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Stark / Anti-Kickback Law Update

Donna S. Clark

Donna S. Clark
Baker & Hostetler LLP
811 Main Street, Suite 1100
Houston, TX 77002
dclark@bakerlaw.com
713.646.1302

STARK / ANTI-KICKBACK LAW UPDATE

Donna S. Clark

dclark@bakerlaw.com

1. New Stark Developments

A. On November 16, 2015, CMS finalized amendments to the Stark regulations in its calendar year 2016 Physician Fee Schedule Final Rule ("New Rules"). 80 Fed. Reg. 71300 (Nov. 16, 2015). Notable provisions from the New Rules include: (1) amendments and policy clarifications targeting Stark technical violations and compliance burdens; (2) a new recruitment exception and other changes focused on access to care; (3) an exception for timeshare licenses; and (4) amendments affecting physician-owned hospitals.

i. Amendments and Policy Clarifications

(1) Writing Requirement. CMS clarified that there is no substantive difference among the writing requirements of the various compensation exceptions, despite the use of different terminology, and finalized its proposal to substitute the word "arrangement" for "agreement" in the leasing exceptions to better reflect this policy. The agency explains there is no requirement that an arrangement be documented in a single formal contract. Rather, the relevant inquiry is whether the contemporaneous documentation of the arrangement would permit a reasonable person to verify compliance with the exception at the time a referral is made.

Examples of documents that may be aggregated to satisfy the writing requirement include:

- Board meeting minutes and other documents authorizing payments for specified services
- Hard copy and electronic communications between the parties
- Fee schedules for specified services
- Check requests or invoices identifying items or services provided, relevant dates, and/or rates of compensation
- Time sheets documenting services performed
- Call coverage schedules or similar documents with dates of services to be provided

- Accounts payable or receivable records documenting the date and rate of payment, and reason for payment
- Checks issued for items, services, or rent

Notably, the New Rules provide that parties considering past conduct may rely on this clarification because it reflects current CMS policy.

(2) **Term of at Least One Year.** The one-year term requirement of the rental of office space, rental of equipment, and personal services exceptions does not need to be memorialized in a formal agreement. Rather, parties must have contemporaneous writings establishing that the arrangement lasted for at least one year, or be able to demonstrate that the arrangement was terminated during the first year and the parties did not enter into a new arrangement for the same space, equipment, or services during the first year.

(3) **Temporary Noncompliance with Signature Requirements.** The New Rules amend the special rule for arrangements involving temporary noncompliance with signature requirements to allow the parties 90 days to obtain the required signatures, even if the noncompliance was not inadvertent. However, CMS did not adopt a commenter's suggestion to remove the provision that allows a designated health services (DHS) entity to use this special rule only once every three years. The New Rules also indicate that what constitutes a "signature" for purposes of meeting an exception is flexible and, depending on the facts and circumstances, could include electronic signatures and typed names.

(4) **Indefinite Holdovers.** The New Rules liberalized the holdover provisions of the rental of office space, rental of equipment, and personal services exceptions to allow for indefinite holdovers, provided that the arrangement continues to meet all other requirements of the exception. Holdovers must continue on the same terms and conditions of the original arrangement, and must continue to meet all other elements of the applicable exception during the holdover period. For example, if office space rental payments are fair market value when the lease arrangement expires, but the rental amount falls below fair market value at some point during the holdover, the lease arrangement would fail to satisfy the requirement as soon as the fair market value requirement is no longer satisfied. CMS also cautioned that,

depending on the facts and circumstances, the failure to apply a holdover premium that is legally required by the original arrangement may constitute a change in the terms and conditions of the original arrangement and therefore not meet the requirement that the arrangement continue on the same terms and conditions of the immediately preceding arrangement.

