**HCCA Compliance Institute**

**Las Vegas, NV**

**306 – Kickback and Stark Developments**

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**A. Enforcement trends and other recent developments in kickback and Stark Law**

 **1. Charitable Contributions**

 a. United Therapeutics - $210 million settlement – Dec. 20, 2017

 <https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability> (last viewed Jan. 24, 2018).

 b. Medco Health Solutions – Defense MSJ upheld on appeal – Jan. 19, 2018

 <http://www2.ca3.uscourts.gov/opinarch/171152p.pdf> (last viewed Jan. 24, 2018).

 **2. *Escobar* Materiality**

 a. Compliance with Stark is material - *United States ex rel. Tullio Emanuele v. Medicor Associates, Inc.*, 2017 WL 1001581 (W D. Pa. Mar. 15, 2017). Available at

<http://bit.ly/2rSydr9> (last viewed Jan. 24, 2018).

 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.

 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). Available at <https://www.leagle.com/decision/infdco20171205d18> (last viewed Jan. 24, 2018). Government won civil FCA verdicts against three individuals – summary available at <https://www.justice.gov/usao-sc/pr/midlands-area-man-found-liable-51-million-health-care-fraud> (Feb. 1, 2018, last viewed Feb. 13, 2018).

 i. Violation of federal kickback law is a far cry from an insubstantial regulatory violation like requiring that government contractors buy American–made staplers rather than foreign staplers. Indeed, Congress has made it a felony offense punishable by up to five years in prison. 42 U.S.C. § 1320a–7b.

 ii. Kickback compliance is critical to the government’s decision to pay federal health benefits claims.

 iii. 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).

 iv. PPACA also made clear that compliance with federal kickback law is a precondition to the payment of claims submitted to these programs, and not merely a condition of participation in the programs. *See U.S. ex rel. Kester v. Novartis Pharm. Corp*., 41 F. Supp. 3d 323, 331 (S.D.N.Y. 2014).

 v. The government routinely punishes kickback violations through criminal proceedings and civil proceedings to recoup funds. The U.S. Department of Health and Human Services has for years issued “Special Fraud Alerts” specifically warning about kickback violations in reimbursement requests, including, for example, for laboratory payments. *See*  <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf> (last viewed Jan. 24, 2018).

 vi. 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).

 **3. 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 Feb. 13, 2018).

 b. HDL Bankruptcy - <http://www.modernhealthcare.com/article/20150609/NEWS/150609890> (June 9, 2015, last viewed Feb. 13, 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 Feb. 13, 2018).

 **4. (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 Feb. 13, 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 Feb. 13, 2018).

**B. What changes to expect from the Trump Administration**

 1. **Fraud Fighting Will Continue.** Fraud fighting has bi-partisan support, no changes expected to the False Claims Act. The federal government needs the money more than ever after the estimated net budget impact of the Tax Cuts and Jobs Act of negative $1.5 trillion. <https://www.jct.gov/publications.html?func=startdown&id=5053> (last viewed Jan. 24, 2018).

 2. **FCA Has Strong Congressional Support**. Senator Grassley (R-Iowa) is a strong supporter of the False Claims Act and a powerful senator as Chairman of the Senate Judiciary Committee. *See* <https://www.grassley.senate.gov/news/news-releases/grassley-scotus-decision-important-step-reducing-fraud-against-taxpayers>(last viewed Jan. 24, 2018).

 3. **DOJ May Seek to Dismiss FCA Complaints.** Michael D. Granston, Director of the DOJ Commercial Litigation Branch, Fraud Section, instructed Assistant U.S. Attorneys handling FCA cases to consider whether the government’s interests are served by seeking dismissal of FCA complaints based on the following factors:

 a. Curbing Meritless *Qui Tams*;

 b. Preventing Parasitic or Opportunistic *Qui Tam* Actions;

 c. Preventing Interference with Agency Policies and Programs;

 d. Controlling Litigation Brought on Behalf of the United States;

 e. Safeguarding Classified Information and National Security Interests;

 f. Preserving Government Resources;

 g. Addressing Egregious Procedural Errors.

<https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf> (Jan. 10, 2018, last viewed Mar. 2, 2018).

 4. **Limiting Use of Agency Guidance Documents in Health Care Enforcement.** Attorney General Jeff Sessions issued a memorandum ("Guidance Policy") prohibiting Department components from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. <https://www.justice.gov/opa/press-release/file/1012271/download>(Nov. 16, 2017, last viewed Feb. 13, 2018). As a follow-up to the Guidance Policy, Associate Attorney General Rachel Brand issued a new policy that prohibits the Department of Justice from using its civil enforcement authority to convert agency guidance documents into binding rules. Under the Department’s new policy, Department civil litigators are prohibited from using guidance documents—or noncompliance with guidance documents—to establish violations of law in affirmative civil enforcement actions.<https://www.justice.gov/file/1028756/download> (Jan. 25, 2018, last viewed Feb. 13, 2018).

