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P5 – Kickback and Stark Developments
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A. Overview of key statutory terms and exceptions for anti-kickback statute (AKS)

1. Key AKS statutory terms

a. Criminal statute - federal anti-kickback statute makes it a crime to **knowingly and willfully** [offer or pay] or [solicit or receive] **any remuneration** to **induce** a person –

(A) to **refer** an individual to a person for the furnishing of **any item or service covered under a Federal health care program**; or

(B) to purchase, lease, order, arrange for **or recommend** any good, facility, service, or item **covered under a Federal health care program**.

42 U.S.C. § 1320a-7b(b)(1) and (2).

b. Criminal intent - Government must prove intent beyond a reasonable doubt, a high legal standard.

c. Any remuneration – Very broad, includes:

(1) 40% of the Medicare payment for cardiac monitoring paid to referring physician - *U.S. v. Greber*, 760 F.2d 68, 70 (3d Cir. 1985);

(2) $1,000 per month from hospital to physician for unspecified marketing duties - *U.S. v. Jain*, 93 F.3d 436, 438 (8th Cir. 1996);

(3) alcoholic beverages received by nursing home administrator from drug supplier – *U.S. v. Perlstein*, 632 F.2d 661, 662 (6th Cir. 1980);

(4) free clerical data entry and billing services for health care providers - free administrative assistance - *U.S. v. Medtronic, Inc*., No. CV 15-6264, 2018 WL 2688424, at *4 (E.D. Pa. June 4, 2018).

d. Covered under a federal healthcare program -

(1) Federal AKS does not apply to private payors, although some state kickback statutes do cover all payors.

(2) Distinguish federal payment methodologies:

(a) Traditional fee-for-service (Medicare Parts A and B) – kickbacks are bad because each referral generates another federal payment.

(b) Managed care (Medicare Part D) – managed care insurer did not violate AKS by offering free in-home clinical visits and gift cards to beneficiaries to induce preventive care that did not change the federal managed care payment to the insurer – *U.S. ex rel. Gray v. UnitedHealthcare Ins. Co.,* No. 15-CV-7137, 2018 WL 2933674, at *7 (N.D. Ill. June 12, 2018).

(c) For managed care, federal law prohibits payments to induce reduction or limitation of services under a different civil statute - 42 U.S.C.§ 1320a-7a(b).

2. Civil false claims based on AKS violations

a. The Patient Protection and Affordable Care Act (PPACA) clarified the law to specify that "a claim that includes items or services resulting from a violation of [federal kickback law] constitutes a false or fraudulent claim." Pub. L. No. 111-148, 124 Stat. 119 (2010) (effective March 23, 2010).

b. Compliance with federal kickback law is *per se* material - *U.S., et al., Plaintiffs, ex rel. Scarlett Lutz, et al., Plaintiffs-Relators, v. Berkeley Heartlab, Inc., et al., Defendants*, No. CV 9:14-230-RMG, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017).

c. Even assuming that the United States had actual knowledge of the defendants' kickback payments and continued to pay claims, such action does not undermine a materiality finding, especially where, as in this case, the government had elected to file an FCA suit against the kickback conspirators demonstrating government action that the defendants' conduct is material. *U.S., et al., Plaintiffs, ex rel. Scarlett Lutz, et al., Plaintiffs-Relators, v. Berkeley Heartlab, Inc., et al., Defendants.*, No. CV 9:14-230-RMG, United States Omnibus Opposition to Defendants' Motions for Summary Judgment, Doc. 522, p. 23 (D.S.C. Jul. 7, 2017); *see also U.S. ex rel. Piacentile v. Snap Diagnostics, LLC,* No. 1:14-CV-3988, 2018 WL 2689270, at *4 (N.D. Ill. June 5, 2018) ("the Court disregards the argument that the Government's routine payment of duplicative claims is strong evidence that the requirements were not material").

d. "It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the

kickback." *U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018)

3. Key AKS statutory exceptions and regulatory safe harbors

a. AKS Safe Harbors - Pursuant to 1987 Congressional mandate, regulatory safe harbors were created to provide some protection from this vague statute. Other safe harbors have been added for risk-sharing arrangements, electronic medical records, etc. Even without an applicable safe harbor, AKS can be defended if the intent to induce referrals is lacking.

b. Employment – Employment relationships are protected from AKS by both a statutory exception and regulatory safe harbor, which are similar. 42 U.S.C. § 1320a-7b(b)(3)(B) and 42 C.F.R. § 1001.952(i). This broad AKS exception covers any amount paid by an employer to an employee for employment in the provision of covered items or services, without specifying the terms, method, or frequency of payment. *Carrel v. AIDS Healthcare Found., Inc.,* No. 17-13185, 2018 WL 3734278, at *5 (11th Cir. Aug. 7, 2018) (*distinguishing U.S. v. Starks*, 157 F3d 833, 836 (11th Cir. 1998)). The AKS employment exception has no fair market value requirement, unlike the Stark employment exception (discussed below).