(5) Other Technical Clarifications and Policy Guidance. CMS finalized a number of technical clarifications and changes to Stark exceptions and definitions aimed at improving clarity and ensuring proper applications of CMS policies. CMS finalized its proposal to remove the reference to "stand in the shoes" in the definition of locum tenens physician to avoid potential confusion with the stand in the shoes concept. The agency affirmed its proposed position that a physician's use of a hospital's resources (e.g., exam room, nursing personnel, and supplies) in split billing arrangements does not constitute remuneration. The New Rules amend certain exceptions to standardize references pertaining to the volume or value of referrals (e.g., takes into account, based on, without regard to) to clarify that there is only one standard. Finally, CMS finalized its proposal to revise the regulatory definition of remuneration to clarify that remuneration excluded from the definition includes items, devices, or supplies used solely for one or more of the six enumerated purposes (e.g., the collection of specimens).

ii. Recruitment and Access to Care

(1) New Exception – Assistance to a Non-Physician Practitioner. The New Rules contain a new exception for recruitment of non-physician practitioners (NPPs) that closely tracks the structure and requirements of the existing exception for physician recruitment, which CMS declined to extend to NPPs in its Phase III rulemaking. CMS explained its change in position was prompted by changes in the healthcare delivery and payment systems and a projected rise in demand for primary care and mental health services, especially in rural and underserved areas. The New Rules expand the exception to apply to payments made by a hospital, federally qualified health center (FQHC), or rural health clinic (RHC) to a physician to compensate a NPP. Substantially all of the NPPs services must be furnished to patients receiving primary care and mental health services. NPPs include PAs, nurse practitioners, clinical nurse specialists, nurse midwives, clinical social workers, and clinical psychologists. There are a number of requirements

and limitations associated with the exception, including a requirement that "substantially all" (defined as at least 75 percent) of the NPP's patient care services be primary care or mental health services and a cap on the amount of assistance that may be provided.

(2) Physician Recruitment. The New Rules amend the physician recruitment exception to add a new definition of the geographic area served by an FQHC or RHC.

iii. New Exception – Timeshare Arrangements. CMS finalized a new exception for timeshare leasing arrangements between hospitals or physician organizations and physicians for the use of premises, equipment, personnel, items, or services used predominately for evaluation and management (E&M) services. In its rulemaking, CMS recognized the existence of legitimate reasons for physicians to enter timeshare arrangements instead of traditional space leases (especially in rural and underserved areas) and acknowledged the challenges of structuring such arrangements in a compliant manner under Stark, including the exclusive use requirements of the rental of office space and equipment exceptions. CMS reiterated in the New Rules that the new exception is not available for traditional lease arrangements that establish a possessory leasehold interest in the space – described as a "right against the world" (including the owner or sub-lessor of the space). The New Rules are more liberal than the proposed rule in that it allows a hospital to be either the grantor or the grantee of the use of the space. This change will allow hospitals to take advantage of the timeshare exception for its employed physicians.

The new timeshare exception includes the following requirements and limitations:

- The parties must be a physician or a physician organization in whose shoes the physician stands and a hospital or physician organization of which the physician is not an owner, employee, or contractor.
- The premises, items, and services must be "predominately" used to furnish E&M services.
- The compensation cannot be based on a percentage of revenues or per unit of services fees to the extent such fees reflect services provided to patients referred by the grantor.
- Any equipment covered by the timeshare arrangement must be (1) located in the same building where the E&M services are furnished, (2) not used to furnish DHS other than those incidental to the E&M services furnished at the time of the E&M visit, and (3) not advanced

imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

CMS provided valuable guidance on the meaning of "predominate use" for E&M services that should be considered when designing an arrangement under this new exception. Additionally, CMS discussed the permissible fee methodologies under the new exception in-depth.

iv. **Physician-Owned Hospitals.** The New Rules address requirements for physician-owned hospitals introduced by the Affordable Care Act, which restricted "grandfathered" hospitals from expanding or increasing the percentage of physician ownership beyond baseline bona fide physician investment levels existing on March 23, 2010.

(1) **Bona Fide Investment Level.** The New Rules adopt CMS's reversal of its prior position by requiring the calculation of the physician ownership level to include direct and indirect ownership and investment interests held by a physician regardless of whether the physician refers patients to the hospital. In recognition that some physician-owned hospitals may have relied on the agency's prior position, which included only referring physicians, CMS delayed the effective date of this revision to January 1, 2017.

(2) **Public Website and Public Advertising Disclosure.** CMS finalized, without modification, its proposed amendment to the Stark regulations to provide more certainty regarding public website and public advertising disclosure requirements for physician-owned hospitals. The New Rules generally limit the required disclosures, for example, clarifying that social media does not qualify as a public website triggering disclosure obligations.

