Medical Director Arrangements

Compliance Primer

HealthValueGroup
Identifying FMV in the healthcare space

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A regulatory compliance reference guide covering **Stark Law**, the **Anti-Kickback Statute, fair market value**, and **commercial reasonableness** requirements for physician medical director arrangements.

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AI Assisted – HVG Verified

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Part I. Regulatory Overview (Sections 1–4)

Purpose and Audience

This Primer is a compliance reference tool for hospital and health system general counsel, chief compliance officers, and healthcare compliance attorneys. Medical director arrangements are among the most frequently scrutinized physician compensation structures in federal healthcare enforcement. This Primer addresses the governing regulatory framework, fair market value and commercial reasonableness requirements, key enforcement precedent, and practical compliance protocols.

This Primer is for informational purposes only. It does not constitute legal advice and does not create an attorney-client relationship. Readers should engage qualified Stark/AKS counsel and independent valuation advisors for guidance on specific arrangements. All statutory and regulatory citations should be verified against current primary sources.[1]

Section 1. The Governing Regulatory Framework

Three federal statutes govern medical director arrangements and frequently operate simultaneously:[1]

Stark Law (42 U.S.C. § 1395nn): Prohibits a physician from referring Medicare/Medicaid patients for designated health services (DHS) to an entity with which the physician has a financial relationship, unless an applicable exception is satisfied. Strict liability intent is irrelevant. Medical director agreements are compensation arrangements requiring a Stark exception.[2]

Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)): Criminal statute prohibiting the knowing and willful offer, payment, or receipt of anything of value to induce or reward referrals of federally covered items or services. Intent-based. Federal courts apply a “one purpose” test: if even one purpose of the compensation is to reward referrals, the statute may be violated.[3,4,5]

False Claims Act (31 U.S.C. §§ 3729–3733): Imposes treble damages and per-claim penalties for knowingly submitting false claims to the government. Authorizes qui tam relator suits. A non-compliant medical director arrangement may create downstream False Claims Act exposure for claims submitted in violation of the Stark Law where the applicable False Claims Act elements, including scienter and materiality, are satisfied.[6]

Section 2. Stark Law — Applicable Compensation Exceptions

Most medical director arrangements rely on one of two Stark exceptions:

Personal Services Exception (42 C.F.R. § 411.357(d)): Requires a signed written agreement; all services covered; term of at least one year; compensation methodology set in advance (hourly rate structures satisfy this requirement under the 2020 Final Rule); compensation not determined by the volume or value of referrals; compensation consistent with FMV; and the arrangement commercially reasonable. An expired arrangement may continue in an indefinite holdover on the same terms and conditions, provided all exception elements remain satisfied (a provision established by the 2015 rulemaking effective January 1, 2016, and codified by the Bipartisan Budget Act of 2018 — not the 2020 Final Rule).[7,8,9]

Employment Exception (42 C.F.R. § 411.357(c)): Requires identifiable services; compensation consistent with FMV and not tied to referral volume or value; and a written agreement. No minimum term is required, but all FMV and commercial reasonableness requirements apply.[10]

Section 3. Holdover Arrangements — Current Standard

STARK HOLDOVER PROVISION — PERSONAL SERVICE ARRANGEMENTS (42 C.F.R. § 411.357(d)(1)(vii))

- The prior six-month cap on holdover arrangements was eliminated by the CY2016 Physician Fee Schedule rule (effective January 1, 2016), and indefinite holdovers for personal service arrangements were subsequently codified into the statute by the Bipartisan Budget Act of 2018. An arrangement may continue indefinitely after its written term expires, provided that: (1) the arrangement satisfied a Stark exception when it expired; (2) the holdover continues on the same terms and conditions as the expired agreement; and (3) all elements of the applicable exception, including FMV and commercial reasonableness continue to be satisfied throughout the holdover period. The 2020 Final Rule did not alter these holdover conditions.

This modernization was intended to eliminate technical compliance traps arising from contract expiration without substantive change. Organizations should still prioritize timely renewals as a best practice. If any terms, duties, or compensation have changed during a holdover period, holdover protection may be defeated, and outside Stark counsel should be engaged promptly.