The AKS employment exception applies only if the employer has a "bona fide" employment relationship with the employee. *See United States v. Borrasi*, 639 F.3d 774, 777 (7th Cir. 2011) ("In order to conceal these bribes, Borrasi and other Integrated employees were placed on the Rock Creek payroll, given false titles and faux job descriptions, and asked to submit false time sheets. Borrasi, for example, was named "Service Medical Director" and was allegedly required to be available at all times; Baig later testified that Borrasi was not expected to perform any of the duties listed in his job description.")

c. Discounts – AKS has both a statutory exception and a regulatory safe harbor for discounts, which differ and do not fully cover all common and desirable business discounts. The statutory exception applies to:

> a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program *if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.*

42 U.S.C. § 1320a-7b(b)(3)(A) (emphasis supplied). The statute makes the discount exclusion dependent on the proper disclosure of the discount to federal health care programs by the recipient of the discount. However, sellers offering the discount have no control over whether buyers properly report the discounts to the government.

The safe harbor regulations address the major problem with the statutory discount exception concerning the lack of seller control over disclosure of the discount. The regulations still require the buyer to fully and accurately disclose the discount in its cost reports or claims for federal reimbursement, but the seller need only report the discount to the buyer (not the government) and notify the buyer of its obligation to report the discount to the government. 42

C.F.R. § 1001.952(h)(2). The seller gets the benefit of the safe harbor even if the buyer fails to satisfy its obligation to report the discount to the government.

The safe harbor regulation (42 C.F.R. § 1001.952(h)(5)) adds four technicalities in order for the discount to be protected from AKS:

1. No Cash Payments. Sellers cannot offer discounts in the form of cash payments or cash rebates, but sellers can offer equivalent incentives in the form of rebate checks.
2. No Bundling. The regulations exclude from the discount exception the common practice of furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service. These types of "discounts" cause problems, according to the regulators, because they often shift costs among reimbursement systems or distort the true costs of all the items. Despite the obvious benefits to healthcare programs from bundling free or discounted goods and services, the regulators excluded this practice from the discount safe harbor because such arrangements do not represent price reductions where the value of the goods received can be measured and fully reported to the Medicare and Medicaid programs.
3. No Price Discrimination Against Medicare/Medicaid.
4. No Waivers of Copayments or Deductibles.

Providers have frequently resorted to OIG Advisory Opinions to seeking assurance that common discount arrangements will not be deemed to violate AKS. See OIG Advisory Opinion Nos. 17-05, 13-07, 99-3, 99-2, and 98-2. The scope of the AKS discount exception has been and continues to be a significant issue in the pharmaceutical industry. *See U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 124–25 (D. Mass. 2011); https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations (last viewed Aug. 31, 2018); https://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/civ-settlement-agreement-ma.pdf (last viewed Aug. 31, 2018).

B. Overview of key statutory terms and exceptions for Stark law

1. Key Stark statutory terms

a. Civil statute - if a **physician** (or an immediate family member of such physician) has a **financial relationship with an entity**, then—

(A**) the physician may not make a referral to the entity** for the furnishing of **designated health services covered under a Federal health program**, and

(B) **the entity may not present a claim** or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a prohibited referral.

42 U.S.C. § 1395nn(a)(1).

b. Intent to induce referrals is irrelevant.

c. Financial relationship with an entity – includes:

(A) an ownership or investment interest in the entity, including equity, debt and indirect ownership through controlling entities; and:

(B) a compensation arrangement involving any remuneration between a physician (or an immediate family member of such physician) and the entity.

42 U.S.C. § 1395nn(a)(2).

d. Remuneration - includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, but excludes –

- forgiveness of amounts owed for inaccurate or mistakenly performed tests or procedures, or the correction of minor billing errors;
- provision of items, devices, or supplies that are used solely to collect specimens or order procedures for the entity;
- certain payments from insurers to physicians on a fee-for-service basis.