B. **CMS Advisory Opinions.** In No. CMS-A0-2016-01, CMS considered whether the addition of outpatient observation beds to an existing physician-owned hospital would violate the limitation on expansion of facility capacity imposed on physician-owned hospitals grandfathered when the exception for hospital ownership was eliminated in the Affordable Care Act. This limitation provides that grandfathered hospitals cannot increase the number of beds, procedure rooms, or ORs above those in existence on the date of enactment of the ACA (March 23, 2010). Because the observation beds were not licensed under state law, CMS ruled that the addition of the observation beds would not cause the hospital to exceed the number of beds licensed as of March 23, 2010.

C. Proposed Updates to the Self-referral Disclosure Protocol (SRDP). On May 6, 2016, CMS issued a Federal Register notice seeking public comments on updates to the SRDP. 81 Fed. Reg. 27450. In the notice, CMS sought to revise the currently approved information collection request (ICR). Under the current ICR, a party must provide a financial analysis of overpayments arising from actual or potential violations based on a 4-year lookback period. However, on February 12, 2016, CMS published the final overpayment rule on the reporting and returning of overpayments. *See* 81 Fed. Reg. 7654 (Feb. 12 2016). The final overpayment rule established a 6-year lookback period for reporting and returning overpayments. CMS is proposing to revise the ICR for the SRDP to reflect the 6-year lookback period established by the final overpayment rule. The 6-year lookback period would apply only to submissions to the SRDP received on or after March 14, 2016, the effective date of the final overpayment rule. Parties submitting self-disclosures to the SRDP before March 14, 2016, would only provide a financial analysis of potential overpayments based on a 4-year lookback period. Additionally, CMS introduced a required form for SRDP submissions, aiming to streamline and simplify the SRDP process. Comments were due by July 5, 2016.

D. Congressional Review. CMS has acknowledged provider struggles with technical violations and revised its regulations in an effort to ease this burden. See Section 1.A.i. above. The agency has also acknowledged that the move away from fee-for-service (FFS) reimbursement to a value-based payment system, as well as innovations in Medicare payment models and private payor arrangements that are designed to integrate physicians and hospitals, can be difficult to achieve under the Stark Law. The Senate Finance Committee (Committee) has turned its attention to the Stark Law by engaging stakeholders in a discussion about these issues. The Committee's recently released white paper describing the concerns of the industry may foreshadow significant changes to the law.

The Committee's white paper is a collection of comments from healthcare thought leaders detailing the challenges that healthcare providers face and suggests changes to the law that would help the industry move toward implementing these alternative payment models. Solutions proposed by commenters ranged from repealing the Stark Law entirely to modifying the existing compensation exceptions and fraud and abuse waivers to accommodate innovative payment arrangements. While the white paper does not make any specific recommendations, it shows that the Committee is considering diverse opinions about how to modernize the Stark Law to deal with clinical and financial integration.

Despite efforts by CMS to clarify the application of the Stark Law, its technical nature and regulations have presented interpretive challenges over the years.

Moreover, the staggering financial penalties that can result when the Stark Law forms the basis for a False Claims Act case have raised the stakes for providers in recent years. The white paper demonstrates that stakeholders are frustrated by the complexities of the law and have a wide variety of opinions about how to revise the law to permit conduct that does not harm the Medicare program. Some commenters advocated for amending the penalty scheme for technical violations, such as failure to maintain documentation of arrangements, suggesting that penalties should apply to the arrangement as a whole rather than on a per-claim basis. Others suggested eliminating penalties for technical violations altogether. However, the comments reveal that what constitutes a "technical violation" is a subjective determination. Thus, some stakeholders proposed, as an alternative, the elimination of the Stark Law's applicability to compensation arrangements.

The white paper describes other comments about the fair market value standard, the volume or value standard in the group practice exception, and the interplay between the Stark Law and the Anti-Kickback Statute. One comment focused on the fair market value standard noted that tax-exempt entities are already subject to compensation restrictions and suggested creating a separate exception for compensation arrangements involving a tax-exempt entity. A sentiment echoed by many commenters is that Congress should ease the compliance burden by aligning the Stark Law with the Anti-Kickback Statute and replacing some Stark exceptions with their safe harbor counterparts.

