

FEDERAL STARK LAW AND ANTI-KICKBACK STATUTE CHANGES FOR 2022 AND BEYOND

Presented by:

John D. Fanburg, Esq.

Isabelle Bibet-Kalinyak, Esq.

Lani M. Dornfeld, Esq.

Joseph M. Gorrell, Esq.

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AGENDA

- Introductions, background on Stark Law and Anti-Kickback Statute (“AKS”).
- Roadmap to changes in Stark Law and AKS from 2020 Final Rule.
- Special rules on compensation and profit sharing – Stark Law changes.
- Fair and general market value compensation and commercial reasonableness – Stark Law definitions.
- Technology and Cybersecurity – Stark Law and AKS changes, new Stark Law exceptions and new AKS safe harbors.
- Innovative Arrangements, Digital Health – New AKS Safe Harbors.
- **Appendix:**
 - References and useful links
 - Stark and AKS history and timeline
 - Value-based care – Stark Law and AKS changes
 - CMS innovation models – New AKS safe harbor
 - Pharmaceuticals – Change to AKS safe harbor

STARK LAW 42 USC § 1395 nn

- Strict liability – No intent required.
- Only applies to “physicians” – MD, DO, DDS, DPM, OD or chiropractor.
- Prohibits a physician from making referrals for certain DHS payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
- Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third-party payer) for those referred services.
- Establishes specific exceptions and grants HHS the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

FEDERAL AKS 42 USC § 1320a-7b(b)

- Criminal statute prohibits knowingly and willfully offering, paying, soliciting, or receive any remuneration directly or indirectly to induce or reward referrals of items or services reimbursable by a Federal health care program (e.g., Medicare, Medicaid, TRICARE, Children's Health Insurance Program).
- Remuneration includes kickbacks, bribes and rebates, cash or in-kind, direct or indirect.
- Intent must be “knowing and willful.”
- Applies to anyone, not just physicians or providers.
- One purposes test: If any one purpose is improper, other legitimate purposes irrelevant.

STARK vs. AKS

	Stark	AKS
Regulated by	<ul style="list-style-type: none">• CMS	<ul style="list-style-type: none">• OIG
Intent	<ul style="list-style-type: none">• Intent is immaterial	<ul style="list-style-type: none">• Intent-based
Liability	<ul style="list-style-type: none">• Civil	<ul style="list-style-type: none">• Both criminal and civil
Application	<ul style="list-style-type: none">• Limited to physicians/ family members	<ul style="list-style-type: none">• Applies to anyone who attempts, accepts, or gives kickbacks
Protection	<ul style="list-style-type: none">• Exceptions must be met	<ul style="list-style-type: none">• Safe harbors may be met, not required

2020/2022 STARK LAW AND AKS, ROADMAP TO CHANGES

2020 CHANGES, STARK LAW

- November 20, 2020, CMS published new Final Rule to the Federal Physician Self-Referral or “Stark Law.”
- 5 new definitions:
 - Value-based activities
 - Value-based arrangement
 - Value-based enterprise (VBE)
 - VBE participant
 - Target patient population
- 3 new Stark Law exceptions:
 - Value-based compensation arrangements.
 - Limited remuneration arrangements.
 - Donations of cybersecurity technology.

- *Changes to the rules governing Group Practice compensation and profit sharing.*
- *Special rules on compensation.*
- Amends existing exception relating to electronic health records (EHR).
- Clarifies guidance on certain previously undefined terms that are fundamental to interpreting the Stark Law.

2020 CHANGES, AKS

- November 20, 2020, HHS OIG published new Final Rule to the Federal Anti-Kickback Statute (“AKS”).
- 5 New AKS safe harbors:
 - Value-based compensation arrangements.
 - Patient engagement.
 - CMS-sponsored models and CMS-sponsored model patient incentives.
 - Cybersecurity technology and services.
 - ACO Beneficiary incentive programs.

- Amends 4 existing safe harbors
 - EHR.
 - Warranties.
 - Local transportation.
 - Discount.