42 U.S.C. § 1395nn(h)(1).

e. Designated health services - means any of the following items or services:

(A) Clinical laboratory services.
(B) Physical therapy services.
(C) Occupational therapy services.
(D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
(E) Radiation therapy services and supplies.
(F) Durable medical equipment and supplies.
(G) Parenteral and enteral nutrients, equipment, and supplies.
(H) Prosthetics, orthotics, and prosthetic devices and supplies.
(I) Home health services.
(J) Outpatient prescription drugs.
(K) Inpatient and outpatient hospital services.
(L) Outpatient speech-language pathology services.

42 U.S.C. § 1395nn(h)(6).

f. Covered under a federal healthcare program – Like federal AKS, federal Stark does not apply to private payors. See Section A.1.d. above.

2. Civil false claims based on Stark violations

a. Government may recover single damages based on equitable claims premised on Stark violations, including payment under mistake of fact and unjust enrichment. *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 396 (4th Cir. 2012).

b. No private right of action for Stark violations. *U.S. ex rel. Bruno v. Schaeffer,* No. CV 16-00001-BAJ-EWD, 2018 WL 3041191, at *8 (M.D. La. June 18, 2018).

c. Whistleblowers can bring False Claims Act actions based on Stark violations because compliance with Stark is material to payment decisions - *United States ex rel. Tullio Emanuele v. Medicor Associates, Inc.*, 2017 WL 1001581 (W D. Pa. Mar. 15, 2017).

i. The Stark Law expressly prohibits Medicare from paying claims for designated health services furnished pursuant to physician referrals unless a Stark Law exception applies. 42 U.S.C. §§ 1395nn(a)(1), (g)(1).

ii. Compliance with the Stark Law goes to the "essence of the bargain" that providers strike with federal healthcare programs.

iii. The United States has consistently and repeatedly pursued FCA claims for violations of the Stark Law.

iv. Alleged violations of Stark's "writing" requirement, if proven, would not be "minor or insubstantial," but rather would constitute significant violations of the Stark Law.

d. The Stark Law does not prohibit buying out physician investors in an isolated transaction through the rescission processes provided by commonplace state securities laws. *U.S. v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 607 (S.D. Tex. 2018).

3. Key Stark statutory and regulatory exceptions

a. Employment – Employment relationships are protected from Stark by both a statutory exception and regulatory safe harbor, which are similar. 42 U.S.C. §§ 1395nn(e)(2), 42 C.F.R. § 411.357(c). Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.
(2) The amount of the remuneration under the employment is—
(i) Consistent with the **fair market value** of the services; and
(ii) N**ot determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals** by the referring physician, except for productivity bonuses based on **services performed personally by the physician**.
(3) The remuneration is provided under an arrangement that would be **commercially reasonable** even if no referrals were made to the employer.

(1) Fair market value - "Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals." 42 C.F.R. § 411.351.

(2) Commercially reasonable - – "An arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals." 69 Fed. Reg. 16054, 16093 (Mar. 26, 2004).

b. In-Office Ancillary Services (IOAS) – In-office ancillary services are protected from Stark by both a statutory exception and regulatory safe harbor, which are similar. 42 U.S.C. §§ 1395nn(b)(2), 42 C.F.R. § 411.355(b). IOAS must meet certain conditions:

- Furnished by or under supervision of physician in the same group practice;
- Location – Same building or other centralized location for group practice services;
- Billing – By physician, group practice, or independent billing company as agent of physician or group practice.

C. Enforcement trends and other recent developments in kickback and Stark Law

1. Charitable Contributions

a. Lundbeck - $52.6 million settlement – June 6, 2018 - Danish drugmaker Lundbeck said that it will pay $52.6 million to resolve a U.S. probe into its financial support of patient assistance charitable foundations. https://www.reuters.com/article/us-h-lundbeck-settlement/drugmaker-lundbeck-to-settle-us-charity-probe-for-526-million-idUSKCN1J22PL (last viewed Sept. 5, 2018).

b. Pfizer - $23.85 million settlement – May 25, 2018 – Pfizer agreed to pay $23.85 million to resolved claims that it used a purportedly independent charity as a conduit to pay illegal kickbacks to Medicare patients. https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks (last viewed Sept. 5, 2018).

