Update on Fraud and Abuse Developments

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Chapter AA

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I. Anti-Kickback Statute Developments

   A. Regulatory Developments – New AKS Safe Harbors and Beneficiary Inducement CMP Exceptions. On December 7, 2016, the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) published a final rule amending the safe harbors to the Anti-Kickback Statute (“AKS”) and the Civil Monetary Penalty (“CMP”) rules prohibiting beneficiary inducements. See 81 Fed. Reg. 88,368. These changes protect certain practices and arrangements from criminal prosecution or civil sanctions under the AKS and/or the CMP. Below is a brief overview of the changes; a more detailed analysis is attached as Exhibit A.

   1. The final rule makes the following changes to the AKS safe harbor regulations:

   - Adds protection for free or discounted local transportation for medically necessary services and shuttle services meeting specified criteria.
   - Adds protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers;
   - Adds protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program;
   - Makes a technical correction to the existing safe harbor for referral services; and
   - Adds protection for certain cost-sharing waivers, including pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries, and waivers of cost-sharing for emergency ambulance services furnished by state- or municipality-owned ambulance services.

   2. In the final rule, the OIG amends the definition of “remuneration” in the CMP regulations applicable to beneficiary inducements to add exceptions covering the following:

   - Copayment reductions for certain hospital outpatient department services;
   - Certain remuneration that poses a low risk of harm and promotes access to care;
   - Coupons, rebates, or other retailer reward programs that meet specified requirements;
   - Certain remuneration to financially needy individuals; and
   - Copayment waivers for the first fill of generic drugs.
B. Selected AKS Settlements in 2016.

1. **Tenet Settlement.** On October 13, 2016, the U.S. Department of Justice (“DOJ”) announced that Tenet Healthcare Corporation and two of its Atlanta-area hospital subsidiaries agreed to pay over $513 million to resolve criminal charges and civil claims relating to a scheme to pay kickbacks in exchange for patient referrals and to obstruct the government’s investigation. See www.justice.gov/opa/pr/hospital-chain-will-pay-over-513-million-defrauding-united-states-and-making-illegal-payments. The government alleged that Tenet paid bribes and kickbacks to the owners and operators of prenatal care clinics serving primarily undocumented Hispanic women in return for the referral of those patients for labor and delivery medical services at Tenet’s hospitals. The kickbacks and bribes allegedly resulted in over 20,000 patient referrals, and helped Tenet obtain more than $145 million in Medicaid and Medicare funds based on those referrals.

2. **Olympus Settlement.** On March 1, 2016, DOJ announced that Olympus Corp. of the Americas, the largest distributor of endoscopes and related equipment, will pay $623.2 million to resolve criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals. See www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals. The government alleged that Olympus won new business sales by giving doctors and hospitals kickbacks in the form of consulting payments, foreign travel, lavish meals, grants and free endoscopes. DOJ’s press release lists the following examples of illegal kickbacks: (1) Olympus gave a hospital a $5,000 grant to facilitate a $750,000 sale; (2) Olympus delayed a $50,000 research grant until a second hospital signed a deal to purchase Olympus equipment; (3) Olympus paid three physicians to travel to Japan as a quid pro quo for their hospital’s decision to switch from a competitor to Olympus; and (4) a doctor with a major role in a New York medical center’s buying decisions received free use of $400,000 in equipment for his private practice. The press release also announces that an Olympus subsidiary, Olympus Latin America Inc., entered into a separate deferred prosecution agreement with DOJ, agreeing to pay $22.8 million to settle criminal allegations under the Foreign Corrupt Practices Act related to payments of kickbacks to physicians at government-owned health care facilities.

II. Stark Law Developments

A. Regulatory Developments.

1. **Stark Law Regulatory Changes in Medicare Physician Fee Schedule for CY 2016.** On October 30, 2015, as part of the Medicare Physician Fee Schedule for calendar year 2016, the Centers for Medicare & Medicaid Services (“CMS”) released final regulations under the physician self-referral law known as the Stark Law. See 80 Fed. Reg. 70886, 71300 (November 16, 2015). The provisions of the final rule are effective on January 1, 2016, except for certain changes on calculating ownership percentages for physician-owned hospitals, which are effective January 1, 2017. The final rule creates two new exceptions, relaxes certain technical requirements, and clarifies some existing regulations. A summary of these Stark Law regulatory changes is attached as Exhibit B.
2. **SRDP Revisions.** On May 6, 2016 and September 9, 2016, CMS published notices inviting comments on revisions to the Medicare Self-Referral Disclosure Protocol (“SRDP”). See 81 Fed. Reg. 27450 and 62503. (The September 2016 notice is the result of few minor terminology and formatting changes to the SRDP Forms released in May 2016.) The SRDP is a vehicle for providers and suppliers to voluntarily self-disclose actual or potential violations of the Stark Law. Under the prior process, a party was required to provide a financial analysis of overpayments arising from actual or potential violations of the Stark Law based on a 4-year lookback period. In light of CMS’s final 60-Day Overpayment Rule, discussed below, which established a 6-year lookback period for reporting and returning overpayments, CMS revised the SRDP to reflect the full 6-year lookback period. The 6-year lookback period applies only to submissions to the SRDP received on or after March 14, 2016 (the effective date of the 60-Day Overpayment Rule); parties submitting self-disclosures pursuant to the SRDP prior to March 14, 2016 need only provide a financial analysis of potential overpayments based on a 4-year lookback period.

CMS’s notices also reported that it has taken the opportunity to simplify the SRDP by issuing standardized forms for SRDP submissions. See Form CMS-10328. The goal of the new forms is to streamline the process and, presumably, to facilitate more efficient review by CMS. Previously, parties made disclosures by crafting their own narratives. The new forms include the SRDP Disclosure Form, the Physician Information Form, the Financial Analysis Worksheet and the Certification. A disclosing party may also submit a cover letter to accompany the submission, but is not required to do so. The SRDP Disclosure Form includes a new requirement that the disclosing party describe the pervasiveness of the noncompliance relative to its similar financial relationships or its similar services. The Physician Information Form calls for information regarding each physician with a noncompliant financial relationship being disclosed. The Financial Analysis Worksheet, which must be submitted in an Excel-compatible format, requires the disclosing party to provide a financial analysis of the potential overpayment during the 6 year lookback period. The SRDP changes also require the disclosing party to update, within 30 days, certain information following submission of its disclosure, such as the filing for bankruptcy, undergoing a change of ownership, or substitution of a new designated representative.

B. **Legislative Developments.**

1. **Senate Finance Committee Report.** On June 30, 2016, the U.S. Senate Committee on Finance released a white paper entitled “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models.” See www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper%20SFC%20Majority%20Staff%20063016.pdf. The white paper was the result of a round table held by the Committee in December 2015 to request feedback from subject-matter experts, and a more widespread call for comments. The white paper focused on potential changes to the Stark Law to remove hurdles to implementation of alternative payment models, such as those authorized by the Medicare Access and CHIP Reauthorization Act of 2015.

Commenters’ suggested changes included: (1) repeal the Stark Law; (2) limit the Stark Law to ownership or investment arrangements (not compensation arrangements); (3) create a waiver for entities whose risk revenue reaches a specified percentage
threshold; (4) extend existing waivers to all payors’ alternative payment arrangements; (5) create a new exception for arrangements that involve risk-sharing and gainsharing in alternative payment models; (6) amend certain compensation arrangement exception requirements, such as the FMV requirement, for arrangements involving alternative payment models; (7) broaden existing exceptions, such as the prepaid plan exception, to accommodate alternative payment models; and (8) expand authority for regulatory waivers, exceptions and advisory opinions.

