STARK AND ANTI-KICKBACK FINAL RULES

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OVERVIEW

- Stark overview & potential penalties for noncompliance
- AKS overview & potential penalties for noncompliance
- New definitions related to value-based environment
- 3 new categories of value-based exceptions/safe harbors
- Compare /contrast differences between Stark/AKS:
  - Full financial risk
  - Meaningful (substantial) downside financial risk
  - Care coordination agreements/outcome-based payments/value-based arrangements

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STARK LAW: GENERALLY

- Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, *unless an exception applies*.
- Strict liability– no proof of intent is required to establish liability
- Purpose: referrals based on best interest of patients, to avoid self-referral, overutilization, fraud and abuse.
- 42 USC § 1395nn; 42 CFR §411.350 – §411-389

COMPENSATION STARK EXCEPTIONS

- Employment
- Personal Services contracts
- Fair market value
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary compensation
- Medical staff incidental benefits
- Professional courtesy
- Health information technology support
- Value-Based Arrangements
- Full Financial Risk value-based arrangements
- Meaningful downside risk value-based arrangements
- Cybersecurity
- Limited remuneration

OWNERSHIP STARK EXCEPTIONS

- Physician supervision
- Group practices
- In-office ancillary services
- Rural providers
- Whole hospital
- Publicly traded securities
- Intra-family rural referrals

- *Some changes to these provisions, not covered today

STARK PENALTIES

- Stark is fundamentally a payment statute: services provided through improper referral cannot receive payment
- Payments that violate Stark are considered overpayments and must be returned within 60 days
- Civil fines/penalties
  - $25,820 *per claim*
  - Circumvention scheme $172,137
  - Can quickly become millions
- Exclusion from participation in federal health care programs
- Can create liability under Anti-Kickback Statute
- Can create liability under the False Claims Act (criminal and civil liability)
  - Repayment, 3x Damages
  - Subject to qui tam claims

ANTI-KICKBACK STATUTE: GENERALLY

- AKS is an intent-based, criminal statute that prohibits any form of remuneration, whether monetary or in-kind, in exchange for referrals or other Federal health care program business by *any person or entity* (not solely a physician or person acting at a physician's direction).
- Includes offering, payment, solicitation, and receipt
- "One-Purpose Rule": where one purpose of the payment was to influence referrals, payment is prohibited unless safe harbor applies
- Safe harbor regulations describe voluntary practices that, if fully followed, will not violate the AKS.
- 42 U.S.C. 1320a-7b(b)

AKS: SAFE HARBORS

- Bona fide employment
- Personal services contracts (including those with outcome-based payments)
- Leases for space or equipment
- Investments in group practice
- Ambulatory Surgery Center investment
- Sale of Practice
- Recruitment
- Certain investment interests
- Waiver of beneficiary coinsurance and deductible amounts.
- ACO incentive payments
- Patient engagement and support programs
- CMS-sponsored model arrangements
- Transportation programs
- OB malpractice insurance subsidies
- Electronic health record items or services
- Referral services
- Referral arrangements for specialty services
- Warranties
- Discounts
- Care coordination agreements
- Substantial downside financial risk
- Full financial risk
- Cybersecurity

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AKS PENALTIES

- Penalties significantly increased by 2018 bipartisan budget act
- Criminal fines: $100,000 per violation (up from $25,000)
- Civil penalties: $104,330 (adjusted for inflation)
- Jail terms up to 10 years in prison (up from 5)
- Creates liability under False Claims Act
- Exclusion from participation in Federal health care programs
- Civil Monetary Penalties Law, 42 U.S.C. 1320a-7a(a): kickbacks can result in penalties per kickback, plus treble (3x) damages based on the kickback value

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TRANSITIONING TO VALUE-BASED CARE

The new value-based care models HHS and CMS pursue in the final rules have their own language, which is similar (but not identical) between the Stark and AKS final rules.

Understanding these value-based terms and their meaning is needed to understand the new rules.

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IMPORTANT NEW TERMS (STARK)

The following new terms are essential to reference when analyzing whether a particular compensation arrangement qualifies for one of the new value-based exceptions:

(1) value-based activity;

(2) value-based arrangement;

(3) value-based enterprise (VBE);

(4) value-based purpose;

(5) VBE participant; and

(6) target patient population.