REFERENCES AND USEFUL LINKS

- **Stark Law, 42 CFR Subpart J, Sections 411.350 to 411.389:** <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-411>
- **Stark Law, CMS Final Rule with comments (CMS-1720-F, 12/2/2020):** <https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>
- **AKS, 42 CFR §1320a-7b:** <https://www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap7-subchapXI-partA-sec1320a-7b.pdf>
- **AKS, 42 CFR § 1001.952 Exceptions:** <https://www.ecfr.gov/current/title-42/chapter-V/subchapter-B/part-1001/subpart-C/section-1001.952>
- **AKS Safe Harbors, OIG Final Rule with comments (RIN 0936-AA10, 12/2/2020):** <https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>

**SPECIAL RULES ON
COMPENSATION, PROFIT
SHARING – STARK LAW
CHANGES**

REVISED DEFINITION: DESIGNATED HEALTH SERVICES (DHS)

Effective Jan 19, 2021, 42 CFR § 411.351.

DHS means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.):

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient* and outpatient hospital services.

*Inpatient hospital services:

- Excludes services paid by Medicare as part of composite rate (*e.g.*, SNF Part A payments or ASC services under 42 CFR § 416.164(a)), except if services are included in definition (*e.g.*, home health services).
- Excludes services to inpatients if furnishing the services does not increase amount of Medicare payment to Hospital under (1) Acute Care Hospital Inpatient (IPPS), (2) Inpatient Rehab. Facility (IRF PPS), (3) Inpatient Psych. Facility (IPF PPS), or (4) Long-term Care Hospital (LTCH PPS).

CMS DHS webpage:

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral>

- Code list only for EPO and other dialysis-related drugs (42 CFR § 411.355(g)), and preventive screening tests and vaccines (42 CFR § 411.355(h))

REVISED DEFINITION: “REMUNERATION”

- Effective Jan 19, 2021, 42 CFR § 411.351.
- “Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:...”
- Carveouts for “items, devices, or supplies (~~not including surgical items, devices, or supplies~~) **that are, in fact,** used solely for [...]” collecting, transporting, processing, or storing specimens, ordering tests or communicating results to the entity providing these items or supplies.
- Carveout for payment made by insurer or self-insured plan must be set in advance, does not exceed FMV, and is not determined in **any** manner that takes into account, ~~directly or indirectly,~~ the volume or value of referrals.

NEW SPECIAL RULE ON COMPENSATION, “SET IN ADVANCE”

- Effective Jan 19, 2021, 42 CFR § 411.354(d)(1).
- Special rule on *compensation only*.
- Compensation is not necessarily required to be “set in advance.”
- Compensation is ***deemed*** to be “set in advance” if aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or services equipment for which the compensation is to be paid.
- **End of prohibition on modifying compensation** (or the formula for compensation) during the term of the arrangement, subject to certain requirements: (1) meet an exception; (2) determined before; and (3) set out in writing before.

NEW SPECIAL RULE ON COMPENSATION, UNIT-BASED COMPENSATION AND THE “VOLUME OR VALUE STANDARD” OR “OTHER BUSINESS GENERATED STANDARD”

- Effective Jan 19, 2021, 42 CFR § 411.354 (d)(2) and (d)(3).
- **New objective, deeming tests** for situations where compensation will be considered not to take into account volume or value of referrals, or the other business generated.
- Includes time-based and per unit of services-based compensation.
- **FMV**
- **Is there a predetermined, direct positive or negative correlation** between the volume or value of the physician’s referrals (or other business generated for the entity) and the rate of compensation paid to or by the physician (or an immediate family member of the physician)?
- Services personally-performed by referring physician are not considered “other business generated.”

NEW SPECIAL RULE ON COMPENSATION, DIRECTED REFERRAL REQUIREMENT

- Effective Jan 19, 2021, 42 CFR § 411.354(d)(4).
- Compensation may be conditioned on physician's referrals to particular provider, practitioner or supplier and **take into account the volume or value of anticipated or required directed referrals (prohibition deleted)**.
 - Can use % or ratio of physician's referrals to a particular provider.
- **Existence of compensation arrangement and amount of compensation may not be contingent on the number or value of physician's referrals.**
- Set in advance for duration of arrangement;
- **Changes to compensation/formula must only be made prospectively;**
- FMV;
- In writing, signed by the parties;
- Patient preference, insurance, and "patient's best medical interest in the physician's judgment" override the directed referral requirement
- Directed referral requirements apply to more exceptions, e.g., physician incentive plans, limited remuneration.