 5. **Reduce Health Care Regulations**. Trump Administration has promised to reduce regulations on health care. *See* <https://www.nytimes.com/2017/12/14/us/politics/trump-federal-regulations.html>(last viewed Jan. 24, 2018). *See also* Executive Order 13771, accessible at <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/> (Jan. 30, 2017, last viewed Mar. 5, 2018); Executive Order 13777, accessible athttps://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda (Feb. 24, 2017, last viewed Mar. 5, 2018.

 6. **Regulations Lacking *Escobar* Materiality Might Be Repealed.** In particular, health care regulations that flunk *Escobar* materiality might be repealed. For example, Medicaid regulation requiring “comprehensive care plan” in specialized nursing facilities lacked *Escobar* materiality, causing District Judge Steven Merryday in the Middle District of Florida to grant the defendant judgment as a matter of law despite a plaintiffs’ jury award of $348 million. *U.S. and State of Florida ex rel. Ruckh v. Salus Rehabilitation, LLC*,

2018 WL 375720 (M.D. Fla., Jan. 11, 2018). Available at <http://www.fdalawblog.net/wp-content/uploads/2018/01/Ruckh-opinion-re-Escobar-280040198229.pdf> (last viewed Jan. 24, 2018).

 7. **Lower Drug Prices**. President Trump and new HHS Secretary Azar have promised to get prescription drug prices “way down.” <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-swearing-ceremony-alex-azar-secretary-department-health-human-services> (Jan. 29, 2018, last viewed Feb. 13, 2018). Value based pricing (VBP) arrangements may become more common for pharmaceuticals. *See* <https://www.citizen.org/sites/default/files/trump-pharma-outcomes-based-arrangements-proposal.pdf> (last viewed Feb. 13, 2018). VBP may require new kickback safe harbors and Stark exceptions. *See* <https://www.bna.com/drug-device-companies-n57982085546> (March 22, 2017, last viewed Feb. 13, 2018).

 8. **Emphasis on Innovation.** The Center for Medicare and Medicaid Innovation develops new payment and service delivery models in accordance with the requirements of section 1115A of the Social Security Act. <https://innovation.cms.gov/initiatives/index.html#views=models> (last viewed March 5, 2018). Additionally, Congress has defined – both through the Affordable Care Act and previous legislation – a number of specific demonstrations to be conducted by CMS.

The Innovation Center also plays a critical role in implementing the Quality Payment Program, which Congress created as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to replace Medicare’s Sustainable Growth Rate formula to pay for physicians’ and other providers’ services. In this new program, clinicians may earn incentive payments by participating to a sufficient extent in Advanced Alternative Payment Models (APMs). In Advanced APMs clinicians accept some risk for their patients’ quality and cost outcomes and meet other specified criteria.

The Innovation Center is working in consultation with clinicians to increase the number and variety of models (PDF) available to ensure that a wide range of clinicians, including those in small practices and rural areas, have the option to participate.

The Innovation Models are organized into seven categories.

* **Accountable Care -** Accountable Care Organizations and similar care models are designed to incentivize health care providers to become accountable for a patient population and to invest in infrastructure and redesigned care processes that provide for coordinated care, high quality and efficient service delivery.
* **Episode-based Payment Initiatives -** Under these models, health care providers are held accountable for the cost and quality of care beneficiaries receive during an episode of care, which usually begins with a triggering health care event (such as a hospitalization or chemotherapy administration) and extends for a limited period of time thereafter.
* **Primary Care Transformation -** Primary care providers are a key point of contact for patients’ health care needs. Strengthening and increasing access to primary care is critical to promoting health and reducing overall health care costs. Advanced primary care practices – also called “medical homes” – utilize a team-based approach, while emphasizing prevention, health information technology, care coordination, and shared decision making among patients and their providers.
* **Initiatives Focused on the Medicaid and CHIP Population -** Medicaid and the Children’s Health Insurance Program (CHIP) are administered by the states but are jointly funded by the federal government and states. Initiatives in this category are administered by the participating states.
* **Initiatives Focused on the Medicare-Medicaid Enrollees -** The Medicare and Medicaid programs were designed with distinct purposes. Individuals enrolled in both Medicare and Medicaid (the “dual eligibles”) account for a disproportionate share of the programs’ expenditures. A fully integrated, person-centered system of care that ensures that all their needs are met could better serve this population in a high quality, cost effective manner.
* **Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models -** Many innovations necessary to improve the health care system will come from local communities and health care leaders from across the entire country. By partnering with these local and regional stakeholders, CMS can help accelerate the testing of models today that may be the next breakthrough tomorrow.
* **Initiatives to Speed the Adoption of Best Practices -** Recent studies indicate that it takes nearly 17 years on average before best practices - backed by research - are incorporated into widespread clinical practice—and even then the application of the knowledge is very uneven. The Innovation Center is partnering with a broad range of health care providers, federal agencies professional societies and other experts and stakeholders to test new models for disseminating evidence-based best practices and significantly increasing the speed of adoption.

**C. 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 Jan. 24, 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?**

 **e. How will your organization be affected by the Trump Administration’s focus on lowering drug prices, reducing regulations and moving away from agency guidance documents?**