The white paper also describes commenters’ suggestions to ease or eliminate sanctions for “technical” violations of the Stark Law. The following were suggested as potential definitions of technical violations: (1) documentation deficiencies (as suggested by Rep. Boustany’s Stark Administrative Simplification Act, discussed below); (2) violations that do not result harm to patients; (3) cases where compensation is consistent with FMV; (4) compensation arrangements that do not violate the AKS; (5) arrangements where the deviations from Stark Law requirements are non-substantive, based on bright line requirements; (6) accidental violation or violations lacking intent. Commenters also suggested changes to the definition of key Stark Law terms, such as FMV or the volume or value standard. Some commenters suggested that mitigating factors be identified that would reduce the sanctions in the case of technical violations.

Additional suggestions from commenters included (1) aligning the Stark Law with the AKS, such as by making AKS exceptions available under the Stark Law; (2) creating an exception for compensation arrangements entered into by tax exempt organizations; (3) shifting the burden of proof to the government to prove a violation; and (4) streamlining and simplifying the law.

2. Stark Administrative Simplification Act. In 2015, Rep. Charles W. Boustany, Jr. (R-LA) introduced H.R. 776, the Stark Administrative Simplification Act of 2015, which garnered 25 co-sponsors. H.R. 776 would provide for an alternative sanction under the Stark Law for instances of “technical noncompliance.” The alternative sanction would be $5,000 for any violation disclosed to CMS within one year after the initial date of noncompliance, and $10,000 for any violation disclosed to CMS more than one year after the initial date of noncompliance. H.R. 776 would establish specific requirements for disclosure to CMS of technical violations. A Stark violation that would be regarded as “technical noncompliance” under H.R. 776 is one where (1) the arrangement is not set forth in writing; (2) the arrangement is not signed by 1 or more parties to the arrangement; or (3) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement.

3. Medicaid Physician Self-Referral Act of 2015. In 2015, Rep. Jim McDermott (D-WA) introduced H.R. 1083, the Medicaid Physician Self-Referral Act of 2015. H.R. 1083 would prohibit payment under a state Medicaid plan for designated health services furnished pursuant to a referral prohibited by the Stark Law. (Current Stark Law provisions prohibit federal financial participation in payment for any such service, although court decisions have allowed False Claims Act cases against the providers submitting Medicaid claims based on the theory that the submission of such claims caused the state Medicaid agency to submit false claims to the United States. See U.S. ex rel. Schubert v. All Children’s Health System, Case No. 8:11-cv-01687-T-27EAJ (M.D. Fla. Nov. 15, 2013).) H.R. 1083 also provides that the False
Claims Act would apply to the submission of Stark Law prohibited claims to a state Medicaid agency, and requires the establishment of a Medicaid self-referral disclosure protocol.

4. **Promoting Integrity in Medicare Act of 2016.** In 2016, Rep. Jackie Speier (D-CA) introduced H.R. 5088, which would make the Stark Law’s in-office ancillary services exception unavailable for certain advanced imaging, anatomic pathology, radiation therapy, and physical therapy services. H.R. 5088 would also establish increased civil monetary penalties for violations of the self-referral prohibition with respect to those services.

5. **Promoting Access, Competition, and Equity Act of 2015.** In 2015, Rep. Sam Johnson (R-TX) introduced H.R. 2513, the Promoting Access, Competition, and Equity Act of 2015, which would extend the Stark Law exception for grandfathered physician-owned hospitals to certain hospitals that were mid-build at the time the whole hospital exception was eliminated, and would ease the restrictions in the Stark Law whole hospital exception on the expansion of grandfathered physician-owned hospitals.

C. **Significant Stark Law Settlements**

1. **Lexington Medical Center.** On July 28, 2016, Lexington Medical Center agreed to pay $17 million to resolve allegations that it entered into financial arrangements with 28 physicians that violate the Stark Law. The government alleged that the hospital entered into asset purchase agreements for the acquisition of physician practices or employment agreements with 28 physicians that violated the Stark Law because they took into account the volume or value of physician referrals, were not commercially reasonable or provided compensation in excess of fair market value. See [www.justice.gov/opa/pr/south-carolina-hospital-pay-17-million-resolve-false-claims-act-and-stark-law-allegations](http://www.justice.gov/opa/pr/south-carolina-hospital-pay-17-million-resolve-false-claims-act-and-stark-law-allegations).

2. **Tuomey Hospital.** In October 2015, Tuomey Hospital agreed to pay $72,406,860 to resolve a $237 million judgment for illegally billing the Medicare program for services referred by physicians with whom the hospital had financial relationships that violated the Stark Law. See [www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital](http://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital). See also Section II.D below.

3. **North Broward Hospital District.** In September 2015, North Broward (FL) Hospital District agreed to pay the United States $69.5 million to settle allegations that it violated the False Claims Act by engaging in financial relationships with referring physicians that violated the Stark Law. The government contended that compensation to physicians exceeded fair market value and was not commercially reasonable. The hospital district allegedly tracked and evaluated the margins it earned from referrals from employed physicians. See [www.justice.gov/usao-sdfl/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act](http://www.justice.gov/usao-sdfl/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act).

4. **Adventist Health System.** In September 2015, Adventist Health System agreed to pay the United States $115 million to settle allegations that it violated the False Claims Act by maintaining improper compensation arrangements with referring physicians and by miscoding claims. The health system allegedly paid bonuses to employed physicians based on a formula that improperly took into account the value of the physicians’ referrals to Adventist

5. Columbus Regional. In September 2015, Columbus (GA) Regional Healthcare System and a physician agreed to pay more than $25 million to resolve allegations that they violated the False Claims Act by submitting claims in violation of the Stark Law and claims that misrepresented the level of services they provided. The government alleged that, between 2003 and 2013, Columbus Regional provided excessive salary and directorship payments to the physician. See www.justice.gov/opa/pr/georgia-hospital-system-and-physician-pay-more-25-million-settle-alleged-false-claims-act-and.

6. Halifax Hospital. In March 2014, Halifax (FL) Hospital agreed to pay $85 million to resolve allegations that it violated the False Claims Act by submitting claims to the Medicare program that violated the Stark Law. The government alleged that Halifax entered into agreements with six medical oncologists that provided an incentive bonus that improperly included the value of prescription drugs and tests that the oncologists ordered and Halifax billed to Medicare. The government also alleged that Halifax paid three neurosurgeons more than the fair market value of their work. See www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-government-85-million-settle-allegations-improper.

D. Other Stark Developments.

1. Tuomey Legal Malpractice Case. As noted above, in October 2015, Tuomey Hospital settled a qui tam lawsuit with the U.S. Department of Justice (“DOJ”) for $72,406,860. The case was originally brought in 2005 by a physician-whistleblower, Dr. Michael Drakeford, who alleged that Tuomey Hospital had entered into part-time employment contracts with 19 other physicians that violated the Stark Law. Under the part-time employment agreements, the physicians, who were surgeons, were regarded as employees of an affiliate of Tuomey Hospital only when they performed outpatient procedures at the hospital, and were paid amounts that exceeded the amount that Tuomey Hospital would collect for their professional services and that varied with their personally performed services as employees (and therefore indirectly with their referrals). The United States intervened in the case in 2007. There were two jury trials in U.S. District Court. In the first, the jury determined that Tuomey Hospital violated the Stark Law but not the False Claims Act, and the judge ordered payment of $45 million on the Stark Law claim and a new trial on the False Claims Act claim. On appeal, the Fourth Circuit vacated the judgment and ordered a new trial on all claims. Following the second trial (in which some evidence was allowed that was excluded from the first trial), in 2013, the jury rejected Tuomey Hospital’s advice of counsel defense and found that Tuomey Hospital violated the Stark Law and the False Claims Act. The court then entered a judgment of $237 million. The Fourth Circuit then affirmed the judgment. Thereafter, Tuomey Hospital was sold and then it settled the case with DOJ, as noted above.