The Committee held a follow-up hearing on July 12, 2016 to discuss ways to improve the Stark Law. A former CMS official in charge of Stark Law policy at the agency was among the witnesses at the hearing and described the law as "a tortured web of confusing standards." During the hearing, Committee members acknowledged that the Stark Law is too complex and creates hurdles to implementing alternate payment arrangements.

2. Case Law Developments / False Claims Act Settlements

A. Tuomey Healthcare System, Inc.

In July 2015, the U.S. Court of Appeals for the Fourth Circuit upheld the judgment against Tuomey Healthcare System, Inc. Dr. Michael Drakeford filed the original whistleblower suit in 2005 alleging that Tuomey entered into illegal part-time employment contracts in which physicians received compensation based on revenues from their personally performed services, a productivity bonus which paid them 80% of the amount of their collections earned for that year, and an incentive bonus of up to 7% of their earned productivity bonus. The 10 year part-time contracts permitted the physicians to maintain their private practices, but required any outpatient surgical procedures to be performed at the hospital. Tuomey entered into these part-time contracts after it was advised

by an attorney that the contracts may implicate the Stark Law and Anti-Kickback Statute. Tuomey then engaged another attorney who provided a positive opinion on the agreements. The district court upheld a jury verdict finding that Tuomey violated the Stark Law because the part-time employment agreements varied with or took into account the volume or value of referrals to the hospital. The district court judgment, which included penalties and damages, totaled over $237 million. On appeal, the Fourth Circuit rejected Tuomey's argument that it did not have the requisite intent to violate the False Claims Act because it reasonably relied on the advice of counsel in structuring the physician compensation arrangements. Tuomey's attacks against the district court's judgement of over $237 million were also rejected. Tuomey entered into a settlement agreement with the U.S. Department of Justice for $72.4 million on October 16, 2015. Tuomey is now owned by Palmetto Health.

B. Memorial Health, Inc.[1]

In December 2015, Memorial Health, Inc., Memorial Health University Medical Center, Inc., Provident Health Services, Inc., and MPPG, Inc. d/b/a Memorial Health University Physicians agreed to pay $9,895,043.04 to resolve allegations that they violated the False Claims Act by submitting claims to the government in violation of the Stark Law. Additionally as part of the settlement, Memorial Health entered into a five year Corporate Integrity Agreement. In March 2011, relator Phillip Schaengold, President and CEO of Memorial Health, Inc., filed a qui tam complaint in which the United States later intervened, alleging Memorial Health, Inc. and other defendants entered into compensation arrangements with physicians that exceeded fair market value, took into account the volume or value of referrals or other business, and were not commercially reasonable in violation of Stark, and in turn the False Claims Act. The compensation agreements in question involved three physicians who were given a base salary and a guaranty, provided that their wRVUs for the prior year were equal to or greater than a specific target. Further, each physician was eligible for incentive compensation depending upon the number of wRVUs produced annually, including a quarterly bonus based on a percentage of the physician's "personal cash collections," plus a credit for 10.5% of "professional cash" generated by midlevel providers personally supervised by the physician, less the base salary paid to the midlevel. Board communications related to the physicians prior to their employment identified them as a "high volume practice with large numbers of hospital admission and referrals to specialists." Revenues from referrals Memorial hoped to capture from a competing hospital were also identified. Net losses were identified in the proforma and hospital revenue was cited in the written recommendation to the Board in support of employment. Memorial

[1] *U.S. ex rel. Schaengold v. Mem'l Health, Inc.*, Case No. 4:11-cv-58 (S.D. Ga.).

Health also tracked the referral rates of the physicians after the acquisition, and compared referrals to its hospitals and those of the competing system.