c. Jazz Pharmaceuticals - $57 million settlement – Jazz agreed to pay $57 million to resolve claims related to charitable contributions to Caring Voice Coalition (CVC), a fund for narcolepsy. https://www.reuters.com/article/us-jazz-phrmt-settlement/jazz-pharmaceuticals-to-settle-u-s-probe-for-57-million-idUSKBN1I93IK (last viewed Sept. 5, 2018). HHS OIG had previously rescinded CVC's favorable advisory opinion letter no. 06-04 due to non-compliance. https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf (last viewed Sept. 5, 2018).

d. United Therapeutics - $210 million settlement – Dec. 20, 2017 – United Therapeutics agreed to pay $210 million to settle claims that it used a charitable foundation to pay kickbacks to induce Medicare patients to purchase its products. https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability (last viewed Sept. 5, 2018).

e. Medco Health Solutions – Payment to charity was not linked to violation of Anti-Kickback Statute. *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. Jan. 19, 2018) – available at http://www2.ca3.uscourts.gov/opinarch/171152p.pdf (last viewed Sept. 5, 2018).

2. HMA $260+ Million Settlement

Multi-district litigation involving eight *qui tam* cases, settlement announced on Sept. 25, 2018 - https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one (last viewed Oct. 4, 2018); settlement agreement available at https://www.justice.gov/opa/press-release/file/1096401/download (last viewed Oct. 4, 2018).

a. $35 million criminal penalty in connection with corporate-driven scheme to defraud Federal health care programs by unlawfully pressuring and inducing physicians serving HMA hospitals to increase the number of emergency department patient admissions without regard to whether the admissions were medically necessary.

b. $62.5 million civil settlement to resolve claims that the inpatient admission of Medicare beneficiaries was not medically necessary, and that the care needed by, and provided to, these beneficiaries should have been provided in a less costly outpatient or observation setting.

c. $93.5 million civil settlement to resolve claims that two HMA hospitals in Florida, Charlotte Regional Medical Center and Peace River Medical Center, billed federal health care programs for services referred by physicians to whom HMA provided remuneration in return for patient referrals. To induce patient referrals, Charlotte Regional provided a local physician group with free office space, staff and equipment, as well as direct payments up to $40,000 per month, which purportedly covered overhead and administrative costs incurred by the group for its management of a Charlotte Regional physician. HMA also provided another local physician with free rent and upgrades to his office space.

d. $55 million civil settlement to resolve claims that two former HMA hospitals, Lancaster Regional Medical Center and Heart of Lancaster Medical Center in Pennsylvania, billed federal health care programs for services referred by physicians with whom the facilities had improper financial relationships. These relationships stemmed from HMA's excessive payments to (1) a large physician group in return for two businesses owned by the group and for services allegedly performed by the group, and (2) a local surgeon that exceeded the value of the services provided. The government alleged that these arrangements were structured in this manner to disguise payments intended to induce the referral of patients.

3. Detroit Area Hospital System to Pay $84.5 Million to Settle False Claims Act Allegations Arising From Improper Payments to Referring Physicians

William Beaumont Hospital, a regional hospital system based in the Detroit, Michigan area, paid $84.5 million to resolve allegations under the False Claims Act of improper relationships with eight referring physicians - https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising (Aug. 2, 2018, last viewed Oct. 4, 2018). The settlement covered four *qui tam* cases in the same federal district. Beaumont provided compensation substantially in excess of fair market value and free or below-fair market value office space and employees to certain physicians to secure their referrals of patients in violation of the Anti-Kickback Statute and the Stark Law, and then submitted claims for services provided to these illegally referred patients, in violation of the False Claims Act.

4. HDL Bankruptcy and Related Litigation

a. HDL Kickback Settlement - https://www.justice.gov/opa/pr/two-cardiovascular-disease-testing-laboratories-pay-485-million-settle-claims-paying (Apr. 9, 2015, last viewed Oct. 4, 2018).

b. HDL Bankruptcy - http://www.modernhealthcare.com/article/20150609/NEWS/150609890 (June 9, 2015, last viewed Oct. 4, 2018).

c. HDL Bankruptcy Trustee Sues Physicians to Recover Kickbacks - http://www.cardiobrief.org/2017/06/12/trustee-for-zombie-lab-sues-thousands-of-doctors-and-dozens-of-nonprofits/ (Jun. 12, 2017, last viewed Oct. 4, 2018).