NEW SPECIAL RULES ON COMPENSATION, COMPENSATION TO OR FROM A PHYSICIAN

- Effective Jan 19, 2021, 42 CFR § 411.354 (d)(5) and (d)(6).
- New objective tests.
- Determination is final – can't use “unit-based” special rules.
- Compensation to Physician (or immediate family member):
 - Volume or value of referrals: Compensation takes into account the volume or value of referrals only if the formula used to calculate the physician's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's compensation (or immediate family member) that **positively correlates** with the number or value of the physician's referrals to the entity.
 - Same for “the volume or value of other business generated.”
 - Not applicable to certain exceptions.
- Compensation from Physician (or immediate family member):
 - **Negatively correlates** with number or value of physician's referrals to entity.
 - **Negatively correlates** with number or value of physician's generation of other business for entity.

NEW STARK EXCEPTION: “LIMITED REMUNERATION ARRANGEMENTS”

- Effective Jan 19, 2021, 42 CFR § 411.357(z).
- Protects remuneration from an entity to a physician for the provision of items or services provided by the physician that does not exceed an aggregate of \$5,000 per calendar year (adjusted each year for inflation).
- Signed written agreement not required.
- Cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by physician.
- FMV.
- Commercial reasonableness.
- Lease or use of office space or equipment – special requirements.
- Directed referrals’ requirements apply.
- Physician may provide items or services through employees, wholly-owned entity, or locum tenens physicians.

CHANGES TO STARK LAW – GROUP PRACTICE COMPENSATION

- Effective Jan 1, 2022, 42 CFR § 411.352(i)(1).
- Group practice requirements, 42 CFR § 411.352.
- “Overall profits:” Profits derived from **all** DHS of any component of the group that consists of at least 5 physicians, which may include all physicians in the group.
- If fewer than 5 physicians in the group, “overall profits” means the profits derived from all DHS of the group.
- No “split pooling” service-by-service.
- Calculated in a reasonable and verifiable manner.
- Overall profits deemed not directly related to volume or value of referrals if:
 - Divided per capita (*i.e.*, per member of group);
 - Distributed based on the distribution of the group’s revenues attributed to services that are not DHS and would not be considered DHS if they were payable by Medicare; or
 - Revenues derived from DHS constitute less than 5% of group’s total revenues, and portion of those revenues distributed to each physician in group constitutes 5% or less of his/her total compensation from the group.

CHANGE TO STARK LAW – GROUP PRACTICE PRODUCTIVITY BONUS

- Effective Jan 1, 2022, 42 CFR § 411.352(i)(2).
- Group practice requirements, 42 CFR § 411.352.
- May pay productivity bonus based on services personally performed by physician, or services furnished “incident to” such services, if it is not directly related to volume or value of the physician’s referrals.
- Calculated in a reasonable and verifiable manner
- Deemed not to directly relate to volume or value of referrals if :
 - Based on the physician’s total patient encounters or the relative value units (RVUs) personally performed by the physician;
 - Services on which the productivity bonus is based are not DHS and would not be considered DHS if they were payable by Medicare; or
 - Revenues derived from DHS constitute less than 5% of group’s total revenues, and the portion of those revenues distributed to each physician in the group consists of 5% or less of his or her total compensation from the group.

**FAIR AND GENERAL MARKET
VALUE AND COMMERCIAL
REASONABLENESS – STARK
LAW DEFINITIONS**

REVISED DEFINITION: FAIR MARKET VALUE DEFINITION

- Effective Jan 19, 2021, 42 CFR § 411.351.
- FMV means the value in an arm's-length transaction, consistent with the general market value of the subject transaction.
- FMV should reflect what a hypothetical buyer would pay a hypothetical seller.
- There are particular nuances to this definition with regard to the rental of equipment or office space.
- In its discussion, CMS noted certain “extenuating circumstances” that may allow payments to physicians that are higher than compensation surveys would seem to justify.