Section 4. AKS — Personal Services Safe Harbor

- The personal services safe harbor (42 C.F.R. § 1001.952(d)) requires:
- a signed written agreement specifying services
- a term of at least one year
- compensation methodology set in advance and consistent with FMV: a per-unit or hourly rate satisfies this requirement (the 2021 OIG Final Rule eliminated both the prior requirement that part-time arrangements specify an exact schedule of intervals and charges and the requirement for a fixed aggregate dollar amount)
- compensation not tied to the volume or value of referrals
- services do not involve counseling or promotion of unlawful arrangements
- the aggregate services contracted for do not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the services. An arrangement outside the safe harbor is not automatically unlawful but is evaluated under a facts-and-circumstances AKS analysis.[11,12,13]

Part II. Fair Market Value of Medical Director Compensation (Section 5)

5.1 The Regulatory Definition

- Under the Stark Law, fair market value means "the value in arm's-length transactions, consistent with the general market value of the subject transaction." [14]
- The 2020 Stark Law Final Rule confirmed that FMV must be assessed in the context of the specific arrangement.[8]
- Importantly, FMV and the volume/value standard are separate and independent legal requirements under Stark CMS. CMS intentionally maintained this distinction in the 2020 Final Rule. Compensation influenced by referral volume may violate the Stark volume/value standard even if the dollar amount otherwise resembles market compensation.

5.2 The Triple Compliance Function of FMV Analysis

- A properly supported FMV analysis simultaneously serves three distinct compliance functions:[8]
- Stark Law: Compensation must be consistent with FMV to satisfy the personal services and employment exceptions.[7,10]
- Anti-Kickback Statute: FMV compensation is material evidence that payments are not intended to induce or reward referrals.[11]
- IRS / Tax-Exempt Organizations: For nonprofit health systems, physician compensation to insiders must not exceed FMV or risk exposure to intermediate sanctions under IRC § 4958. Loss of tax-exempt status is an available remedy but is rarely imposed; intermediate sanctions including excise taxes on the excess benefit represent the primary consequence in practice.[15]

5.4 The Benchmarking-Only Trap

Relying solely on survey percentile data without additional documented analysis does not constitute a legally defensible FMV determination. Survey data provides market context. It does not substitute for an independent analysis of the specific arrangement.

Neither Stark nor the AKS legally mandates an independent third-party FMV opinion; CMS has intentionally declined to prescribe a particular valuation methodology. However, an independent written opinion represents a leading compliance practice and provides the strongest evidentiary support for demonstrating FMV. Hospitals relying solely on survey data are exposed to the argument that compensation decisions were not independently validated. No percentile threshold carries independent legal significance; CMS has expressly rejected bright-line percentile rules. Higher-percentile compensation is not presumptively unlawful; rather, it warrants more robust documentation of the unique facts and circumstances supporting the arrangement.

5.5 When an Independent FMV Opinion Is Strongly Advisable

- An independent written FMV opinion is neither required by Stark nor by the AKS CMS has intentionally declined to mandate third-party valuations. However, an independent written opinion represents a leading compliance practice and provides the strongest evidentiary foundation in the following circumstances:[8]
- Compensation at higher percentile ranges of applicable benchmarks, warranting additional documentation of supporting facts and circumstances.
- The physician is an active referral source.
- The arrangement includes multiple compensation components (clinical, administrative, call coverage, co-management).
- The arrangement has not been independently analyzed within the organization's established revalidation cycle.
- The arrangement is the subject of internal audit findings or government inquiry.

Best Practices

- Obtain an independent FMV opinion for all new arrangements and any renewal where compensation or scope of duties has changed. While not legally mandated, an independent opinion provides the strongest evidentiary support for FMV defensibility.[8]
- Avoid relying solely on survey percentile data as your FMV determination. Surveys provide market context; a documented, independent analysis of the specific arrangement provides meaningfully stronger compliance support.
- Engage a qualified independent valuation firm such as HealthValueGroup (www.hvg-fmv.com) for arrangements with active referral sources or higher-percentile compensation.
- Establish a revalidation schedule appropriate to the risk profile of each arrangement. Many organizations adopt a two- to three-year revalidation cycle or update upon material change in compensation, duties, or market conditions though no specific regulatory timeframe is mandated.[8]

Part III. Commercial Reasonableness — A Three-Part Compliance Framework (Section 6)

Commercial reasonableness and fair market value are legally distinct and independently required elements under the Stark Law. An arrangement may satisfy FMV and still fail commercial reasonableness. Both must be satisfied independently. The three-part framework used in this section is a practical compliance review tool not a regulatory formulation prescribed by CMS.