5. (Stark) Self-Referral Disclosure Protocol (SRDP)

a. New CMS forms for SRDP became effective June 1, 2017 - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html (last viewed Oct. 4, 2018).

b. Data on SRDP settlements - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html (Feb. 2, 2018, last viewed Oct. 4, 2018).

D. Practical tips for navigating kickback and Stark Law compliance

1. Physician Compensation and Practice Acquisitions

a. Trend toward hospital employed physicians

i. Trend may have stabilized temporarily as hospitals digest many acquired physicians. *See* https://www.hfma.org/Content.aspx?id=54498 (last viewed Oct. 4, 2018).

ii. Some states still prohibit hospital employed physicians due to corporate practice of medicine laws (including California).

b. Hospital employed model

i. Broad kickback safe harbor for employed physicians for "any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." 42 C.F.R. §1001.952(i).

ii. Stark employment exception is more restrictive than the kickback safe harbor, and requires that the remuneration is:

(A) Consistent with the fair market value of the services;

(B) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, except for productivity bonuses based on services performed personally by the physician; and

(C) Provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer. 42 C.F.R. § 411.357(c).

iii. Variable physician compensation in a hospital employed model is permitted as long as the productivity bonuses are based on services personally performed by the physician.

iv. Variable physician compensation in a hospital employed model are frequently based on the physician work component of the physicians' Relative Value Units (RVUs/wRVUs).

v. Compliance tips in a hospital employed model

(A) RVUs should not include the practice expense component or malpractice component of the physician's RVUs;

(B) Rate of $ per wRVU should not increase as RVUs increase because this method can result in compensation exceeding FMV;

(C) wRVUs should be limited to the physician's personally performed wRVUs and should not include wRVUs performed by physician extenders (nurse practitioners or physician's assistants);

(D) Compensation should not vary with the volume or value of referrals. *See U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.,* 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *8 (M.D. Fla. Nov. 13, 2013) (incentive bonus equal to 15 percent of the operating margin of the Medical Oncology program, and the program's revenue included fees for designated health services such as outpatient prescription drugs and outpatient services not personally performed by the Medical Oncologists, varied with the volume or value of referrals in violation of Stark Law).

vi. Compliance tips on physician compensation unrelated to direct patient care

(A) Medical directorships

(1) Should not exceed FMV for the time required.

(2) Time sheets?

(3) Redundancy - multiple directorships within the same medical specialty.

(B) Call coverage

(1) Should not exceed FMV for the time required and the opportunity to performed collectible professional services when called.

(2) Changes in call compensation should be well-justified.

(3) Exclusive call arrangements for all 365 days per year.

(C) Hospital paying for physician extenders benefiting the physician practice.

(1) Should not include extenders productivity in RVU-based physician compensation in a hospital employed model.

(2) Need to delineate extenders services that benefit the hospital vs. extender services that benefit the physicians.

c. Physician group practice model

i. Broad kickback safe harbor for Stark compliant physician group practices. 42 CFR § 1001.952(p).

ii. Stark – Physician group practice is technically not a Stark exception, but Stark-compliant physician group practices gain greater compensation flexibility under Stark's in-office ancillary services (IOAS) exception. 42 C.F.R. 411.355.

iii. Benefits to being a Stark-compliant physician group practice

(A) Allows remuneration that varies with referrals of physician services and IOAS within group practice.

(B) Special physician compensation rules under Stark permit the group practice to share profits with its member physicians and pay productivity bonuses (including services performed by other members of the group practice) to its member physicians.

(C) Kickback safe harbor available if Stark group practice requirements are satisfied.

iv. Eight requirements for a Stark-compliant physician group practice:

(A) Single Legal Entity - Group practice must be single legal entity operating primarily for the purpose of being a physician group practice.

(B) At Least 2 Physicians - Group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners).

(C) Range of Care - Each physician who is a member of the group must furnish substantially the full range of patient care services that the physician routinely furnishes. Physicians may work elsewhere, but must provide substantially the full range of services for the group.

(D) Substantially All Services Billed Through Group - Substantially all (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group.

(E) Distribution of Expenses and Income - The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income.

(F) Unified Business - The group practice must be a unified business having at least the following features:

(1) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(2) Consolidated billing, accounting, and financial reporting.

(G) Can't Vary with Volume or Value of Referrals - No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in § 411.352(i).

(H) Physician-Patient Encounters - Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice. 42 C.F.R. §411.352.

