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# Key Definitions for New Stark Law Exceptions and Anti-Kickback Statute Safe Harbors for Value-Based Care Arrangements

As the health care industry continues to integrate, providers and health care professionals are challenged to develop innovative relationships that lower cost, increase quality, and improve the patient experience. Final Rules revising the Stark Law and the Anti-kickback Statute were promulgated to remove regulatory barriers for clinical integration activities that promote this triple aim. Practitioners can review the tables below to easily compare and contrast arrangements and related definitions used in the new Stark Law exceptions and Anti-kickback Statute safe harbors for value-based arrangements.

Frost Brown Todd will continue to provide updates and further analysis as it relates to the application and impact of Stark Law exceptions and Anti-kickback Statute safe harbors. Please reach out to the authors of this article with any questions. You can also visit our Health Law Matters blog for more insight into legal issues impacting the health care industry.

## Key Definitions for New Stark Law Exceptions and Anti-Kickback Statute (AKS) Safe for Value-Based Care Arrangements

| New Definitions | Stark Law (Final Rule) | AKS Statute (Final Rule) |
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| **Coordination and Management of Care** | Not Applicable | The deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.<br>42 CFR § 1001.952(ee)(14)(i) |


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| **Outcome Measure** | A benchmark that quantifies either improvements in or maintenance of the quality of patient care, or reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.<br>42 CFR § 411.357(aa)(3)(xii) | Not Applicable |
| **Target Patient Population** | An identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—<br>(1) Are set out in writing in advance of the commencement of the value-based arrangement; and<br>(2) Further the value-based enterprise's value-based purpose(s).<br>42 CFR § 411.351 | Same as Stark Law definition.<br>42 CFR § 1001.952(ee)(14)(v) |


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| **Value-Based Activity** | 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:<br>(1) The provision of an item or service;<br>(2) The taking of an action; or<br>(3) The refraining from taking an action.<br>42 CFR § 411.351 | Same as Stark Law definition except that the AKS specifically states that the making of a referral is not a value-based activity.<br>42 CFR § 1001.952(ee)(14)(vi) |
| **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—<br>(1) The value-based enterprise and one or more of its VBE participants; or<br>(2) VBE participants in the same value-based enterprise.<br>42 CFR § 411.351 | Same as Stark Law definition.<br>42 CFR § 1001.952(ee)(14)(vii) |


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| **Value-Based Enterprise (VBE)** | Two or more VBE participants—<br>(1) Collaborating to achieve at least one value-based purpose;<br><br>(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE;<br><br>(3) That have an accountable body or person responsible for the financial and operational oversight of the VBE; and<br><br>(4) That have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).<br><br>42 CFR § 411.351 | Same as Stark Law definition.<br>42 CFR § 1001.952(ee)(14)(viii) |


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| **VBE Participant** | A person or entity that engages in at least one value-based activity as part of a VBE. 42 CFR § 411.351 | Same as Stark Law definition except that the AKS specifically excludes a patient acting in their capacity as a patient. 42 CFR § 1001.952(ee)(14)(ix) |


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| **Value-Based Purpose** | (1) Coordinating and managing the care of a target patient population;<br>(2) Improving the quality of care for a target patient population;<br>(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or<br>(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.<br>42 CFR § 411.351 | Same as Stark Law definition.<br>42 CFR § 1001.952(ee)(14)(x) |




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| Type of Exception/Safe Harbor | Key Stark Law Exception Requirements | Key AKS Safe Harbor Requirements |
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| **Low or No Risk:**<br>Low Risk Stark Law Exceptions and AKS Safe Harbors | **Low Risk Value-Based Arrangements**<br>This exception permits payments to a physician by a DHS entity under a value-based arrangement involving low or no risk. If any outcome measures exist, they must be objective and measurable and changes to them must be made prospectively.<br><br>The arrangement must be in a writing which describes:<br><br>(1) the value-based activities to be provided;<br><br>(2) how these activities will further a value-based purpose;<br><br>(3) the target patient population;<br><br>(4) the type of remuneration and how it is determined; and<br><br>(5) the outcome measures against which the recipient of the remuneration is addressed.<br><br>42 CFR § 411.357(aa)(3) | **Care Coordination Arrangements**<br>Care coordination arrangements that improve quality, health outcomes, and efficiency are not considered "remuneration" under the AKS between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement.<br><br>The remuneration exchanged between the parties must be:<br><br>(1) in-kind remuneration only, like sharing services between the parties; and<br><br>(2) predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and not result in more than incidental benefits to persons outside of the target patient population.<br><br>The parties to the value-based arrangement must establish one or more |


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| **Meaningful or Substantial Risk:** Meaningful Risk Stark Law Exception and Substantial Downside Financial Risk AKS Safe Harbor | This exception permits a payment by a DHS entity under a value-based arrangement to a physician with meaningful downside financial risk to the physician of the failure to achieve the value-based purpose of the value-based enterprise during the entire duration of the value-based arrangement. Physician must be responsible to repay or forego at least 10% of the total remuneration the physician is to receive under the arrangement.<br><br>42 CFR 411.257(aa)(2) | This safe harbor permits the exchange of in-kind and monetary remuneration between a VBE and a VBE participant, so long as the VBE has assumed "substantial downside financial risk."<br>Substantial downside financial risk means:<br><br>(1) 30% of any shared losses.<br><br>(2) 20% of any loss pursuant to a defined clinical episode of care.<br><br>(3) The VBE receives a per-patient payment for a set period of time to cover the expected total cost of expenditures.<br><br>The VBE participant must:<br><br>(1) Assume two-sided risk for at least 5% of the losses and savings realized by the VBE; or<br><br>(2) Receive from the VBE a prospective, per-patient payment for a set period of time to cover the expected total cost of expenditures.<br><br>Excludes certain |


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| **Full Financial Risk:** Full Financial Risk Stark Law Exception and Full Financial Risk AKS Safe Harbor | This exception permits remuneration paid under a value-based arrangement where the VBE is at "full financial risk" during the entire duration of the value-based arrangement. Full financial risk means that the VBE is financially responsible prospectively for the cost of all patient care covered by the applicable payor for each patient in the target patient population for a set period of time.<br><br>42 CFR § 411.357(aa)(1) | This safe harbor permits the exchange of in-kind and monetary remuneration between a VBE and a VBE participant, so long as the VBE has assumed "full financial risk." Full financial risk means the VBE is financially responsible for the cost of all patient care covered by the applicable payor for each patient in the target patient population for at least one year.<br><br>Excludes certain entities, including but not limited to labs, medical device and supply manufacturers, pharmacy benefit managers, pharmaceutical manufacturers, distributors, or wholesalers.<br><br>42 CFR § 1001.952(gg) |


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