6.1 The Legal Standard

CMS 2020 STARK LAW FINAL RULE; DEFINITION CODIFIED AT 42 C.F.R. § 411.351
"Commercially reasonable means that the particular arrangement furthers 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. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

6.2 The Governing Standard for Medical Director Arrangements

THE COMMERCIAL REASONABLENESS STANDARD
Does this medical director position make sense from a clinical and operational standpoint does it serve a legitimate purpose that advances the organization's healthcare delivery objectives?

- This formulation positions commercial reasonableness as a purpose-driven, operational-necessity inquiry, not primarily a referral-neutrality test. The physician's referral relationship with the hospital is a scrutiny-elevating factor requiring careful documentation. It is not the definitional core of the standard. For compliance review purposes, organizations often evaluate commercial reasonableness through three related inquiries addressing the existence of the position, the appropriateness of the compensation amount, and the actual performance of contracted duties. Each inquiry is discussed below.[16]

6.3 Inquiry One — Commercial Reasonableness of the Arrangement's Existence

Does This Position Need to Exist?

The threshold commercial reasonableness question is whether the medical director position is clinically and operationally justified. This must be answered before analyzing compensation level or service delivery. An arrangement failing this threshold cannot be saved by FMV compensation or perfect documentation.

A position fails commercial reasonableness of existence when:

- The clinical or operational function the position is designed to serve does not genuinely exist, is already performed by another resource, or does not require physician-level expertise.
- The position was created or expanded in connection with the physician's referral relationship rather than in response to an identified organizational need.
- The organization cannot articulate in writing, at contracting, what specific clinical or operational objective the position advances.
- The position exists primarily to provide a compensation vehicle for a referring physician beyond what clinical productivity alone can justify.

Hallmarks of a Sham Medical Directorship

- No defined program, service line, or clinical initiative the physician leads or supports.
- Generic, undefined duties identical to every other medical director regardless of specialty.
- Compensation set based on the physician's clinical revenue contribution rather than the value of administrative services.
- A title conferred for relationship management rather than in response to an operational need.

Best Practices

- Require a written Legitimate Business Purpose Memorandum for every new arrangement documenting the specific clinical or operational need the position will serve.
- Conduct an annual review of each position to confirm that the operational need continues to exist and is being actively addressed.
- Ask the fundamental audit question: if this physician stopped referring tomorrow, would we still want this medical director position? If no immediate review is required.

6.4 Inquiry Two — Commercial Reasonableness of the Compensation Amount

Does the Compensation Reflect What a Reasonable Entity Would Pay?

- The second inquiry asks whether total compensation reflects what a reasonable healthcare entity, operating in a competitive market, would agree to pay for the services described independent of any referral relationship. This inquiry is related to but distinct from the FMV analysis. FMV establishes the market rate for the services described; commercial reasonableness asks whether the compensation structure as a whole reflects a sensible business decision.[16]
- Red flags suggesting the compensation amount may fail commercial reasonableness:
- Total compensation significantly exceeding higher percentile ranges of market data with no documented justification.
- Administrative compensation increasing in proportion to the physician's referral volume rather than expanded duties.
- Multiple compensation components that, when aggregated, exceed market norms without independent FMV support for each.

Best Practices

- Perform a total compensation analysis for every physician holding multiple compensated positions aggregate all streams against market benchmarks.
- Document the compensation rationale in writing: basis for hours contracted, duties assigned, and rate applied.
- Stress-test compensation-to-hours: if limited hours imply significant annual compensation, document why that rate is appropriate.