NEW DEFINITION: GENERAL MARKET VALUE

- Effective Jan 19, 2021, 42 CFR § 411.351.
- For Assets: With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of a bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
- For Compensation: With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of a bona fide bargaining between a well-informed parties that are not otherwise in a position to generate business for each other.
- For Rental of Equipment or Office Space: With respect to rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of a bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

REVISED DEFINITION: COMMERCIALY REASONABLENESS

- Effective Jan 19, 2021, 42 CFR § 411.351.
- Means the arrangement must further a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.
- CMS clarified that an arrangement may be commercially reasonable even if it does not result in profit for the parties.

REVISED DEFINITION: VOLUME AND VALUE

- Effective Jan 19, 2021, 42 CFR § 411.354(d)(5)-(6).
- Many Stark Law exceptions include a requirement that the compensation under the arrangement is not determined in any manner that takes into account the volume or value of referrals and some also require that the compensation is not determined in any manner that takes into account other business generated between the parties (the “other business generated standard”).
- CMS acknowledged that an objective test was needed to determine whether a compensation arrangement implicates these standards, and finalized special rules to establish such a test.
- These new special rules, which are found at 42 C.F.R. § 411.354(d)(5) and (6), describe compensation that does take into account the volume/value of referrals or other business generated.

**FAIR MARKET VALUE
COMPENSATION EXCEPTION
– STARK LAW CHANGES**

FAIR MARKET VALUE COMPENSATION EXCEPTION UPDATED REQUIREMENTS

- Effective Jan 19, 2021, 42 CFR § 411.357(l).
- Requirements:
 - Writing.
 - Timeframe: May be for any time period.
 - Compensation: Must be set in advance, be consistent with FMV, and must not take into account the referring physician's volume or value of referrals or other business generated.
 - Commercial Reasonableness: Even if there were no referrals made between the parties.
 - Compliance with other laws: Arrangement must not violate AKS.

OFFICE SPACES AND LEASES

- Effective Jan 19, 2021.
- Rental of Office Space. 42 CFR § 411.357(a).
- Rental of Equipment. 42 CFR § 411.357(b).
- FMV compensation exception applies to both office space and equipment leases.
- FMV compensation exception does not require a one-year term, offering greater flexibility for shorter-term arrangements.

REVISED DEFINITION/CLARIFICATION: “WRITING REQUIREMENTS”

- Effective Jan 19, 2021, 42 CFR § 411.357(l)(1).
- Under the Final Rule, the signed writing required by the exception must specify:
 - The items, services, office space, or equipment covered by the arrangement;
 - The compensation to be provided; and
 - The timeframe.

**TECHNOLOGY AND
CYBERSECURITY – STARK LAW
AND AKS CHANGES, NEW STARK
LAW EXCEPTIONS AND AKS
SAFE HARBORS**

CHANGES TO AKS SAFE HARBOR AND STARK EXCEPTION FOR EHR ITEMS & SERVICES

- Effective Jan 19, 2021 - AKS: 42 CFR § 1001.952(y).
- Effective Jan 19, 2021 - Stark: 42 CFR § 411.357(w).
- Compensation arrangements or payments for electronic health records (EHR) items and services.
- Nonmonetary items and services in the form of software or information technology and training services, including cybersecurity software and services, ***necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records.***
- Software must be interoperable at the time it is provided to the physician/recipient.
 - Software is deemed to be interoperable if, on the date provided, it is certified by a certifying body recognized by the National Coordinator for Health Information Technology.

DONOR/RECIPIENT RESTRICTIONS & COST-SHARING

- Donor cannot be a laboratory company.
- Cost-sharing by recipient:
 - Stark and AKS: Initial donation of EHR items and services, or replacement of all or part of an EHR system: 15% of the donor's cost, paid in advance.
 - Stark: Items and services donated after the initial donation: 15% of the donor's costs paid "at reasonable intervals."
 - AKS: Updates to previously donated EHR items and services: 15% of the donor's costs, but need not be paid in advance.
- Donor cannot loan or finance cost-share amounts.