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IMPORTANT NEW TERMS (AKS)

- Four of the new terms in Stark are identical.
- "VBE participant" slightly different from Stark (expressly excludes patients acting qua patients from definition).
- Value-Based Activity same, except, AKS specifies that it "does not include the making of a referral."
- Coordination and management of care:
  - "[T]he 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."
  - 42 C.F.R. 1001.952(ee)(14)(i).
- Additional new terms added, and new safe harbors, not covered today.

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VALUE-BASED ACTIVITY

Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

*(for AKS) *and* does not include the making of a referral

42 CFR §411.351; 42 CFR §1001.952(ee)(14)(vi)

VALUE-BASED ARRANGEMENT

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

42 CFR §411.351; 42 CFR §1001.952(ee)(14)(vii)

VALUE-BASED ENTERPRISE

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve **at least one value-based purpose**;

(2) Each of which is a party to a **value-based arrangement** with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that *describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)*.

42 CFR §411.351; 42 CFR §1001.952(ee)(14)(viii)

VALUE-BASED PURPOSE

Value-based purpose means any of the following:

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

42 CFR §411.351; 42 CFR §1001.952(ee)(14)(x)

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VBE PARTICIPANT

Stark Definition

VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.

42 CFR § 411.351

AKS Definition

Value-based enterprise participant or VBE participant means 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 their capacity as a patient.

42 CFR §1001.952(ee)(14)(ix)

TARGET PATIENT POPULATION

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

42 CFR §411.351; 42 CFR §1001.952(ee)(14)(v)

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AKS – CMS-SPONSORED MODEL

CMS-sponsored model means:

(A) A model being tested under section 1115A(b) of the Act or a model expanded under section 1115A(c) of the Act; or

(B) The Medicare shared savings program under section 1899 of the Act.

42 C.F.R. 1001.952(ii)(3)(i).

N.B. – this rule generally applies to payment models developed and tested by the Center for Medicare and Medicaid Innovation (CMMI) prior to broader adoption.

STARK / AKS – FULL FINANCIAL RISK

FULL FINANCIAL RISK - 1

***Full financial risk*—**

(1) The VBE is at *full financial risk* (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

"Full financial risk" means that the VBE is financially responsible on a *prospective basis* for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

"Prospective basis" means that the VBE has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor *prior to* providing patient care items and services to patients in the target patient population.

FULL FINANCIAL RISK - 2

(2) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(3) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(4) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(5) **Records** of the methodology and actual amount of remuneration paid under the value-based arrangement must be maintained for 6 years.

FULL FINANCIAL RISK - 3

(6) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is in a signed **writing**.

(B) The req't to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a different preference; the patient's insurer determines the referral is not in the patient's best medical interests in the physician's judgment.

AKS: FULL FINANCIAL RISK 1

A value-based arrangement with full financial risk exists where a VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target population for a term of at least 1 year. 42 C.F.R. § 1001.952(gg)(10)(i). Must satisfy 9 requirements:

(1) Certain entities prohibited from participating in full financial risk arrangement: pharmaceutical manufacturer, distributor, wholesaler; pharmacy benefit manager; laboratory company; pharmacy with primarily compounded drugs; device or medical supply manufacturer; entity/individual that sells/rents DME; medical device distributor or wholesaler.

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AKS: FULL FINANCIAL RISK 2

(2) VBE, on its own or through a non-payor participant, has entered into a written agreement to accept full financial risk from a payor for one (1) full year.

(3) Writing contains all material terms, including the value-based activities and total duration of the agreement, and is signed by the parties.

(4) VBE participant does not claim payment from payor for items or services covered under the contract or value-based arrangement between VBE and payor.

(5) Remuneration is (i) directly connected to one or more value-based purpose; (ii) does not include the offer or receipt of ownership interest in an entity or distributions arising from same; and (iii) is not exchanged or used for marketing of VBE or VBE participant's services to patients.

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AKS: FULL FINANCIAL RISK 3

(6) Value-based arrangement cannot induce parties to reduce or limit medically necessary items or service furnished to any patient.

(7) VBE or VBE participant offering remuneration does not take into account the volume or value of, or condition remuneration of referrals of patients who are not part of the target patient population; or business not covered by the value-based arrangement.

(8) VBE uses quality assurance program to protect against underutilization and assesses the quality of care rendered to target patient population

(9) VBE or VBE participant must make available books and records evidencing compliance to the HHS Secretary.