6.5 Inquiry Three — Were the Duties Actually Performed?

The Documentation and Performance Imperative

- The third inquiry and most significant from an enforcement standpoint asks whether the contracted services were actually rendered. If services were not performed, the compensation cannot be justified as FMV for services rendered, and the arrangement loses its commercial reasonableness foundation entirely.[17,18,19]
- *The absence of contemporaneous documentation significantly undermines the ability to demonstrate that contracted services were actually performed. Enforcement agencies frequently cite the lack of documentation as evidence supporting their theory that services were not rendered and courts have found it persuasive.*

Best Practices

- Require all medical directors to submit monthly or quarterly service attestations documenting specific services, dates, hours, and deliverables. This is a recommended internal control which may also be satisfied through manager certification, work product review, or committee minutes not a statutory requirement.
- Conduct annual compliance audits confirming service documentation is current, complete, and retained.
- For legacy arrangements where historical documentation is absent, engage outside Stark/AKS counsel promptly to evaluate repayment obligations and whether disclosure under the CMS Self-Referral Disclosure Protocol (SRDP), the OIG Self-Disclosure Protocol, or another reporting mechanism is appropriate — or whether repayment without formal disclosure is the correct course.[20]

Part IV. Enforcement Landscape (Section 7)

- The following matters have directly shaped compliance standards for medical director arrangements and should be used as an internal audit template. Case citations and settlement details should be independently verified against primary sources before reliance.[20]

Case / Settlement	Amount	Key Compliance Lesson
United States ex rel. Drakeford v. Tuomey Healthcare Sys., 792 F.3d 364 (4th Cir. 2015)	$72.4M settlement	Part-time employment contracts with 19 specialists compensated in a manner the Fourth Circuit found tied to the volume and value of their referrals and above FMV, to retain surgical volume. Compensation structured to retain or reward a referral stream fails Stark regardless of label.
United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002 (M.D. Fla. 2014)	$85M settlement	Employed oncologists received a bonus pool tied to the oncology program's operating margin, which included revenue from DHS the oncologists referred to but did not personally perform; three neurosurgeons were separately paid above FMV. The court held the bona fide employment exception was not met because the bonus varied with referral value. Incentive formulas that capture referral-driven DHS revenue fail Stark.
United States ex rel. Longo v. Wheeling Hospital, No. 5:19-cv-00169 (N.D. W. Va. 2020)	$50M settlement	DOJ alleged that management systematically paid referring physicians including medical directors' compensation, that considered the volume or value of referrals or exceeded FMV, to capture referral revenue and market share. A mid-size regional hospital: enforcement is not limited to large systems.
NY-Presbyterian / Hudson Valley Hospital (S.D.N.Y. 2025)	$616K settlement	Hospital paid an oncology practice over $4M under three medical directorship / management agreements for work that (per the hospital's own admission) was not performed, not performed as required, or unsupported by time records and kept paying for three years after it knew or should have known. The absence of contemporaneous documentation may be cited by enforcement agencies as evidence that contracted services were not actually performed, supporting allegations that compensation functioned as remuneration for referrals.

Part V. OIG Guidance and Documentation Requirements (Sections 8–9)

Section 8. OIG Guidance — Key Reference Points

- OIG General Compliance Program Guidance (2023): Identifies medical director arrangements as a high-risk area requiring written policies, independent FMV/CR analysis, ongoing monitoring of services rendered, and periodic portfolio-wide auditing.[20]
- OIG Fraud & Abuse Laws (Physician Education): Physician compensation paid to referral sources must reflect genuine services that are actually needed and actually performed. Compensation functioning as a vehicle for rewarding referrals even when documented as administrative violates the AKS.[1]
- AKS One-Purpose Test: The dominant judicial interpretation of the AKS is the "one purpose" test, originating with United States v. Greber (3d Cir. 1985) and most recently adopted by the Second Circuit in United States ex rel. Camburn v. Novartis Pharms. Corp. (2d Cir. 2024). Under this doctrine, the AKS may be violated if even one purpose of the compensation is to induce or reward referrals regardless of whether legitimate services were also provided.[4,5]