OTHER KEY REQUIREMENTS

- Recipient cannot make the receipt or amount of the donated items or services a condition of doing business with the donor.
- Cannot directly take into account volume or value of referrals or other business generated between the parties.
- Items and services cannot:
 - include staffing of the recipient's office.
 - be used primarily to conduct personal business or business unrelated to clinical practice or operations.
- Agreement in writing.
- AKS: Donor cannot shift costs to federal health care programs.

NEW AKS SAFE HARBOR AND STARK LAW EXCEPTION: “CYBERSECURITY”

- Donation of Cybersecurity Technology and Services.
 - Effective Jan 19, 2021, AKS: 42 CFR 1001.952(jj).
 - Effective Jan 19, 2021, Stark: 42 CFR § 411.357(bb).
- Must be non-monetary.
- Technology and services *necessary and used predominantly to implement, maintain or re-establish cybersecurity.*
- Technology = software and other types of information technology.
 - Can include hardware if all elements are met.
 - Definition of technology is “agnostic.”
- Cybersecurity = the process of protecting information by preventing, detecting and responding to cyberattacks.

CYBERSECURITY – DIFFERENCES BETWEEN STARK LAW AND AKS

Stark Law 42 CFR § 411.357(bb)	AKS 42 CFR § 1001.952(jj)
<p>The eligibility of the physician for the technology or services and the amount or nature of the technology or services is not determined in any manner that directly takes into account the value or volume of referrals or other business generated between the parties</p>	<p>The donor does not directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of technology or services to be donated, nor does the donor condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.</p>
<p>The arrangement must be in writing.</p>	<p>A general description of the technology and services being provided and the amount of the recipient's contribution, if any, must be set forth in writing and signed by the parties.</p>
	<p>The donor does not shift the costs of the technology or services to any Federal health care program.</p>

TECHNOLOGY & SERVICES

Potentially Protected*	Not or Probably Not Protected
<p>Single-use or stand-alone cybersecurity hardware such as computer privacy screens, two-factor authentication dongles and security tokens, facial recognition cameras for secure access, intrusion detection systems, and biometric authentication.</p>	<p>Locks on doors, physical security systems, fire retardant or warning technology, high security doors – these are not “technology.”</p>
<p>Services associated with developing, installing and updating cybersecurity software; cybersecurity patches and updates; cybersecurity training services; help desk services specific solely to cybersecurity.</p>	<p>Software or hardware with multiple functionality, even if cybersecurity is one functionality; general IT help desk services.</p>
<p>Cybersecurity services for business continuity and data recovery services to ensure the recipient’s operations can continue after a cyber attack.</p>	<p>Payment of ransom to a cyber-attacker; payment of legal fees, fines or penalties stemming from a cyberattack; reimbursement to the recipient for costs expended for cybersecurity software and hardware.</p>

*Assuming all other conditions are met, including that the technology/services are necessary and used predominantly to implement, maintain or reestablish cybersecurity

INNOVATIVE ARRANGEMENTS, DIGITAL HEALTH

NEW AKS SAFE HARBOR: CARE COORDINATION ARRANGEMENTS

- Effective Jan 19, 2021, 42 CFR § 1001.952(ee).
- Protects care coordination arrangements designed to improve quality, health outcomes, and efficiency and to facilitate the shift to value-based care.
- This new safe harbor applies to VBE participants that have little or no financial risk.
 - Although the safe harbor is flexible, it is also complex.
- Permits the exchange of in-kind remuneration (excluding cash and gift cards) among VBE participants for coordinating and managing patient care activities.
 - Recipient must pay at least 15% of the offeror's cost.

REMUNERATION

- The remuneration exchanged (e.g., a digital health device) must be used *predominantly* to engage in value-based activities that are directly connected to the coordination and management of care for the target population and does not result in more than incidental benefit to persons outside the target population.

COORDINATION AND MANAGEMENT OF CARE

- The deliberate organization of patient care activities and sharing of information between or among VBE participants and may include patients.
- Must be designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient populations.
- Can include a “limited technology participant” that exchanges digital health technology with another VBE participant, with conditions and limitations.