(I) Special Compensation Rules - A "physician in a group practice" (which includes employees, owners, and some independent contractors) may be paid a share of overall profits of the group or a productivity bonus based on services that he or she has personally performed (including services "incident to").

(1) Division of overall profits must be done in a "reasonable and verifiable" manner that does not directly relate to volume or value of referrals of DHS.

(2) Share of the profits will be deemed not to relate directly to volume/value in the following situations:

- Per capita division;
- DHS revenues are distributed based on distribution of group's non-DHS revenues; or
- Revenues from DHS are less than 5% of group's total revenues and allocated portion of the DHS revenues constitute 5% or less of individual physician's total compensation.

(3) Overall profits means group's entire profits derived from DHS, or profits derived by any component of the practice consisting of at least 5 physicians ("Rule of 5's").

(4) Productivity bonus should be calculated in a "reasonable and verifiable" manner not directly related to volume/value of physician's referrals of DHS.

(5) A productivity bonus will be deemed not directly related to volume/value if:

- Based on physician's total patient encounters or wRVU's (including "incident to");

- Based on allocation of physician's compensation attributable to services that are not DHS; or

- Revenues derived from DHS are less than 5% of group's total revenues and the allocated portion of the revenues to each physician represent 5% or less of that physician's total compensation from the group.

v. Practice loss theory

(1) "A support payment is a payment to a medical practice, not to a doctor; therefore, it is not a direct compensation arrangement because there is an intervening entity between the doctor and the hospital." Pamela J. Nix, Hospital Support Payments and Stand in the Shoes, A Look at the Legality of Support Payments and Possible Revisions to SITS Provisions, 10 J. Health Care Compliance 59, 60 (2008). An indirect compensation arrangement would exist under Stark only if the compensation paid to the physician from the entity in the chain with which the physician has a direct financial relationship varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. 42 C.F.R. § 411.354(c)(2)(ii).

(2) "In most cases, the payments from the hospital-owned [physician group] practice to the doctor do not take into account the volume or value of referrals from the physician to the hospital." Nix, supra, at 60. "As such, the support payment does not meet the definition of an indirect compensation arrangement." *Id.* "Consequently, [the mission support payment] is not a transaction governed by the Stark law." *Id.* "Under this analysis, many hospitals have made support payments when needed as they are not prohibited by the Stark law." *Id.*

(3) Hospitals (particularly non-profits) may subsidize physician practice losses with mission support payments to physician group practices without automatically violating kickback or Stark. 72 Fed. Reg. 64161 (Nov. 15, 2007); 73 Fed. Reg. 23685 (Apr. 30, 2008); 73 Fed. Reg. 48690-93 (Aug. 19, 2008).

(4) Individual physician compensation within the physician group practice must still be within FMV, commercially reasonable in the absence of referrals, and cannot vary with volume or value of referrals except as permitted under the Stark group practice rules.

vi. Compliance tips in a physician group practice model

(1) Maintain compliance with the eight requirements of a Stark compliant group practice (single legal entity, etc.).

(2) Monitor compliance with the Rule of 5's, particularly with physician specialists.

(3) IOAS exception is limited to "in-office," cannot include hospital-based services in the compensation model.

(4) "Incident to" services do not include services and supplies furnished in the hospital, diagnostic tests, or the technical component of inpatient and outpatient hospital services, and cannot be included in the compensation model. 42 C.F.R. § 410.26(b)(1).

(5) Examine physician practice loss subsidies to ensure that individual physician compensation still complies with a Stark exception (FMV, commercial reasonableness and not vary with volume or value of referrals except as permitted under Stark group practice rules).

d. Distinguishing fair market value (FMV) and commercial reasonableness (CR)

i. FMV – "Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals." 42 C.F.R. § 411.351.

ii. CR – "An arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals." 69 Fed. Reg. 16054, 16093 (Mar. 26, 2004) (note this is merely CMS guidance that can no longer be used in health care enforcement).

iii. How do relators and DOJ see FMV vs. CR?

iv. What are the risk areas in FMV and CR?

v. Practical tips for compliance with FMV and CR.

2. Considerations for Compliance Officers

a. What new risk areas may impact your organization given recent case law and regulatory developments in kickback and Stark?

b. Would any new kickback or Stark developments warrant an internal investigation in your organization?

c. How would the organization calculate the amount of any overpayments received in non-compliant kickback or Stark arrangements?

d. Should the compliance officer recommend new policies or modifications to existing policies for kickback and Stark compliance?