Section 9. Documentation — Minimum Requirements

- Contemporaneous documentation of services rendered is the single most important compliance safeguard for medical director arrangements. At minimum:[17,19]
- Signed written agreement executed before services begin and compensation is paid, satisfying the Stark writing requirement.[7]
- Specific scope of services identified duties, minimum hours, named deliverables, and reporting obligations. Generic "medical direction and oversight" language is not sufficient.
- Monthly or quarterly service verification, which may take the form of a signed attestation, manager certification, work product review, or committee minutes. (Recommended internal control.)
- Supporting evidence: meeting minutes, committee attendance records, written reports, protocols, and other work products.
- Centralized compliance file retaining all of the above, accessible for audit.
- The "contract in the drawer" problem a signed agreement with no operational follow-through may satisfy the technical Stark writing requirement while simultaneously failing AKS and commercial reasonableness standards. Execution of the agreement is the beginning of the compliance obligation, not the end.[11,16]

Part VI. Checklists, Compliance Program, and Outside Resources (Sections 10–12)

Section 10. Pre-Engagement Compliance Checklist

- 1. Documented clinical or operational need for the position (commercial reasonableness existence inquiry).[16]
- 2. Legitimate Business Purpose Memorandum prepared and approved.
- 3. Independent FMV analysis completed and documented. (Leading compliance practice; not legally mandated.)[8]
- 4. Arrangement mapped to a specific Stark compensation exception.[7,10]
- 5. All AKS safe harbor elements reviewed and documented.[11]
- 6. Scope of services specific: duties, minimum hours, deliverables, reporting obligations.
- 7. Total compensation analyzed in aggregate across all compensated positions.
- 8. Compliance and legal review and approved the arrangement. (Recommended governance practice.)
- 9. Agreement in writing; signed by both parties before services begin.[7]
- 10. Service verification protocol in place of attestations, manager certifications, or equivalent. (Recommended internal control.)

Section 11. Red Flag Escalation Matrix

Red Flag	Risk	Action Required
Higher-percentile compensation with no independent FMV analysis or documented facts-and-circumstances support	HIGH	Commission independent FMV analysis; document supporting rationale
No service verification on file for prior 12 months	HIGH	Engage outside counsel; evaluate self-disclosure options
Agreement expired or operating in holdover with changed terms	HIGH	Engage Stark counsel; confirm holdover conditions are met
No documented business purpose for the position	HIGH	Prepare business purpose memo; conduct CR analysis
Compensation increases correlate with referral volume increases	CRITICAL	Suspend; immediate outside counsel review
Multiple compensation streams with no aggregate FMV analysis	HIGH	Commission aggregate compensation analysis
No FMV analysis within organization's revalidation cycle	MEDIUM	Commission updated FMV analysis
Duties vague or generic in the agreement	MEDIUM	Amend agreement; obtain updated FMV analysis

Section 12. Compliance Program — Core Requirements

- A sustainable medical director compliance program requires at minimum:[20]
- Clear governance ownership compliance owns the arrangement database and audit function; legal reviews all agreements; finance approves above-threshold compensation; the board/compliance committee receives periodic portfolio reports.
- Written policies covering initiation, approval, execution, FMV requirements, service documentation, renewal protocols, aggregate compensation analysis, red flag escalation, and self-disclosure evaluation.
- Annual portfolio-wide audit, not just newly executed arrangements.
- Risk-tiered audit frequency: high-risk arrangements audited semi-annually.
- When a compliance issue is identified: immediately engage outside Stark/AKS counsel; preserve all relevant documentation; evaluate repayment obligations and whether disclosure under the CMS SRDP, the OIG Self-Disclosure Protocol, or another mechanism is appropriate; and document all remediation steps taken.[20]

About HVG

HealthValue Group (www.hvg-fmv.com) provides independent FMV opinions, commercial reasonableness analyses, business valuations, and transaction advisory services exclusively in the healthcare industry. HVG supports Stark Law, Anti-Kickback Statute, and IRS compliance for medical directorships, call coverage, co-management, employment agreements, and PSAs. HVG serves as a resource for general counsel, chief compliance officers, and outside transactional counsel requiring independent, defensible FMV support.