C. Columbus Regional Healthcare System[2]

In early September 2015, Columbus Regional Healthcare System and Dr. Andrew Pippas agreed to pay more than $25 million to resolve allegations brought by whistleblower Richard Barker, the Administrative Director of the John B. Amos Cancer Center (JBACC), that they violated the False Claims Act by submitting claims in violation of the Stark Law. The relator filed two suits alleging that the defendants submitted claims to Medicare and Medicaid for E&M services and facility fees at higher levels than supported in patients' medical records, and that Columbus Regional paid Dr. Pippas above fair market value based upon his productivity. The relator contended that Dr. Pippas was paid at least twice the collections Columbus Regional received for his personally performed services, paid for services he did not personally perform (services performed by an assisting physician and a nurse practitioner), and allowed to increase his compensation by fraudulently upcoding the billing level for services personally performed, which provided him with 54% more income than the normal distribution of coding. Additionally, there were concerns surrounding Dr. Pippas' performance of Medical Director duties (he received stipends equaling $300,000 and logged 60 to 80 hours a week). The settlement structure is unique and provides that the Columbus Regional defendants will make an initial payment of $10 million and pay the remaining $15 million plus interest over a period of five years. Additionally, the Columbus Regional defendants will pay the United States and the State of Georgia:

1. 1.5% of all annual net patient revenues as set forth in their audited financial statements that exceed $445 million;

2. all annual earnings that exceed $3 million from the joint venture entity of TMC and HealthSouth Corporation from FY 2016 through FY 2020; and

3. a security interest in the Columbus Healthcare Resources, Inc.'s Main Street Village property in the amount of $4.5 million, which after making three years of installment payments, may be released by paying $1 million.

The total amount of the settlement, including the contingent payments, is not to exceed $35 million. The relator was awarded 15% of the first $10 million payment paid to the U.S. and Georgia, as well as later payments. Dr. Pippas agreed to pay $425,000 within seven days of finalizing the settlement. Finally,

[2] *United States ex rel. Barker v. Columbus Regional Healthcare System, et al.*, Case No. 4:12-cv-108 (M.D. Ga.) and *United States ex rel. Barker v. Columbus Regional Healthcare System, et al.*, Case No. 4:14-cv-304 (M.D. Ga.).

the Columbus Regional defendants entered into a Corporate Integrity Agreement with the OIG that requires Columbus Regional to institute measures to avoid and detect future fraudulent conduct.

D. North Broward Hospital District[3]

In September 2015, the North Broward Hospital District in Broward County, Florida settled a suit brought by whistleblower Dr. Michael Reilly and the Department of Justice for $69.5 million. The suit alleged that Broward Health compensated employed physicians at levels which exceeded the fair market value for their personal services, caused major net operating losses and would not be commercially reasonable if the physicians were not in a position to generate referral business for Broward Health, and were determined based in part on the volume and value of referrals to Broward Health hospitals and clinics. The relator also alleged that Broward Health maintained "contribution margin reports" which tracked whether the physicians generated enough referral revenue to offset their compensation. The settlement agreement specifically resolves allegations surrounding nine physician employment agreements that were alleged to be improper. Finally, the settlement required Broward Health to enter into a Corporate Integrity Agreement with the OIG which obligates Broward Health to undertake internal compliance reforms and submit its federal health care program claims to independent review for the next five years.

E. Citizens Medical Center[4]

A county-owned hospital located in Victoria, Texas, Citizens Medical Center, agreed to pay $21.75 million to settle allegations of engaging in improper financial relationships with referring physicians. In the suit, the relators, three cardiologists, alleged CMC violated the Stark Law by implementing bonus programs for emergency room physicians that improperly took into account the value of their cardiology referrals, compensating cardiologists above fair market value for their services and providing them discounted office space. The relators also alleged that CMC demanded that the relators refer all their surgical patients to the hospital's exclusive cardiac surgeon, paid for advertisements for preferred physicians and false advertisements listing inflated surgical accomplishments, and submitted false or fraudulent claims to Medicare and Medicaid. Additionally, the ER physicians were allegedly bonused for each patient that was referred to the Chest Pain Center. The relators also alleged that in 2008, the "CMC Cardiologists' office practices lost over $400,000, and in 2009 their practices lost nearly $1,000,000." Despite that, CMC makes "enormous profits" off of the cardiologists' Medicare and Medicaid patient referrals. Accordingly,

[3] *United States ex rel. Reilly v. N. Broward Hosp. Dist.*, Case No. 10-60590 (S.D. Fla.).
[4] *United States ex rel. Parikh, et al. v. Citizens Medical Center, et al.*, Case No. 6:10-cv-64 (S.D. Tex.).