NEW AKS SAFE HARBOR: PATIENT ENGAGEMENT AND SUPPORT

- Effective Jan 19, 2021, 42 CFR § 1001.952(hh).
 - Protects remuneration (non-cash) in the form of certain patient engagement tools and support furnished by a VBE participant to a patient in the target population.
 - \$500 annual cap/patient; adjusted annually.
 - Preventative items, goods, or services, or items, goods or services such as health related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health, that have a direct connection to the coordination and management of care of the patient population.

AMENDMENTS TO EXISTING AKS SAFE HARBORS

- Warranties (42 CFR § 1001.952(g)) – Effective Jan 19, 2021
 - Expanded the existing safe harbor to protect bundled warranty arrangements involving multiple items or bundles of items and services.
- Local Transportation (42 CFR § 1001.952(bb)) – Effective Jan 19, 2021
 - Expanded mileage limits for rural areas (from 50 to 75 miles).
 - Removed mileage limits for transporting patients discharged from an inpatient facility following an inpatient admission or released from a hospital after spending at least 24 hours in observation status.

AMENDMENTS TO EXISTING AKS SAFE HARBORS

- Personal Services and Management Contracts, 42 CFR § 1001.952(d)
 - Effective Jan 19, 2021.
 - Amended to provide safe harbor protection to certain payment structures that incorporate value-based care models.
 - Replaced requirement for aggregate compensation to be set forth in advance with a requirement that the *methodology (such as a compensation formula) for determining the compensation* be set forth in advance.
 - Increased flexibility for part-time or sporadic arrangements and arrangements for which the aggregate compensation is not known in advance.

Questions?

Contact Information



John D. Fanburg, Esq.
Managing Member and Chair,
Healthcare Law
jfanburg@bracheichler.com
973-403-3107



Isabelle Bibet-Kalinyak, Esq.
Member, Healthcare Law
ibibetkalinyak@bracheichler.com
973-403-3131



Lani M. Dornfeld, Esq.
Member, Healthcare Law
ldornfeld@bracheichler.com
973-403-3136



Joseph M. Gorrell, Esq.
Member, Healthcare Law
jgorrell@bracheichler.com
973-364-3112

Brach Eichler LLC
101 Eisenhower Parkway, Roseland, New Jersey 07068
www.bracheichler.com

Appendix

REFERENCES AND USEFUL LINKS

- **Stark Law, 42 CFR Subpart J, Sections 411.350 to 411.389:** <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-411>
- **Stark Law, CMS Final Rule with comments (CMS-1720-F, 12/2/2020):** <https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>
- **AKS, 42 CFR §1320a-7b:** <https://www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap7-subchapXI-partA-sec1320a-7b.pdf>
- **AKS, 42 CFR § 1001.952 Exceptions:** <https://www.ecfr.gov/current/title-42/chapter-V/subchapter-B/part-1001/subpart-C/section-1001.952>
- **AKS Safe Harbors, OIG Final Rule with comments (RIN 0936-AA10, 12/2/2020):** <https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>

STARK HISTORY/TIMELINE

- 1989: Physician self-referral law, known as the “Stark I” passed;
- 1995: “Stark II” amendments included in the Omnibus Budget Reconciliation Act of 1993
- 1995: Stark I final regulations published.
- 2001: CMS published “Phase I” final rule.
- 2004: CMS published “Phase II” final rule.
- 2007: CMS published “Phase III” final rule.
- 2015: CMS eased the burden of some of the strict requirements under certain exceptions by implementing certain modifications.
- 2019: Proposed regulations issued.
- Nov. 20, 2020: CMS published Final Rule: 85 Fed. Reg. 77492-77682.

AKS HISTORY/TIMELINE

- 1972: Congress passed the AKS as an amendment to the Social Security Act.
- 1977: Congress broadened the law to make AKS violations felonies punishable by up to 5 years imprisonment.
- 1987: Medicare and Medicaid Patient and Program Protection Act of 1987 codified the Federal AKS.
- 2010: Congress amended the AKS through the Patient Protection and Affordable Care Act to make clear that “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the False Claims Act.”
- 2019: Proposed regulations issued.
- Nov 20, 2020: OIG published Final Rule: 85 Fed. Reg. 77684-77895.