Appendix A. Stark Law Personal Services Exception — Element Checklist

Use this checklist to confirm that a medical director arrangement satisfies the personal services exception under 42 C.F.R. § 411.357(d).[7,8]

1. Arrangement is set out in writing and signed by both parties.[7]

2. Arrangement covers all services provided by the physician to the entity.

3. Aggregate services do not exceed those reasonable and necessary for the arrangement's legitimate business purposes.

4. Term of arrangement is for at least one year. Note: indefinite holdover is permitted after expiration provided the arrangement continues the same terms and conditions and all exception elements remain satisfied.[9,8]

5. Compensation methodology is set in advance. A per-unit or hourly rate structure satisfies this requirement under the 2020 Final Rule a fixed aggregate dollar amount is not required.[14,22]

6. Compensation is not determined by the volume or value of referrals or other business generated between the parties.[7]

7. Compensation is consistent with fair market value.[14]

8. Services do not involve counseling or promotion of arrangements violating state or federal law.

9. Arrangement reviewed and approved by compliance and legal prior to execution. (Recommended governance practice.)

Appendix B. AKS Personal Services Safe Harbor — Element Checklist

Use this checklist to confirm that a medical director arrangement satisfies the personal services safe harbor under 42 C.F.R. § 1001.952(d).[11,12]

1. Signed written agreement specifying the services to be provided.[11]

2. Term of the arrangement is for not less than one year.[11]

3. Compensation methodology is set in advance and consistent with FMV in arm's-length transactions. A specified hourly or per-session rate satisfies this requirement; a fixed aggregate dollar amount is not required.[13]

4. The prior requirement that part-time arrangements specify an exact schedule of intervals, precise length, and exact charge was eliminated by the 2021 OIG Final Rule and no longer applies.[13]

5. Compensation is not determined by the volume or value of referrals or other business generated between the parties.[11]

6. The aggregate services contracted for do not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the services.[11]

7. Services do not involve counseling or promotion of arrangements violating state or federal law.

Appendix C. Medical Director Agreement — Red Flag Checklist

Review each active or proposed arrangement against the following. Any flag identified should be escalated to compliance and legal.

1. Higher-percentile compensation with no independent FMV analysis or documented facts-and-circumstances rationale on file.[8]

2. No written documentation of the legitimate clinical or operational purpose for the position.

3. Duties are vague, generic, or not tied to a specific program, service line, or clinical initiative.

4. No service verification protocol in place.

5. Service verification not completed for the prior 12 months.

6. Agreement is expired or operating in holdover with any change in terms, compensation, or duties.[9]

7. Compensation increased concurrently with an increase in the physician's referral volume.

8. Multiple compensated positions with no aggregate compensation analysis performed.

9. No current FMV analysis within the organization's established revalidation cycle.

10. Position created or compensation increased at the physician's request rather than in response to an identified operational need.

11. No meaningful accountability, reporting, or performance review structure for the medical director.

Appendix D. Sample Medical Director Service Attestation

Adapt this template for monthly or quarterly use. Completed attestations should be retained in the compliance file. Organizations may use alternative service verification methods including manager certification, work product review, or committee minutes.

Physician Name: _____
Medical Director Role / Program: _____
Attestation Period (Month / Quarter / Year): _____
Total Hours of Service This Period: _____
Description of Services Performed (attach supporting documentation — meeting minutes, reports, committee records): _____
Certification: I certify that the services described above were actually performed during the attestation period, in my capacity as Medical Director, pursuant to my written agreement with the organization. The hours reported accurately reflect time devoted exclusively to medical director duties.
Signature: _____ Date: _____

Appendix E. Glossary of Key Terms

Anti-Kickback Statute (AKS): Federal criminal statute prohibiting knowing and willful payment, offer, solicitation, or receipt of remuneration to induce or reward referrals of federally covered items or services.[3]

Commercial Reasonableness: Stark Law requirement that an arrangement make clinical and business sense for a prudent healthcare executive motivated by legitimate business reasons. Governing standard: does the position serve a legitimate purpose in advancing the organization's healthcare delivery objectives? [16]

Designated Health Services (DHS): Healthcare service categories subject to the Stark Law physician self-referral prohibition, including inpatient and outpatient hospital services.[2]

Fair Market Value (FMV): The value in arm's-length transactions consistent with general market value. FMV and the Stark volume/value standard are separate legal requirements; compensation influenced by referral volume may violate the volume/value standard even if the amount otherwise resembles market compensation.[14,8]