CMC continued to pay the cardiologists "several times what they earned in private practice" regardless of the losses because the venture was still profitable. Regarding salaries, in the year prior to working for CMC, three physicians earned a combined salary of $630,000. Upon employment, the three physicians were guaranteed salaries of $400,000, $500,000, and $500,000, each. The relators also alleged that CMC threatened to revoke their hospital privileges when relators failed to refer their patients to a certain cardiac surgeon. Lastly, the relators were removed from various leadership positions on the Peer Review Committee and the Chest Pain Center Committee.

F. Adventist Health System[5]

In September 2015, Adventist Health System agreed to pay $118.7 million to settle allegations it offered physicians compensation that exceeded fair market value in exchange for referrals in violation of the Stark Law and the False Claims Act. The plaintiffs' allegations primarily relate to compensation for physicians employed by Florida Hospital Medical Group, an Adventist-owned physician practice in Florida. The complaint alleges that the hospitals lost "large sums of money on most (and, in some cases, all) of the physician practices" because the level of income generated in the practices was insufficient to sustain the above-market salaries, bonuses, and other perks and benefits provided to employed physicians. The complaint specifically alleged that one hospital realized losses of over $5 million on its physician practices, but accepted these losses because they were offset by the physicians' referrals to the hospital. One specific example identified by the plaintiffs was an urologist who was paid $300,000 a year for working 3 days each month at one of the Adventist hospitals. The plaintiffs alleged that the hospital agreed to this arrangement despite having concerns with the fair market value of the arrangement because the physician would perform 80-85% of his surgical procedures at the hospital. The complaint alleges that 35% of the physicians employed by the Florida practice exceed the 90th percentile of the MGMA standards while falling below the 50th percentile of productivity. The plaintiffs further alleged that Adventist paid for the leases of a BMW and Mustang for a surgeon. The complaint specifically alleged that physicians were credited with technical revenue resulting from their professional services when calculating bonuses. The bonus structure reportedly resulted in a bonus of over $368,000 for a dermatologist who only worked 3 days a week. Other conduct that was resolved as part of the settlement includes allegations that Adventist permitted its employed physicians to upcode E&M services and improperly use modifiers, bill for non-physician practitioner services under the physicians' provider numbers, and bill for medically unnecessary services.

[5] *United States ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al.*, Case No. 12-856 and *United States ex rel. Dorsey v. Adventist Health System Sunbelt Healthcare Corp., et al.*, Case No. 13-217.

G. Tri-City Medical Center

In January 2016, Tri-City Medical Center, located in Oceanside, California, agreed to pay more than $3.2 million to settle self-disclosed Stark Law violations. The violations involved nearly 100 arrangements with physicians. In the disclosure, Tri-City identified five arrangements with its former chief of staff that, in the aggregate, appeared not to be commercially reasonable or fair market value. Additionally, Tri-City identified 92 financial arrangements with community-based physicians and practice groups that did not satisfy an exception to the Stark Law because the written agreements were expired, missing signatures, or could not be located.

H. Lexington Medical Center[6]

On July 20, 2016, Lexington Medical Center (LMC), located in West Columbia, South Carolina, agreed to pay $17 million to settle allegations that it violated the Stark Law and the False Claims Act by purchasing physician practices for access to referrals. LMC is a political subdivision of the State of South Carolina and operates clinics and a medical center. The plaintiff, a former LMC neurologist, alleged that LMC: (1) bought access to patients through the acquisition of physician practices with 28 physicians; (2) paid these physicians commercially unreasonable compensation in exchange for their practices and their employment at LMC; (3) imposed a de facto mandate that required, and closely tracked, referrals to LMC to ensure the hospital received DHS referrals; and (4) punished physicians who refused to refer to LMC. LMC acquired the practice that employed the plaintiff in 2011. As part of the acquisition, the plaintiff contended that LMC entered into physician employment agreements with physicians with generous compensation provisions to reward physicians for anticipated ancillary referrals. Once part of LMC, the plaintiff alleged that LMC held meetings with the physicians to discuss declines in the number of imaging referrals. In July 2013, LMC terminated the plaintiff allegedly because he refused to send all imaging referrals to LMC. In addition to the plaintiff's group, the settlement involved similar allegations related to four other physician groups.

