exception is available for Cybersecurity Remuneration, if all of the following conditions are met: • 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. • Neither the physician nor the physician’s practice (including employees and staff members) makes the receipt of the donation, or the amount or nature of the donation, a condition of doing business with the donor. • The arrangement is documented in writing. 42 C.F.R. § 411.357(bb). **Stark**, unlike AKS, does not (1) prohibit the donor from conditioning the donation upon future referrals, (2) require that the written documentation of the arrangement is signed by the parties, or (3) require that the donor does not shift the costs of technology or services to any federal health care program.
Documentation Requirements (in	Set forth in writing a general description of the technology and services being provided and the amount of the recipient’s	Document the arrangement in writing. CMS clarified that the requirements would be satisfied if contemporaneous documents

	ADDITIONS TO AKS	ADDITIONS TO STARK
writing/ form of agreement)	contribution, if any, that must be signed by the parties. 42 C.F.R. § 1001.952(jj)(3).	would permit a reasonable person to verify compliance with the exception at the time that a referral is made. 42 C.F.R. § 411.357(bb)(1)(ii).
Protected Donors	Unlike the EHR safe harbor, there are no donor restrictions finalized for cybersecurity donations under cybersecurity safe harbor.	Unlike the EHR exception, there are no donor restrictions finalized for cybersecurity donations under cybersecurity exception.
Physician Contribution	Unlike the EHR safe harbor, there is no 15% contribution requirement for cybersecurity donations made under the cybersecurity safe harbor (which is distinctly different from a cybersecurity donation made under the EHR safe harbor). Parties that want to donate a joint EHR and cybersecurity donation and avoid the 15% contribution for the cybersecurity portion required under the EHR safe harbor must structure the arrangement to meet all of the conditions under both the EHR and cybersecurity safe harbors.	Unlike the EHR exception, there is no 15% contribution requirement for cybersecurity donations made under the cybersecurity safe harbor (which is distinctly different from a cybersecurity donation made under the EHR safe harbor). Parties that want to donate a joint EHR and cybersecurity donation and avoid the 15% contribution for the cybersecurity portion required under the EHR safe harbor must structure the arrangement to meet all of the conditions under both the EHR and cybersecurity safe harbors.

Warranties AKS Safe Harbor

The table below provides a brief summary of the Warranties AKS safe harbor, which finalized the safe harbor in largely the same form as described in the proposed rule. This table provides a broad overview on all of the key changes to the Warranties AKS safe harbor, codified at 42 C.F.R. § 1001.952(g). There is no substantive change to the definition of "warranty."

	CURRENT REQUIREMENTS	REVISED REQUIREMENTS
Protected Remuneration	The former warranties safe harbor protected remuneration consisting of "any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item," so long as the buyer and seller comply with the safe harbor's terms. 42 C.F.R. § 1001.952(g). • OIG Advisory Opinion No. 18-10 states that safe harbor applies only to warranties for a single item and not to bundled items.	The Final Rule expands protection to remuneration of an item, bundle of items, or services in combination with one or more related items (provided the warranty covers at least one item). This revision represents the first time that AKS will protect warranties covering services, but the safe harbor does not protect any warranty arrangements for services only. 42 C.F.R. § 1001.952(g). • "Remuneration" does not include exchange of value under a warranty provided by a manufacturer or supplier of the items and services, as long as the buyer complies with all of the applicable standards and conditions. 42 CFR § 1001.952(g). • Safe harbor may be used to protect warranty arrangements that span multiple years. • If non-reimbursable items or services offered for free as part of a bundled warranty have independent value to a buyer, the parties to the warranty arrangement may look to other safe harbors to protect the exchange of those items and services, such as the personal services and management contracts and outcomes-based payments safe harbor.
Report of Price Reductions	The former warranties safe harbor required the buyer to fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost-reporting mechanism or claim for payment filed with the Department or a State agency. 42 C.F.R. § 1001.952(g)(1).	The Final Rule clarified that buyers that are Federal health care program beneficiaries are excluded from reporting requirements. 42 C.F.R. § 1001.952(g)(1).
Remedy Cap	Under the former warranties safe harbor, the manufacturer or supplier must not pay any remuneration beyond the cost of the item itself. 42 C.F.R. § 1001.952(g)(4).	The Final Rule extends the remedy cap to include the cost of the services subject to the warranty. 42 C.F.R. § 1001.952(g)(4). • This revised warranty cap protects warranties in which vendors offer to reimburse any medical, surgical, or hospital expense incurred, up to the cost of the warrantied items and services incurred by the buyer to acquire those items and services. The safe harbor could be used to protect reimbursement for hospital

	CURRENT REQUIREMENTS	REVISED REQUIREMENTS
		expenses incurred as a result of, for example, a bundle of items that failed to meet the clinical outcomes guaranteed by a warranty arrangement.
Same Program/Same Payment Requirement	Not applicable because multiple items or services were not protected remuneration.	Under the Final Rule, if a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same federal health care program and in the same federal health care program payment. 42 C.F.R. § 1001.952(g)(5). • This requirement is a close cousin of the "same methodology" requirement in the discount safe harbor. • Same program/same payment requirement would not prohibit the inclusion of non-federally reimbursable items or services in the bundle of items and services being warrantied.
Exclusivity and Minimum Purchase Requirements	None in former AKS warranty safe harbor.	Under the Final Rule, a manufacturer or supplier may not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services. 42 C.F.R. § 1001.952(g)(6).