In developing the part-time employment agreements, Tuomey Hospital was represented primarily by its long-time outside counsel at Nexsen Pruet, who developed the agreements and concluded that they complied with the Stark Law. Some meetings between Tuomey Hospital representatives and Nexsen Pruet lawyers were tape recorded. Other advisors who weighed-in on the legality of the agreements included (1) Cejka, a consulting firm that
concluded that the physicians’ compensation was consistent with FMV, but included in its analysis the value of lost revenue to Tuomey Hospital if the physicians were to set up competing ASC; (2) Richard Kusserow, former Inspector General of HHS, who said, “It does not appear as if there are significant Stark issues”; (3) Nelson Mullins, a law firm that advised several physicians who did enter into the part-time employment agreements; (4) Womble Carlisle, a law firm that advised relator Dr. Drakeford, to whom Tuomey Hospital had proposed a part-time employment agreement; (5) Kevin McAnaney, former head of the OIG’s industry guidance branch, who was brought in by Tuomey Hospital and Drakeford to resolve a difference of opinion on the legality of the agreements, and who identified several “red flags” and concluded that contracts did not pass the “red face test”; (6) Hall Render, a law firm retained by Tuomey Hospital after hearing McAnaney’s assessment, which provided a written opinion that the part-time employment arrangements complied with the Stark Law (although the District Court suggested that Tuomey Hospital may not have provided full information to that firm).

In July 2016, Tuomey Hospital brought a legal malpractice suit against Nexsen Pruet in South Carolina state court, which Nexsen Pruet removed to Federal District Court. In Tuomey Hospital’s complaint, it alleges, among other things, that Nexsen Pruet negligently advised Tuomey Hospital that the part-time employment agreements were compliant with the Stark Law, failed to convey the full substance and import of McAnaney’s views (and in fact misled Tuomey Hospital by discrediting McAnaney), and advised Tuomey not to unwind the agreements during a period when it had a conflict of interest because both Tuomey Hospital and Nexsen Pruet were under investigation by the government. The complaint seeks damages of $117 million.

On August 18, 2016, Nexsen Pruet filed a Motion to Dismiss, which is pending as of this writing. In its Motion to Dismiss, Nexsen Pruet first argued that Tuomey Hospital is estopped from pursuing the malpractice case in light of the jury’s determination in the underlying case that Tuomey Hospital could not rely on the advice of counsel defense. That is, the firm contended that, since the jury had determined that Tuomey Hospital did not reasonably rely on Nexsen Pruet’s advice, it cannot sustain a malpractice action that is based on it having relied on Nexsen Pruet’s incorrect advice. Second, Nexsen Pruet argued that Tuomey Hospital’s position in the malpractice case is inconsistent with positions it took in the underlying False Claims Act case, such as its admissions in the settlement agreement with DOJ, and is therefore barred by principles of judicial estoppel. Third, Nexsen Pruet argued that any recovery by Tuomey Hospital against Nexsen Pruet would violate the public policy against allowing indemnification or contribution in favor of qui tam defendants. Fourth, Nexsen Pruet argued that Tuomey Hospital’s alleged damages are not recoverable for various other reasons.

2. Tuomey CEO Settlement. On September 27, 2016, DOJ announced that the former CEO of Tuomey Hospital, Ralph J. Cox III, agreed to pay $1 million to settle claims arising from his involvement in the hospital’s violations of the Stark Law. See www.justice.gov/opa/pr/former-chief-executive-south-carolina-hospital-pays-1-million-and-agrees-exclusion-settle. The settlement agreement also calls for Cox to be excluded from participating in federal health care programs for four years, and required Cox to fully cooperate with the government’s investigation of other individuals and entities. The government’s press release indicated that the government alleged that Cox caused Tuomey to enter into the illegal physician agreements, and that “Cox ignored and suppressed warnings from one of Tuomey’s
attorneys [presumably, McAnaney] that the physician contracts were ‘risky’ and raised ‘red
flags.’”

Seemingly, the government sought to ensure that Cox would suffer a financial penalty in the settlement that was significant to him. It appears that the amount of the settlement was based on sworn financial statements provided by Cox to verify his ability to pay. The settlement agreement allows the government to rescind the settlement or collect the full settlement payment amount plus 100 percent of the value of Cox’s undisclosed net worth if it learns that Cox failed to disclose more than $150,000 of assets. Moreover, under the settlement, Cox agreed to release Tuomey Hospital from any indemnification claims or reimbursement of the settlement payment amount, thus ensuring that Cox would pay the settlement amount himself.

The Cox settlement has been cited as an example of the application of the September 15, 2015 Yates Memo. In that document, Deputy Attorney General Sally Yates articulated DOJ policy to combat corporate misconduct by seeking accountability from individuals who perpetrated the wrongdoing. See www.justice.gov/dag/file/769036/download. The memo sets forth certain steps that should be taken by government attorneys in any investigation of corporate misconduct, including civil matters. The identified steps include (1) requiring disclosure of facts relating to the individuals responsible for the corporate misconduct as a condition for a corporation to receive cooperation credit; (2) investigative focus on individuals from the inception of any corporate investigation; (3) communication among criminal and civil DOJ attorneys handling corporate investigations; (4) no release of individuals when resolving a matter with a corporation, except in extraordinary circumstances; (5) no resolution of a matter with a corporation unless there is a clear plan to resolve individual cases; and (6) consistent focus by civil attorneys on individuals as well as corporations, including evaluation of whether to bring a suit against an individual based on considerations beyond the individual’s ability to pay.

III. Other Developments

A. Universal Health Services v. United States ex rel. Escobar. On June 16, 2016, in the closely watched False Claims Act case, a unanimous U.S. Supreme Court upheld the validity of the implied certification theory of FCA liability. In so doing, the Court discarded a judicially created check some courts had imposed on the theory, and which defendants had used with some success in obtaining dismissals of FCA suits. But the Court also set forth strict new limits on the implied certification theory; announced a new, pro-defendant materiality requirement; and strongly reiterated that the statute is not intended to be used to remedy minor regulatory violations or contractual breaches. For an analysis of the Escobar decision, see www.reedsmith.com/US-Supreme-Court-Adopts-a-Limited-Implied-Certification-Theory-of-FCA-Liability-and-Establishes-a-Robust-New-Materiality-Requirement-06-17-2016/.

B. 60-day Repayment Rule.

to reduce fraud, waste, and abuse in the Medicare program. The final rule relaxes some of the onerous requirements that were included in CMS’s 2012 proposed rule. Noteworthy provisions of the 60-Day Overpayment Rule include:

- Clarifying that a person has “identified” an overpayment when the person has or should have, through the exercise of “reasonable diligence,” determined that the person has received an overpayment and quantified the amount of the overpayment;
- Establishing, in the preamble to the final regulations only, that “reasonable diligence” is demonstrated through the timely, good faith investigation of credible information, which is, at most, 6 months from the receipt of the credible information, except in extraordinary circumstances;
- Starting the 60-day clock when either the reasonable diligence is completed or on the day the person received credible information of a potential overpayment if the person failed to conduct reasonable diligence and the person in fact received an overpayment;
- Indirectly requiring all Medicare Part A and Part B providers and suppliers to have effective compliance programs (via an interpretation of “reasonable diligence” that includes both “proactive and reactive activities”);
- Omitting Medicaid from the scope of any existing regulations;
- Narrowing the lookback period during which identified overpayments must be reported and returned from 10 years to 6 years;
- Tolling the deadline for returning overpayments when a provider or supplier files for an extended repayment plan; and
- Revising the allowable reporting process to include an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare Contractor.