I. Sweet Dreams Nurse Anesthesia[7]

In August 2016, Sweet Dreams Nurse Anesthesia (Sweet Dreams) agreed to pay over $1 million to resolve several kickback allegations in a false claims lawsuit. Sweet Dreams, a Georgia based company, is a partnership of certified registered nurse anesthetists who provide anesthesia services to health care providers. The

[6] *United States ex rel. David H. Hammett, M.D. v. Lexington County Health Services District d/b/a Lexington Medical Center*, Case No. 3:14-cv-03653-CMC.

[7] *United States and State of Georgia ex rel. Adam Nauss v. Sweet Dreams Nurse Anesthesia, et al.*, Case No. 5:14-cv-330.

settlement addressed several kickback schemes, including allegations that Sweet Dreams provided free anesthesia drugs to ambulatory surgery centers (ASCs) in exchange for the ASCs granting Sweet Dreams an exclusive contract to provide anesthesia services at those ASCs. A second alleged scheme involved the agreement of an affiliate of Sweet Dreams to fund the construction of an ASC in Marietta, Georgia, in exchange for contracts as the exclusive anesthesia provider at that facility and a number of other podiatry-based ASCs affiliated with the Marietta ASC.

J. Hollister Inc. and Byram Healthcare Centers, Inc. [8]

In April 2016, Hollister Inc., a manufacturer of disposable health care products, and Byram Healthcare Centers, Inc., a supplier of medical products, agreed to pay over $20 million to settle allegations related to kickbacks. In particular, the settlement resolves allegations that over a seven year period Hollister paid kickbacks to Byram in return for marketing promotions, conversion campaigns, and other referrals of patients to Hollister's ostomy and continence care products. The alleged kickbacks also consisted of bonus commissions that Byram paid to its sales personnel for each new patient order for a Hollister product. Additionally, Hollister allegedly agreed to pay Byram $200,000, for "catalog funding" that was actually intended to induce Byram's recommendation of Hollister products to patients. The settlement amount paid by Byram also resolved kickback allegations relating to three other manufacturers of ostomy products. The settlement resolves a qui tam case filed by former and current employees.

K. CCS Medical Inc.[9]

In August 2016, a Massachusetts judge revived a kickback case against supplier, CCS Medical Inc. Previously, the judge dismissed the kickback case alleging CCS of converting customers to Coloplast Corp products, including catheters, in exchange for discounts, ruling that CCS was protected under a safe harbor provision. After the dismissal, the Department of Justice (DOJ) filed a statement of interest, arguing that the discount safe harbor of the anti-kickback law did not shield an arrangement in which Coloplast granted price reductions to CCS. Specifically, the DOJ explained that because the price reductions were contingent on CCS' converting patients to Coloplast products, they were kickbacks, not discounts. The case is currently pending in the District of Massachusetts.

[8] *United States ex rel. Herman, et al. v. Coloplast Corp., et al.*, Case No. 11-cv-12131-RWZ.
[9] *United States of America et al. v. Coloplast A/S et al.*, Case No. 1:11-cv-12131.

3. New Anti-Kickback Law Developments

A. Anti-Kickback Law Criminal Indictments and Convictions

i. Dr. Pedro Garcia

A federal grand jury indicted Dr. Pedro Garcia of Mission, Texas, on August 30, 2016 for his alleged scheme to defraud Medicare by soliciting and obtaining cash in exchange for referrals of beneficiaries to home health agencies. Specifically, Dr. Garcia allegedly signed patient forms for patients (some deceased) that he did not treat or provide services to, yet he transmitted these forms to home health agencies, representing that he treated or provided services to the patients.

ii. Dr. Jagdish Shah

Dr. Jagdish Shah, a Chicago physician, pled guilty to two counts of Medicare fraud for his role in the Sacred Heart Hospital kickback scheme. Dr. Shah may face as little as 12 months in prison for receiving $2,000 monthly checks from the hospital in return for referrals. On paper the monthly payments were for the development of a cancer screening program; however, Dr. Shah admitted that he did not perform the work required under the agreement.

iii. Sundae Williams

A federal grand jury convicted the owner of a Chicago area telemarketing company for accepting kickbacks in return for referrals to home health agencies. Williams owned Serenity Marketing, Inc., which phoned patients for home health care services. Once Williams secured referrals, the home health agencies would make a per-patient payment to her.