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STARK / AKS – DOWNSIDE RISK

- Less than full financial risk, the Stark and AKS final rules allow for VBE models where the VBE or VBE Participants are allowed to receive certain financial and in-kind remuneration in exchange for accepting partial—but not total—financial risk.
- The Stark Law defines these relationships as representing "meaningful" downside risk; AKS defines similar agreements as presenting "substantial" downside risk.
- Standards are similar.

MEANINGFUL DOWNSIDE RISK -1

Value-based arrangements with meaningful downside financial risk to the physician—

(1) Physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

"Meaningful downside financial risk" means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

(2) A description of the nature and extent of the physician's downside financial risk is **set forth in writing**.

MEANINGFUL DOWNSIDE RISK - 2

(3) The methodology used to determine the amount of the remuneration is set in advance of commencing the value-based activities.

(4) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(5) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(6) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(7) Records of the methodology and actual amount paid under the value-based arrangement must be maintained for 6 years.

MEANINGFUL DOWNSIDE RISK - 3

(8) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

> (A) The requirement to make referrals to a particular provider, practitioner, or supplier is in a signed writing.
>
> (B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if patient expresses a different preference; the patient's insurer determines the referral is not in the patient's best medical interests in the physician's judgment.

AKS: SUBSTANTIAL DOWNSIDE RISK 1

The definition of "substantial downside financial risk" can be satisfied by three different standards, in addition to meeting 8 other criteria. Substantial downside financial risk exists where there is:

(1) risk equal to at least 30% of any loss based on a comparison of current expenditures of all items and services furnished to target patient population against bona fide benchmarks to approximate the total cost of care;

(2) risk equal to at least 20% of any loss based on a comparison of current expenditures against bona fide benchmarks to approximate the cost of items and services for a defined clinical episode in more than one care setting as agreed upon by the parties; or

(3) a prospective, per-patient payment that is designed to produce material savings and paid at least annually for a defined set of services or items furnished to the target patient population, anticipated to satisfy the costs for those defined items and services.

42 CFR § 1001.952(ff)(9)(i)(A)-(C).

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AKS: SUBSTANTIAL DOWNSIDE RISK 2

Contractual terms, such as for a written agreement signed by all parties and creating substantial downside risk for the VBE or VBE participant, are largely the same as for full financial risk arrangements.

Distinctions:

42 C.F.R. 1001.952(ff)(4)(ii) and 5(i): Allows parties to enter into contract with wind-up time of up to 6 months prior to assuming downside risk.

42 C.F.R. 1001.952(ff)(7): Prohibits limitation of VBE participants' ability to make care decisions or to direct referrals to a non-participating health care provider.

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VALUE-BASED ARRANGEMENTS

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VALUE-BASED ARRANGEMENTS

Value-based arrangements.

(1) ***Signed writing*** describes:

(A) The value-based activities to be undertaken;

(B) How the value-based activities are expected to further the value-based purpose(s) of the VBE;

(C) The target patient population;

(D) The type or nature of the remuneration;

(E) The methodology used for remuneration; and

(F) The outcome measures for assessing the recipient (if any).

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VALUE-BASED ARRANGEMENTS

(2) The outcome measures: objective, measurable, and selected based on clinical evidence or credible medical support. Outcome Measures:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

(3) Any changes to the outcome measures are made prospectively & in writing.

(4) The methodology is set in advance of commencing value-based activities.

(5) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(6) Records of the methodology for determining & actual amount of remuneration paid under the value-based arrangement maintained 6+ years.

(7) The arrangement is commercially reasonable.

VALUE-BASED ARRANGEMENTS

(8)(A) At least once a year (once during term if < 1 yr), VBE or the 1+ parties monitor:

(1) Have the parties furnished the value-based activities?

(2) Will continuation of value-based activities further the value-based purpose(s)? and

(3) What progress toward outcome measure(s) has been made?

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Grace period:

(1) 30 days after monitoring end, if the parties terminate; or

(2) 90 days after monitoring end, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is **unattainable** during the remaining term, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

VALUE-BASED ARRANGEMENTS

(9) remuneration is not an inducement to reduce or limit medically necessary items or services.