The 60-Day Overpayment Rule is applicable only to repayments by providers and suppliers of overpayments originating under Medicare Parts A and B. For a discussion of the overpayment repayment obligations of providers and suppliers billing Parts C or D plans, see [link](http://www.healthindustrywashingtonwatch.com/2016/06/articles/fraud-and-abuse-developments/so-youre-an-overpaid-medicare-part-cd-provider-or-supplier-can-you-keep-the-change/).

2. Beth Israel, St. Luke’s-Roosevelt and Continuum Settlement. On August 24, 2016, the U.S. Attorney’s office in Manhattan announced that Beth Israel Medical Center, St. Luke’s-Roosevelt Hospital Center and Continuum Health Partners agreed to pay $2,950,000 to settle a civil fraud lawsuit alleging that the defendants willfully delayed repayment of over $800,000 in Medicaid overpayments in violation of the 60-Day Overpayment Rule. [See](http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-295-million-settlement-hospital-group-improperly).

C. Increase in FCA, AKS and Stark Law Penalties. The Bipartisan Balanced Budget Act of 2015 required federal agencies to update civil penalty amounts for inflation. On June 30, 2016, DOJ published an Interim Final Rule increasing the minimum per-claim penalty under the False Claims Act from $5,500 to $10,781, and increasing the maximum per-claim penalty from
The increases apply to civil penalties assessed after August 1, 2016, whose violations occurred after November 2, 2015. On September 6, 2016, HHS published an Interim Final Rule updating the civil monetary penalties administered by its various components, effective on the date of publication. In that release, among other things, HHS increased the civil money penalties for payment or receipt of a kickback in violation of the AKS from $50,000 to $73,588, and for submitted claims in violation of the Stark Law from $15,000 to $23,863.

D. Fraud and Abuse Waivers. Congress has granted the Secretary of Health and Human Services the authority to waive certain provisions of the fraud and abuse laws for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation ("CMMI"). Waivers have been issued with respect to a number of CMMI programs, as described below. The waivers apply to an entity’s arrangements only if the entity is eligible to use the waiver and if all conditions of the waiver are met.


2. Bundled Payment for Care Improvement (BPCI) Models. OIG and CMS have jointly issued waivers for specified arrangements involving BPCI Model participants. In particular waivers for BCPI Model 1 were issued on September 13, 2012, and waivers for BCPI Models 2, 3 and 4 were issued on July 26, 2013.


4. Comprehensive ESRD Care Model. On July 15, 2015, OIG and CMS jointly issued waivers for specified arrangements involving large dialysis organizations and small dialysis organizations participating in the Comprehensive ESRD Care Model.


6. Next Generation ACO Model. On December 9, 2015, OIG and CMS jointly issued waivers for specified arrangements involving ACOs participating in the Next Generation ACO Model. On December 29, 2016, OIG and CMS jointly issued amended waivers as a result of certain programmatic changes made to the Model.

7. Oncology Care Model. On July 1, 2016, OIG and CMS jointly issued waivers for specified arrangements involving ACOs participating in the Oncology Care Model.

9. **Medicare Shared Savings Program.** On November 2, 2011, OIG and CMS jointly published an interim final rule establishing waivers in connection with the Shared Saving Program. On October 17, 2014, OIG and CMS jointly published notice extending the effectiveness of the interim final rule and the timeline for publication of a final rule through November 2, 2015. On February 12, 2015, OIG and CMS jointly issued additional guidance concerning three areas covered by the waivers: (1) public disclosures required under the ACO Pre-Participation and ACO Participation Waivers, (2) notification of failure to submit a timely application by parties who used the ACO Pre-Participation Waiver, and (3) requests for an extension of the ACO Pre-Participation Waiver period. On October 29, 2015, OIG and CMS jointly published a final rule establishing waivers in connection with the Shared Saving Program.

E. **PhysicianOwned Distributors.** In May 2016, the Senate Finance Committee issued a comprehensive report entitled “Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern”. The Report was highly critical of the entire POD industry and its surgeon participants, and it urged not only expanded regulation in this area, but also increased and expanded investigative and enforcement activity by OIG and DOJ. For more information, see www.reedsmith.com/Physician-Owned-Distributor-POD-Update-05-17-2016/.

On January 9, 2017, DOJ announced that a Detroit-area surgeon was sentenced to nearly 20 years in prison for his role in a $2.8 million health care fraud scheme involving a physician owned distributor, Apex Medical Technologies, which he partly-owned. See www.justice.gov/opa/pr/detroit-area-neurosurgeon-sentenced-235-months-prison-role-28-million-health-care-fraud. In connection with his guilty plea, the surgeon admitted that the financial incentives provided to him by Apex caused him to use more spinal implant devices than were medically necessary to treat his patients in order to generate more sales revenue for Apex, which resulted in serious bodily injury to his patients. The surgeon also admitted that, on a few occasions, the money he made from using Apex spinal implant devices motivated him either to refer patients for unnecessary spine surgeries or for more complex procedures that they did not need.
Appendices

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Appendix B: Exhibit B - CMS Publishes Final Stark Law Regulations
Analysis of HHS OIG Final Rule to Amend the Anti-Kickback Safe Harbors and CMP Rules on Beneficiary Inducements

On December 7, 2016, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published a final rule amending the safe harbors to the Anti-Kickback Statute (AKS) and the Civil Monetary Penalty (CMP) rules prohibiting beneficiary inducements. These changes protect certain practices and arrangements from criminal prosecution or civil sanctions under the AKS and/or the CMP (Final Rule).¹ The Final Rule follows a proposed rule published October 3, 2014 (Proposed Rule).² The Final Rule finalizes all of the AKS safe harbors proposed in the Proposed Rule, with certain modifications, and all of the beneficiary inducement CMP exceptions proposed in the Proposed Rule.

The AKS prohibits individuals or entities from knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward business reimbursable under federal health care programs. As required by Congress, the OIG has issued safe harbor regulations that identify business practices that are not subject to sanction under the AKS. The Final Rule makes the following changes to the AKS safe harbor regulations:

- Adds protection for free or discounted local transportation for medically necessary services and shuttle services meeting specified criteria
- Adds protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers
- Adds protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program
- Makes a technical correction to the existing safe harbor for referral services
- Adds protection for certain cost-sharing waivers, including pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries, and waivers...
of cost-sharing for emergency ambulance services furnished by state- or municipality-owned ambulance services

The beneficiary inducement CMP prohibits offering or transferring remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider of Medicare or Medicaid payable items or services. In the Final Rule, the OIG amends the definition of “remuneration” in the CMP regulations at 42 C.F.R. Part 1003 to add exceptions that accord with statutory enactments covering the following:

- Copayment reductions for certain hospital outpatient department services
- Certain remuneration that poses a low risk of harm and promotes access to care
- Coupons, rebates, or other retailer reward programs that meet specified requirements
- Certain remuneration to financially needy individuals
- Copayment waivers for the first fill of generic drugs

As a matter of policy, the OIG does not apply the beneficiary inducement CMP to inexpensive gifts of nominal value that are not cash or cash equivalents. In 2000, the OIG announced its interpretation of “inexpensive” or “nominal value” to mean a retail value of no more than $10 per item or $50 in the aggregate per patient on an annual basis. On the same day that the OIG published the Final Rule, it separately issued a policy statement increasing these limits to $15 per item or $75 in the aggregate per patient per year. Gifts to beneficiaries below these thresholds do not need to meet an exception to the beneficiary inducement CMP.

The Proposed Rule also included a proposal to codify in regulations the statutory “gainsharing” CMP set forth in section 1128A(b) of the Social Security Act, which prohibits a hospital or a critical access hospital from knowingly paying a physician to reduce or limit services provided to Medicare or Medicaid beneficiaries. However, after the Proposed Rule was published, Congress amended the law so that only payments to reduce or limit medically necessary services (as opposed to any services) are prohibited. As such, the OIG did not finalize in the Final Rule the proposed regulatory text or definitions related to the gainsharing CMP.