B. OIG Alerts

i. Improper Arrangements and Conduct Involving Home Health Agencies and Physicians

On June 22, 2016, the Office of Inspector General (OIG) issued an alert targeting home health agencies, individual physicians, and heads of home-visiting physician companies that are purportedly defrauding Medicare by making (or accepting) payments for patient referrals, falsely certifying patients as homebound, and billing for medically unnecessary services or for services that were not provided. The OIG noted that many home health agencies are disguising payments to physicians in exchange for referrals as compensation arrangements for services provided, such as payments for serving as a medical director of a home health agency. Further, the OIG explained that in addition to anti-kickback statute violations, the government alleged that these parties

engaged in other health fraud activities, including billing Medicare for medically unnecessary nursing services provided to patients who were not confined to their homes, home visiting physician companies upcoding patient visits, and billing for care plan oversight services that were not actually rendered. Notably, the OIG explained that the physicians involved in these schemes typically were not the beneficiaries' primary care physicians, who were often unaware of the home health services.

ii. Information Blocking and the Federal Anti-Kickback Statute

On October 6, 2015, the OIG released an OIG Policy Reminder with respect to the electronic health records (EHR) safe harbor and information blocking. Specifically, the EHR safe harbor requires that "[t]he donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other [EHR] systems (including, but not limited to, health information technology applications, products, or services)."[10] The OIG provided several examples of arrangements that fail to satisfy the EHR safe harbor by information blocking: (1) any arrangement in which a donor limits the use, communication, or interoperability of donated items or services by entering into an agreement with a recipient to preclude or inhibit any competitor from interfacing with the donated system; (2) arrangements in which EHR vendors agree with donors to charge high interface fees to non-recipient providers or suppliers or to competitors; and (3) any arrangements involving actions taken by a donor (or any person on behalf of the donor, including the EHR vendor or the recipient) to limit the use of the donated items or services by charging fees to deter non-recipient providers and suppliers and the donor's competitors from interfacing with the donated items or services. Finally, the OIG reminded readers that laboratories are no longer potentially protected donors under the EHR safe harbor.

4. Inflated Penalties. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Act) requires federal agencies to make cost-of-living adjustments to civil monetary penalty (CMP) amounts based on increases in the Consumer Price Index (CPI). On September 6, 2016, HHS issued its interim final rule (IFR) updating its CMP regulations for all agencies within HHS. (81 Fed. Reg. 61537). Under the Act, agencies are required to make a "catch-up" adjustment, which is the difference between the CPI of the calendar year in which the penalties were last adjusted and the CPI for the current year. However, the "catch up" adjustments are capped at 150% of the current penalty amount. The IFR sets forth the initial "catch-up" adjustment for CMPs as well as any necessary technical conforming changes to the language of the various regulations affected by the IFR. Going forward, the CMP amounts will be adjusted without notice

[10] 42 C.F.R. § 1001.952(y)(3).

and comment rulemaking each January based on changes in the CPI. The table below provides several examples of updated CMPs:

Citation		Description	Pre-Inflation Penalty ($)	Maximum Adjusted Penalty ($)
USC	CFR			
1320a-7a(a)	42 CFR Part 1003	Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	10,000	15,024
1320a-7a(a)	42 CFR Part 1003	Penalty for employing or contracting with an excluded individual.	10,000	14,718
1320a-7a(a)	42 CFR Part 1003	Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	50,000	73,588
1395nn(g)(3)	42 CFR Part 1003	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	15,000	23,863
1395nn(g)(4)	42 CFR Part 1003	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	100,000	159,089

The adjusted civil penalty amounts are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015. Violations occurring on or before November 2, 2015 and assessments made before August 1, 2016, will continue to be subject to the civil monetary penalty amounts set forth in the existing regulations or as set forth by statute if the amount has not yet been adjusted by regulation.