(10) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(11) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier:

> (A) The req't to make referrals to a particular provider, practitioner, or supplier is in a signed writing.
>
> (B) The requirement to make referrals does not apply if the patient expresses a preference for a different provider; the patient's insurer determines the referral is not in the patient's best medical interests in the physician's judgment.

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AKS CARE COORDINATION AGREEMENTS

- Care coordination agreements define coordination and management of care as the deliberate organization of patient care activities and sharing of information between (1) two or more VBE participants, (2) one or more VBE participants and the VBE, (3) or one or more VBE participants and patients, and is designed to achieve safer, more effective, or more efficient care to improve the target patient population's health outcomes. 42 C.F.R. § 1001.952(ee)(14)(i).
- As this definition is focused on conduct and activity rather than financial participation and applies only to in-kind remuneration. 42 C.F.R. § 1001.952(ee)(1)(i).
- Care coordination agreements fill the gap where AKS could otherwise prohibit management and administrative services provided for free.

AKS CARE COORDINATION AGREEMENTS

- AKS safe harbor for care coordination agreements creates conditions for value-based arrangements that are similar to the Stark law definitions.
- AKS defines a value-based arrangement as:

  [A]n 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.

42 C.F.R. § 1001.952(ee)(14)(vii).

The conditions of coordination-of-care agreements, however, resemble those limitations found in the Stark Law exceptions, with some variations.

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VALUE-BASED MONITORING DIFFERENCES

- AKS: If monitoring/assessment show the value-based arrangement has "resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care" 60 days to terminate **OR** develop a corrective action plan designed to remedy deficiencies 120 days (if corrective plan fails in the 120 days, then must terminate),
- Stark: If monitoring shows value-based activity is not expected to further the value-based purpose of the VBE the parties must terminate after 30 days or, if the parties modify the arrangement to terminate the ineffective value-based activity, they have a 90-day grace period for non-terminated activities to demonstrate improvement in value-based metrics.

AKS: OUTCOMES-BASED PAYMENTS 1

- AKS amended the personal services and management contracts safe harbor to allow for outcomes-based payment agreements, creating an entire new subsection to this longstanding safe harbor.
- This addition brings the personal services and management contracts safe harbor up to date with Stark Law exceptions, which have taken a more permissive view of compensation fixed in advance and performance-based compensation (e.g., compensation formulas versus fixed sums).
- Outcomes-based payment standards resemble value-based arrangement requirements. 42 C.F.R. § 1001.952(d)(2).

AKS: OUTCOMES-BASED PAYMENTS 2

Eight requirements to comply with outcomes-based payments safe harbor:

(1) Outcomes measures set in advance based on quantifiable benchmarks, informed by clinical evidence or credible medical support, that measure improvements (or maintained improvement) in patient care or material reduction of costs or expense growth without loss of care.

(2) Methodology of determining aggregate compensation is set in advance commercially reasonable, consistent with fair market value, and does not directly account for the volume or value of any referrals for federal health care program business.

(3) Parties must sign a written agreement setting forth material terms of agreement and services to be performed, including measures for performance, sources relied upon in reaching those measurements, and a schedule for monitoring performance.

AKS: OUTCOMES-BASED PAYMENTS 3

(4) Agreement cannot limit any party's ability to make decisions in their patient's best interest or induce a party to reduce or limit medically necessary items or services.

(5) Term of agreement must be for at least 1 year.

(6) Services under the outcomes-based payment arrangement cannot counsel or promote a business arrangement that violates state or federal law.

(7) Parties must monitor performance under outcomes measures, including quality of care, and asses (revising if necessary) benchmarks and compensation – including recoupment

(8) Policies and procedures must be in place to correct material performance failures or deficiencies in quality of care due.

AKS: OUTCOMES-BASED PAYMENTS 4

Other considerations under new section 42 C.F.R. § 1001.952(d)(3):

- Outcomes-based payments can only reward agent for achieving appropriate measurable outcomes or recoup funds for failing to achieve those outcomes; is not a catch-all for every variable payment scenario.
- Restrictions similar to value-based arrangements, and payments cannot be made to: pharmacy manufacturers / distributors / wholesalers; pharmacy benefit managers; laboratory companies; compounding pharmacies; medical device manufacturers or distributors / wholesalers; or DME sellers.
- Outcomes-based payments cannot be based solely on internal cost savings or patient satisfaction or patient convenience measures.

QUESTIONS?

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