According to the OIG, the Final Rule is intended to “enhance flexibility for providers and others to engage in health care business arrangements to improve efficiency and access to quality care while protecting programs and patients from fraud and abuse.” The OIG also notes that it has taken changes in health care payment and delivery into account in finalizing the Final Rule. Yet, while the OIG recognizes that “the transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers,” it concedes that the Final Rule “does not specifically address many emerging arrangements.” While the OIG allows that many new relationships
do not implicate fraud and abuse laws or can fit within existing safe harbors or exceptions, it promises in the Final Rule to continue to monitor changes in the industry and consider whether additional rulemaking is needed.

The following is our analysis of the Final Rule.

**Amendments to the AKS Safe Harbors**

**Local Transportation**

**Individual Transportation for Medically Necessary Services** – In 2002, the OIG sought comments from the industry regarding the establishment of an exception to the definition of “remuneration” under the statutory beneficiary inducement prohibition that would allow for the provision of complimentary local transportation of a nominal value. As explained in that solicitation for comments and in the Proposed Rule, Congress did not intend that the statutory prohibition would preclude free, local transportation of a nominal value. Twelve years after the OIG’s 2002 solicitation for comments, the agency proposed a regulatory safe harbor for free and discounted local transportation in the Proposed Rule, to apply to both the AKS and the beneficiary inducement prohibition. The proposal largely codified a series of OIG Advisory Opinions related to complimentary transportation that the agency had issued over the years.

In the Final Rule, the OIG finalizes a safe harbor at 42 C.F.R. § 1001.952(bb) for local transportation to enable an established patient to be transported to a provider or supplier of services and back to a patient’s home to receive medically necessary services. Specifically, under the safe harbor, remuneration does not include free or discounted local transportation made available by an eligible entity to federal health care program beneficiaries if all of the following requirements are met:

1. The availability of the free or discounted local transportation services:
   - is set forth in a policy, which the eligible entity applies uniformly and consistently; and
   - is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;

2. The free or discounted local transportation services are not air, luxury, or ambulance-level transportation;

3. The eligible entity does not publicly market or advertise the free or discounted local transportation services, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;
4. The eligible entity makes the free or discounted transportation available only:

- to an individual who is: (1) an established patient of the eligible entity that is providing the free or discounted transportation, if the eligible entity is a provider or supplier of health care services; and (2) an established patient of the provider or supplier to or from which the individual is being transported;

- within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area; and

- for the purpose of obtaining medically necessary items and services.

5. The eligible entity that makes the transportation available bears the costs of the free or discounted local transportation services, and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals.

**Eligible Entities**

Citing fraud and abuse concerns, the OIG used a narrow definition of “eligible entity” in the Proposed Rule, proposing to exclude suppliers of items and certain groups of providers or suppliers of services that may be more likely to offer transportation to their patients in exchange for referrals, such as durable medical equipment (DME) suppliers, pharmaceutical companies, laboratories, and home health agencies.

In the Final Rule, the OIG defines “eligible entities” as “any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items.”

Under this definition, eligible entities are those that provide services (or services and items), but not those that provide items. In the Final Rule, the OIG notes that physical therapists, dialysis facilities, home health agencies, and laboratories are therefore eligible entities, but pharmacies and pharmaceutical manufacturers are excluded from the definition because they primarily provide items. The OIG also clarifies that entities that do not directly render health care services to patients, such as health plans, MA organizations, MCOs, ACOs, clinically integrated networks, and charitable organization, are not excluded from the definition of eligible entity, and are eligible to provide transportation under this safe harbor.

**Established Patients**

In the Proposed Rule, the OIG proposed to limit the safe harbor to “established patients,” but it did not define that term. Instead, in the Proposed Rule’s preamble discussion, the OIG noted that a patient would be “established” once a patient had selected a provider or supplier, and had attended an appointment with that provider or supplier.
In the Final Rule, the OIG defines the term “established patient” as a “person who has selected and initiated contact to schedule an appointment with a provider or supplier to schedule an appointment [sic], or who previously has attended an appointment with the provider or supplier.” This established-patient requirement does not apply to shuttle service transportation, further discussed below.

According to the OIG, the definition is intended to offer flexibility to improve patient care while limiting the risk of the transportation being used as a recruiting tool, or to bring patients in for unnecessary services. Therefore, the OIG is finalizing a definition that includes new patients (or their representatives) who contact the provider or supplier on their own initiative. The safe harbor does not protect transportation provided as a result of a provider or supplier reaching out to a patient (or the patient’s case manager) and asking to have a new patient come in via offered transportation.

The safe harbor does not require documentation that the patients receiving transportation are established patients, but the OIG notes that maintaining such documentation may be “best practice” to demonstrate compliance with the safe harbor.

**Shuttle Transportation Services** – In the Proposed Rule, the OIG sought comments on whether to separately protect a second form of transportation furnished to beneficiaries akin to a shuttle service. In the Final Rule, the OIG separately protects free or discounted local transportation made available by an eligible entity in the form of a “shuttle service” – a transportation service that runs on a set route and on a set schedule – if all of the following requirements are met:

1. The shuttle service is not air, luxury, or ambulance-level transportation;

2. The shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

3. The eligible entity makes the shuttle service available only within the eligible entity’s local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 50 miles between that that stop and all providers or suppliers on the route; and

4. The eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals.

As the OIG noted in the Final Rule, some of the safeguards applicable to the safe harbor for local transportation for medically necessary services also apply to the safe harbor for shuttle transportation services, while others do not. For example,
the shuttle transportation services’ safe harbor is not limited to established patients, does not mandate where the shuttle may or may not make stops, and permits use of the shuttle for reasons other than to obtain health care items or services.

**Remuneration Between Medicare Advantage Organizations and Federally Qualified Health Centers**

In the Proposed Rule, the OIG proposed incorporating into the AKS regulations, at a new 42 C.F.R. § 1001.952(z), a statutory exception to the AKS created by section 237 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Previously, section 237 of the MMA added a provision to the then-existing statute governing contracting with Medicare Advantage (MA) organizations to the effect that any agreement between such an organization and a federally qualified health center (FQHC) must require “a level and amount of payment” for services by the MA plan to the FQHC “that is not less than the level and amount of payment” the MA plan would pay to another, non-FQHC entity for similar services. Section 237 also added a provision to the then-existing version of the AKS itself that excluded from the scope of that statute’s prohibitions “any remuneration between a [FQHC] (or an entity controlled by such a health center) and a MA organization pursuant to a written agreement” described in the existing statute governing payment to MA organizations.

Accordingly, the Proposed Rule proposed excluding from potential AKS enforcement any remuneration between an MA organization and an FQHC that meets the foregoing requirements – i.e., that is pursuant to a written agreement between the two requiring the MA plan to pay the FQHC at rates no lower than those the plan pays to other types of providers for similar services. The Final Rule finalizes this proposal.

In recognition of the key role FQHCs play in serving the poor and medically underserved, federal law requires the Centers for Medicare & Medicaid Services (CMS) to make supplemental payments to such centers for services they render to MA plan members to cover the portion of the center’s costs not covered by the MA plan’s reimbursement. The new regulatory exclusion at 42 C.F.R. § 1001.952(z) furthers the policy goal of supporting FQHCs by limiting their potential AKS liability, while also ensuring that MA plans cover their fair share of the cost of operating such centers, which otherwise would become the responsibility of CMS under the supplemental FQHC payment program.