False Claims Act (FCA): Federal statute imposing treble damages and civil monetary penalties for knowingly submitting false claims to the government. Authorizes qui tam relator suits.[6]

One Purpose Test: Judicial doctrine originating in United States v. Greber (3d Cir. 1985) and adopted by the majority of federal circuits, including the Second Circuit in United States ex rel. Camburn v. Novartis Pharms. Corp. (2d Cir. 2024). Under this doctrine, the AKS may be violated if even one purpose of a payment is to induce or reward referrals, regardless of other legitimate purposes.[4,5]

Personal Services Exception: Primary Stark Law compensation exception for independent contractor medical director arrangements.[7,8]

Personal Services Safe Harbor: Primary AKS protection for personal services and management contract arrangements meeting all specified conditions.[11,12]

Stark Law: Physician Self-Referral Law. Prohibits referrals of Medicare/Medicaid DHS to entities with which the physician has a financial relationship absent from a qualifying exception. Strict liability.[2]

Volume or Value Standard: Requirement that physician compensation not be determined in a manner considering the volume or value of the physician's referrals to the compensating entity.[7,11]

References and Citations

The following citations correspond to the superscript reference numbers used throughout this Primer. All citations should be independently verified against current primary sources.

1. OIG, Fraud & Abuse Laws — Physician Education, oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/.

2. 42 U.S.C. § 1395nn (Physician Self-Referral Law / Stark Law).

3. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute).

4. United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985) (originating the one purpose test).

5. United States ex rel. Camburn v. Novartis Pharms. Corp., No. 22-2708 (2d Cir. Dec. 27, 2024) (Second Circuit adopting the “at least one purpose” rule).

6. 31 U.S.C. §§ 3729–3733 (False Claims Act). See also 18 U.S.C. § 287 (criminal false claims).
7. 42 C.F.R. § 411.357(d) (Personal Services Exception).

8. CMS, Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77492 (Dec. 2, 2020), effective Jan. 19, 2021.

9. 42 C.F.R. § 411.357(d)(1)(vii) (personal service arrangements holdover). Indefinite holdover established by the CY2016 PFS Final Rule, 80 Fed. Reg. 70886 (Nov. 16, 2015), effective Jan. 1, 2016, and codified by the Bipartisan Budget Act of 2018, Pub. L. 115-123.

10. 42 C.F.R. § 411.357(c) (Employment Exception).

11. 42 C.F.R. § 1001.952(d) (AKS Personal Services and Management Contracts Safe Harbor).

12. OIG, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute, 85 Fed. Reg. 77684 (Dec. 2, 2020), effective Jan. 19, 2021.

13. OIG, 85 Fed. Reg. 77684 (2020) (compensation-methodology / set-in-advance discussion; elimination of the exact-schedule requirement for part-time arrangements).

14. 42 C.F.R. § 411.351 (Stark Law definitions, including fair market value and general market value).

15. I.R.C. § 4958 (Excess Benefit Transactions — intermediate sanctions for tax-exempt organizations).

16. CMS, 85 Fed. Reg. 77492 (2020) (commercial reasonableness discussion); definition codified at 42 C.F.R. § 411.351.

17. United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002 (M.D. Fla.) (partial summary judgment for the United States on Stark, Nov. 13, 2013; $85 million settlement, March 2014).

18. United States ex rel. Longo v. Wheeling Hosp., Inc., No. 5:19-cv-00169 (N.D. W. Va.). $50 million settlement announced by DOJ on Sept. 9, 2020.

19. United States v. New York and Presbyterian Hospital / NYP–Hudson Valley Hospital, U.S. Attorney’s Office, S.D.N.Y.; $6.8 million settlement announced Dec. 23, 2025. See DOJ (SDNY) and HHS-OIG press releases.

20. OIG, General Compliance Program Guidance (Nov. 2023), oig.hhs.gov.

21. United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 792 F.3d 364 (4th Cir. 2015), cert. denied, 577 U.S. 1002 (2015). Settlement: $72.4 million.

22. CMS, 85 Fed. Reg. 77492 (2020) (set in advance — hourly / per-unit methodology discussion).

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