VALUE-BASED CARE

CHANGES TO STARK LAW REGULATIONS – NEW EXCEPTIONS

- Value-Based Compensation Arrangements, Effective Jan 19, 2021, 42 CFR § 411.357(aa)
 - Remuneration is paid regardless of whether there is any downside financial risk undertaken by the participants.
 - Signed writing required.
 - The participants take on “meaningful downside financial risk” amounting to at least 10% of the total value of the remuneration received under the arrangement.
 - Nature and extent of risk assumed should be written.
 - The participants take on full financial risk for the duration of the arrangement.
 - No writing required.

CHANGES TO AKS REGULATIONS – NEW AKS SAFE HARBORS

- Value-Based Compensation Arrangements, 42 CFR § 1001.952 – Effective Jan 19, 2021
 - Care coordination arrangement (1001.952(ee))
 - In-kind remuneration only
 - All recipients must pay 15% of the offeror's cost or 15% of the FMV of remuneration
 - Substantial downside financial risk (1001.952(ff))
 - Full financial risk (1001.952(gg))

AKS - INELIGIBLE ENTITIES

- Pharmaceutical manufacturers, distributors, and wholesalers
- PBMs
- Laboratory companies
- Pharmacies that primarily compound drugs or primarily dispense compounded drugs
- Manufacturers of devices or medical supplies
- DMEPOS

NEW FRAMEWORK FOR VALUE-BASED CARE

Level of Risk	Stark Exceptions	AKS Safe Harbors
Tier 1: No/Low Risk	<ul style="list-style-type: none">• Value-Based Arrangements	<ul style="list-style-type: none">• Outcome Based Payment Arrangements• Care Coordination Arrangements
Tier 2: Substantial/ Meaningful Risk	<ul style="list-style-type: none">• Meaningful Risk Value-Based Arrangements	<ul style="list-style-type: none">• Substantial Downside Risk
Tier 3: Full financial Risk	<ul style="list-style-type: none">• Full Financial Risk	<ul style="list-style-type: none">• Full Financial Risk

CMS INNOVATION MODELS – NEW AKS SAFE HARBORS

NEW AKS SAFE HARBORS (CONT'D)

CMS-SPONSORED MODEL ARRANGEMENTS AND CMS-SPONSORED MODEL PATIENT INCENTIVES

- Effective Jan 19, 2021, 42 CFR § 1001.952(ii)
- Requirements:
 - CMS must determine that the model qualifies for the safe harbor.
 - Only apply to CMS-sponsored model participants and their agents.
 - Parties must document how their transactional arrangement advances the model's aims, including discouraging the provision of medically-unnecessary items or services.
 - Patient incentives must have a direct connection to the patient's health care.
 - Protects only financial arrangements among, and patient incentives furnished by, parties participating in the CMS-sponsored model.

NEW AKS SAFE HARBORS (CONT'D)

ACO BENEFICIARY INCENTIVE PROGRAMS

- Effective Jan 19, 2021, 42 CFR § 1001.952(kk),
- Codifies the statutory exemption for Accountable Care Organizations (ACO)s operating a CMS-approved beneficiary incentive program under the Medicare Shared Savings Program (MSSP).
- The exception clarify that an ACO may furnish payments only to assigned beneficiaries.
- OIG declined to add any additional conditions for purposes of satisfying the regulatory safe harbor.

**PHARMACEUTICALS –
CHANGES TO AKS
“DISCOUNT” SAFE HARBOR**

CHANGES TO AKS SAFE HARBOR: DISCOUNT

- Effective Jan 1, 2022, 42 CFR § 1001.952(h)
- Affects Pharmaceutical companies and PBMs.
- Explicitly excludes discounts and rebates on drug utilization made available to Medicare Part D plan sponsors and their PBM agents from the definition of “discounts” which may receive protection from AKS exposure under the Discount Safe Harbor.