**Manufacturer Discounts Under Part D Coverage Gap Discount Program**

The 2010 health reform legislation, the Patient Protection and Affordable Care Act (ACA), included a statutory exception to the AKS for discounts provided by pharmaceutical manufacturers under the Medicare Part D Coverage Gap Discount Program (CGDP). Under this program, manufacturers agree with CMS to provide discounted prices to certain Medicare beneficiaries at the point of sale, while they are in the so-called “donut hole.”
As proposed in the Proposed Rule, the Final Rule codifies this exception in the safe harbor regulations at 42 C.F.R. § 1001.952(aa). Under the new safe harbor, “remuneration” does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the CGDP, as long as all the following requirements are met:

1. The discounted drug meets the definition of “applicable drug” under the CGDP;
2. The beneficiary receiving the discount meets the definition of “applicable beneficiary” under the CGDP; and
3. The manufacturer of the drug participates in, and is in compliance with the requirements of, the CGDP.

While there can be little question that an AKS exception is appropriate for these statutorily mandated discounts, manufacturers might take issue with the fact that OIG has drafted the safe harbor to apply only to discounts provided to “applicable beneficiaries” on “applicable drugs” (each as defined under the CGDP), since manufacturers do not control the provision of the discounts—rather, they must pay the amounts invoiced to them for CGDP discounts by CMS’ third-party administrator, subject to limited audit and appeal rights.

**Technical Correction to Referral Services Safe Harbor**

The Final Rule makes a technical correction to the referral services safe harbor at 42 C.F.R. § 1001.952(f), which provides that payments (or other exchanges of value) between a participant (i.e., the person or entity that receives referrals through the arrangement) and a referral service (i.e., the person or entity that is making referrals to the participant) are not remuneration for purposes of the AKS, provided that the arrangement meets the safe harbor’s four requirements. The OIG previously made this same change in 1999, but then inadvertently undid the change in 2002.14

As finalized, the second of the four requirements of the safe harbor is now that “any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.”15 Previously, the relevant phrase was “either party for the referral service,” which was a source of confusion. As amended, the safe harbor makes clear that the volume or value of referrals or business otherwise generated “by either party for the other party” cannot affect the referral service’s fee to participants.

In the Final Rule, the OIG also notes that it received a comment recommending that OIG modernize this safe harbor to permit the use of online, Internet-based tools. Although outside the scope of the rulemaking, the OIG does nonetheless
confirm in the Final Rule that the safe harbor does not exclude the use of online tools, and notes that it may consider revisions to the safe harbor in the future if it determines that online referral sources need additional or different protection.

Cost-Sharing Waivers

The AKS may be implicated by the reduction or waiver of Medicare or other federal health care program cost-sharing amounts, and OIG has consistently expressed concerns regarding providers and suppliers that routinely waive Medicare cost-sharing amounts unrelated to individualized, good faith assessments of financial hardship. The OIG has long maintained that such waivers may constitute prohibited remuneration to induce referrals under the AKS or improper beneficiary inducements under the CMP.

Nonetheless, certain waivers arguably pose a low risk of harm to federal health care programs, while benefitting patients and enhancing the efficient and effective delivery of health care. Recognizing this, OIG finalized its proposal to modify 42 C.F.R. § 1001.952(k) to protect certain cost-sharing waivers related to Part D and emergency ambulance services, further discussed below. In the Final Rule, the OIG also expands the scope of 42 C.F.R. § 1001.952(k) to all federal health care programs, recognizing that the safe harbor may not apply to all federal health care programs because of the varying methods of payment. The OIG also revises the regulatory language to define “cost-sharing” to include “copayment, coinsurance, or deductible” (previously, the reference was limited to “coinsurance or deductible”).

Part D Cost-Sharing Waivers and Reductions by Pharmacies – The MMA included a statutory exception to the AKS for waivers of Part D cost-sharing by pharmacies that meet certain requirements. In the Proposed Rule, the OIG proposed to add a regulatory safe harbor at 42 C.F.R. § 1001.952(k)(3) reflecting the statutory exception. The basic requirements of the proposal were as follows:

1. That the waiver not be offered as part of an advertisement or solicitation;
2. That the pharmacy does not routinely waive cost-Part D sharing; and
3. That the waiver is provided only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing despite making reasonable collection efforts.

However, consistent with the statutory exception, requirements (2) and (3) would not apply to waiver of cost-sharing for Part D low-income, subsidy-eligible individuals.

In the Final Rule, the OIG finalizes its proposal so that waivers and reductions of Part D cost-sharing obligations by pharmacies that meet the requirements noted above will be protected. As with all 42 C.F.R. § 1001.952(k)-protected cost-sharing waivers, this new safe harbor is not limited to Part D cost-sharing, but now applies to all federal health care programs. However, the safe harbor is applicable to
pharmacies only, and does not protect waivers by physicians for copayments of Part B drugs, nor any MA or other plans’ “cost-saving programs.”

As in the Proposed Rule, the OIG continues to stress in the Final Rule that this safe harbor protects only against AKS liability and the beneficiary inducement CMP provisions – a particular practice could still implicate other CMS program rules (such as chapter 5 of the Prescription Drug Benefit Manual).

**Emergency Ambulance Services Cost-Sharing Waivers by Certain Ambulance Providers and Suppliers** – In multiple advisory opinions, the OIG has approved the reduction or waiver of coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier that is owned and operated by a state or political subdivision of the state. However, no safe harbor expressly protected such arrangements. In the Proposed Rule, the OIG proposed to establish a new safe harbor at 42 C.F.R. § 1001.952(k)(4) to protect such arrangements, and in the Final Rule the OIG finalizes the same.

Under the new safe harbor, reductions or waivers of cost-sharing owed to an ambulance provider or supplier for emergency ambulance services for which a federal health care program pays under a fee-for-service payments system are protected if the following requirements are met:

1. The ambulance provider or supplier is owned and operated by a state, a political subdivision of a state, or a tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act;

2. The ambulance provider or supplier is engaged in an emergency response;

3. The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or tribal members, or to all individuals transported; and

4. The ambulance provider or supplier does not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

**Amendments to the Beneficiary Inducement CMP**

Under section 1128A(a)(5) of the Social Security Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services, may be liable for CMPs of up to $10,000 for each wrongful act. In the Proposed Rule, the OIG proposed to add five new exclusions to the beneficiary inducement CMP regulations, four of which emanated from statutory provisions contained in the ACA. The Final Rule incorporates these changes.
into the definition of “remuneration” under the applicable regulations (42 C.F.R. § 1003.110).

**Copayment Reductions for Outpatient Department Services**

The CMP regulations include an exception that permits hospitals to give reductions in copayment amounts for certain outpatient department (OPD) services. In the Proposed Rule, the OIG proposed to update the statutory citation to the definition of “covered OPD services” included in the regulations, and having received no comments regarding this proposal, the OIG finalizes this change in the Final Rule, so that the regulations now refer to the current statutory section (section 1833(t)(8)(B) of the Social Security Act).

**Promotes Access to Care and Presents a Low Risk of Harm to Beneficiaries and Federal Health Care Programs**

The ACA included an exception that protects “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” In the Proposed Rule, the OIG proposed certain interpretations of this statutory language, and also solicited comments on a number of aspects of the statutory language, including what constitutes “care,” what it means to “promote access to care,” and what type of remuneration poses a low risk of harm.

Under the Final Rule, 42 C.F.R. § 1003.110 is amended to provide that the following is not considered “remuneration” and is therefore not subject to the beneficiary inducement CMP:

Items or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—

1. Being unlikely to interfere with, or skew, clinical decision making;
2. Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
3. Not raising patient safety or quality-of-care concerns.\(^{17}\)

Pursuant to the relevant statutory language, this exception requires an assessment of (1) whether the remuneration at issue promotes access to care (i.e., improves a beneficiary’s ability to obtain payable items and services), and (2) if so, whether it poses a low risk of harm to beneficiaries and programs.

As an initial matter, in the Final Rule the OIG notes that this exception should be read in the context of more specific CMP exceptions and AKS safe harbors (which are incorporated by reference into the exceptions to the beneficiary inducements CMP), and that activities and arrangements that are addressed by and meet the elements of another applicable safe harbor or exception will be considered low risk under this exception. For example, a transportation arrangement that meets
all of the requirements of the AKS safe harbor discussed above related to local transportation would be low risk under this exception. However, if the arrangement did not meet all of the AKS safe harbor requirements, but had different safeguards in place, it may still be low risk under this exception (even if the AKS safe harbor is not available).

In addition, the Final Rule makes clear that if remuneration at issue is not likely or intended to induce a beneficiary to use a particular provider, practitioner, or supplier, the beneficiary inducements CMP will not be implicated in the first place (although the AKS may still be implicated).

Finally, in response to comments related to whether there should be special provisions for incentives offered by participants in CMS-sponsored initiatives and demonstrations, such as the Bundled Payment of Care Initiatives, the OIG confirms in the Final Rule that all entities seeking to rely on this exception must meet its terms.

“Care”

In the Proposed Rule, OIG characterized the term “care” as “medically necessary health care items and services,” but solicited comments on whether it should interpret “care” more broadly to include care that is non-clinical but reasonably related to the patient’s medical care, such as social services.

In the Final Rule, OIG declines to expand the term “care” beyond items and services that are payable by Medicare or a state health care program (e.g., Medicaid), but does not limit the term to strictly “medically necessary” services, recognizing that Medicaid covers some services that are not strictly medical (e.g., personal care services).

As finalized, the term “care” in the context of “access to care” means access to items and services that are payable by Medicare or a state health care program for the beneficiaries that receive them. As such, this exception protects remuneration that promotes access to items and services that are payable by Medicare or a state health care program.

The OIG makes clear that the type of care at issue is care provided by a particular provider, practitioner, or supplier. As noted above, individuals and entities (including health plans) can still help and encourage beneficiaries to access nonpayable care without implicating the beneficiary inducement CMP, as long as any remuneration associated with such assistance is not intended to induce a beneficiary to use a particular provider, practitioner, or supplier for an item or service payable by Medicare or a state health care program.

“Promotes Access”

In the Proposed Rule, OIG proposed that this exception would include only remuneration that “improves a particular beneficiary’s ability to obtain medically necessary items and services,” but solicited comments on whether it should
interpret “promotes access” more broadly to include encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient. The OIG also solicited comments on whether remuneration would have to promote access to a particular beneficiary, or whether it should also apply to a defined beneficiary population.

In the Final Rule, the OIG declines to adopt a broader interpretation of the phrase “promotes access to care” than that proposed (subject to the finalized definition of “care” discussed above), but OIG does note that items or services that help or support patients’ access to care, or make access more convenient that it otherwise would be, will often meet the originally proposed, and now finalized, interpretation. The OIG also finalizes that the exception applies to remuneration that promotes access either to a particular individual or a defined beneficiary population.

OIG’s interpretation of items or services that “promote access to care” encompasses giving patients the tools they need to remove certain socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care, but does not include rewarding patients for accessing care, including compliance with a treatment plan, or inducements to seek care. For example, if a patient had a health condition for which a smoking-cessation program was a payable service, a provider could offer free child care to the patient so that the patient could attend the program. Such remuneration would be protected by this exception because the patient might not be able to attend the program without child care assistance. However, the provider could not give movie tickets as a reward for attending the session, as movie tickets would not improve the patient’s ability to attend the appointment.

Notwithstanding the foregoing and as noted above, the OIG makes clear in the Final Rule that inducements to comply with a treatment, rewards for compliance with treatment, incentives to seek preventative health services, or incentives to achieve certain health-related benchmarks offered to patients by individuals and entities (including health plans), will not implicate the beneficiary inducements CMP if such inducements or rewards do not influence a beneficiary to use a particular provider, practitioner, or supplier (although the AKS may still be implicated).

“Low Risk of Harm”

In the Proposed Rule, the OIG proposed that, for remuneration to involve a “low risk of harm” to Medicare and Medicaid beneficiaries and programs, the remuneration must (1) be unlikely to interfere with, or skew, clinical decision-making; (2) be unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient-safety or quality-of-care concerns.

The Final Rule accepts this interpretation. In the Final Rule, the OIG also discusses risk with respect to marketing and educational activities and materials. The OIG
confirms that remuneration given in connection with marketing is not low risk and will not be protected by this exception, since such remuneration is given for the purpose of influencing the choice of a particular provider, practitioner, or supplier, and may induce overutilization or inappropriate utilization. In contrast, the OIG does not consider educational materials alone (even those that include information about a particular provider’s qualifications) to be remuneration. As such, a provider supplier may offer educational materials or informational programs to patient or prospective patients without implicating the beneficiary inducement CMP.

The Final Rule otherwise discusses various examples of item or services proposed by commenters for protection by this exception, with the OIG noting that whether such items and services will be protected will depend on the applicable facts and circumstances. The OIG does confirm, consistent with its previous guidance, that the remuneration cannot be cash or cash equivalents, and cannot take the form of copayment waivers (under this exception).

**Retailer Rewards Programs**

The ACA includes an exclusion from remuneration for the offer or transfer of items for free or for less than fair market value through coupons, rebates or rewards from a retailer to the general public, regardless of payor status, as long as the remuneration is not tied to items and services reimbursable by federal health care programs.

In the Proposed Rule, the OIG proposed using that statutory language as the text for a corresponding regulation. The proposal was intended to address the practice of many retailers to exclude federal health care program beneficiaries from their rewards programs in order to avoid running afoul of OIG guidance on the beneficiary inducement CMP. In the Final Rule, the OIG finalizes the proposed language. According to the OIG, this retailer rewards exception “creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs without violating…the beneficiary inducements CMP.”

Under the Final Rule, 42 C.F.R. § 1003.110 is amended so that the definition of “remuneration” now excludes the offer or transfer of items or services for free or less than fair market value by a person if the following criteria are met:

1. The items or services consist of coupons, rebates, or other rewards from a retailer;

2. The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

3. The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Medicare or State health care programs.
**Coupons, Rebates, or Other Rewards from a Retailer**

The Proposed Rule included interpretations of the terms “retailer,” “coupon,” “rebates,” and “other rewards.” The Final Rule includes specific discussion of certain of these terms, but not all.

**Retailer** – According to the Final Rule, the term “retailer” should be interpreted in accordance with its “commonly understood meaning.” That is, an entity that sells items directly to consumers, including independent or small pharmacies, online retailers, and entities that sell a single category of items.21 “Retailer” does not include individuals or entities that primarily provide services (e.g., hospitals or physicians). This exception is limited to items or services “from a retailer,” and therefore the OIG confirms that non-retailers, including manufacturers, may not provide retailer rewards under this exception. As a result, this exception does not protect a situation in which a manufacturer offers or transfers to patients any retailer rewards acquired or paid for by the manufacturer.

**Other Rewards** – In the Final Rule, the OIG confirms its position that “other rewards” is a broad concept and, although OIG expects these would primarily be in the form of free items or services, reduced priced items or services may also qualify. According to the OIG, “other rewards” include gasoline discounts, frequent flyer miles, items purchased in the retailer’s store, educational information or programs, and health care items or services (except that the reward cannot be in the form of a copayment waiver, which would not meet the third criteria above).

**Coupons and Rebates** – The Final Rule does not include specific discussion of the terms “coupon” or “rebate,” but the discussion in the Proposed Rule remains applicable. In the Proposed Rule, the OIG proposed to interpret a “coupon” as something authorizing a discount on merchandise or services, such as a percentage discount on an item or a “buy one, get one free” offer. The OIG proposed to interpret “rebate” as a return on part of a payment, with the caveat that a retailer could not “rebate” an amount that exceeds what the customer spent at the store.

**Offered or Transferred on Equal Terms**

According to the Final Rule, the second criteria of the new retailer rewards exclusion requires that the retailer reward is offered to everyone regardless of health insurance status, and that the general public must have the same access to, and use of, the retailer reward as the retailer’s insured customer base. The OIG also clarifies that this requirement does not prohibit a retailer from having an enrollment process, as long as the terms do not vary based on insurance status or plan. In addition, a rewards program targeted to patients with a particular disease state may be offered, but it would need to meet the requirement that the reward not be tied to other reimbursable items or services.
Not Tied to Other Reimbursable Items or Services

With respect to the third criteria of this exclusion, the Final Rule confirms that the reward cannot be tied to the provision of other reimbursable items, both in the manner in which the reward is earned and redeemed. Permitted rewards include either discounts that could be used on anything in the store (among them covered items or services), or those that are specific to non-reimbursable items.

For example, a copayment waiver (or a $20 coupon off of a copayment) would not meet the third criteria of the exclusion because the reward is tied to the purchase of a reimbursable item (the item for which the copayment is waived or discounted). In contrast, a $20 coupon to be used on anything in the store would not be considered tied to other reimbursable items or services, even if the coupon was redeemable as a copayment, since the coupon is not limited to a reduction in price on a reimbursable item or service.

Similarly, coupons to transfer prescriptions are not protected under this exception because they tie the remuneration to purchasing a reimbursable item or service.

Financial-Need Based Exception

The ACA added an exclusion from prohibited remuneration for the offer or transfer of items or services for free or for less than fair market value to financially needy individuals if certain criteria are met. In the Final Rule, the OIG codifies this requirement in regulations and spells out the four statutory criteria.

Specifically, the term remuneration does not include the offer or transfer of items or services for free or less than fair market value by a person if the following requirements are met:

1. The items or services are not offered as part of any advertisement or solicitation;
2. The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by Medicare or a State health care program;
3. There is a reasonable connection between the items or services and the medical care of the individual; and
4. The person provides the items or services after determining in good faith that the individual is in financial need.

Reasonable Connection to Medical Care

In order for remuneration to be “reasonably connected” to medical care, it must be reasonable from both a medical perspective and a financial perspective.

With respect to the first perspective, the OIG provides in the Final Rule that the concept of a reasonable connection to the medical care of an individual can be interpreted broadly, to include items related to prevention of illness or injury,
if specifically pertinent to a particular patient’s medical care, as well as items related to medical treatment (e.g., extra bandages for wound care). In addition, items crucial to a patient’s safety (such as car seats for infants) are reasonably connected to medical care. However, not everything beneficial to a patient is connected to medical care, according to the OIG. For example, school backpacks are beneficial to children but are not connected to medical care.

The exception is designed to be patient-specific, so whether something is reasonably connected to a patient’s medical care must be determined on a case-by-case basis. The OIG recognizes that it is the medical professional working with the patient who is in the best position to determine what is reasonably connected to his or her patient’s medical care.

With respect to remuneration having a reasonable connection to medical care from a financial perspective, if a provider or supplier gives remuneration that has a high financial value, it is less likely to be “reasonably” connected to the medical care. It is for this reason that the OIG finalizes its proposed concept of ensuring that the value of the items and services is not disproportionately large compared with the medical benefits. However, the OIG declines to provide a specific retail value for something that is disproportionately large. Instead, the provider or supplier must consider whether the cost of the item or service is proportional to the possible harm it is designed to prevent.

*Individualized Determination of Financial Need*

Under this exception, the items or services can only be provided after a good-faith, individualized assessment of the patient’s financial need on a case-by-case basis. As finalized, the OIG will not require specific documentation of financial need. However, entities offering these items must do so in accordance with a set policy, based on income or other factors, that is uniformly applied. Providers and suppliers have the flexibility to determine the appropriate policy for their own patient populations.

Further, the Final Rule makes clear that while the financial need determinations must be done on an individual basis, OIG is not mandating any particular basis for determining need. In the Final Rule, the OIG declines to adopt a uniform measure of need (e.g., specific percentage of the Federal Poverty Level) and also declines to adopt a minimum threshold of assistance before a determination of need is required.

*Waivers of Part D Cost-Sharing for First Fill of a Generic Drug*

The ACA included a statutory exclusion from the beneficiary inducement CMP for waivers by Part D plan sponsors of a Part D enrollee’s copayment for the first fill of a generic drug. In the Proposed Rule, the OIG proposed codifying this exception and does so in the Final Rule, applicable to coverage years beginning on or after January 1, 2018.
Under the new CMP exception, remuneration does not include waivers by a Part D Plan sponsor of any copayment for the first fill of a covered Part D drug that is a generic drug or an authorized generic drug for individuals enrolled in the Part D plan, as long as such waivers are included in the benefit design package submitted to CMS.

The purpose of this exception is to minimize drug costs by encouraging the use of lower cost generic drugs.

* * * * *

By adding specific regulatory provisions and offering interpretations, the Final Rule provides clearer protection for a number of types of arrangements that the OIG and/or Congress had previously concluded should not result in sanctions under the AKS or the beneficiary inducement CMP. As a result, health industry participants now are able to structure these types of arrangements to comply with the regulatory requirements, resulting in greater comfort that their arrangements will not be found to violate these laws. On the other hand, not unexpectedly, the Final Rule did not break new ground by establishing AKS safe harbors or CMP exceptions that address emerging arrangements in the industry that are responsive to the transition from volume to value-based and patient-centered care. More flexibility from the OIG must await another day.

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7 The OIG has issued a variety of Advisory Opinions discussing providers furnishing free transportation services to patients and their friends and family, such as OIG Advisory Opinion Nos.: 00-7, 07-02, 09-01, 11-01, 11-02, and 11-16. In addition, the OIG published a letter regarding complimentary local transportation programs on December 9, 2002, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/sabgiftsandinducements.pdf.
8 In the Final Rule, the OIG declines to mandate the parameters for this policy, other than the fact that it must comply with the terms of the safe harbor (including distance, and the prohibition on transporting only to referral sources), and it must be applied uniformly and consistently. 81 Fed. Reg. 88,385.
9 The OIG clarifies in the Final Rule that drivers may be paid on the basis of total distance traveled by a vehicle, and if the transportation is provided in the form of non-private transportation (e.g., bus or taxi), the transportation can be paid for or reimbursed to the individual patients through taxi vouchers, bus fare, or cash reimbursement if the patient has the necessary receipts. 81 Fed. Reg. 88,387.
10 An eligible entity that does not itself provide health care services (such as a charitable organization, health plan, ACO, or other entity) is not required to have an established patient relationship with a patient in order to provide transportation that is protected by this safe harbor. 81 Fed. Reg. 88,385.
11 In the Final Rule, the OIG explains that this mileage can be measured directly (i.e., “as the crow flies”), which would include any route within that radius (even if such route is more than 25 or 50 miles when driven). 81 Fed. Reg. 88,387.
In the Proposed Rule, the OIG requested comments on whether free or discounted transportation should be available for non-health-care-related trips, e.g., to obtain social services or to visit food banks. In the Final Rule, the OIG declines to extend the safe harbor protection to transportation for purposes other than to obtain medically necessary items or services. This same restriction does not apply to shuttle transportation. 81 Fed. Reg. 88,384.


With respect to this requirement (3), the Final Rule removes reference to providing the waivers “without regard to patient-specific factors,” included in the Proposed Rule; but the OIG notes that this requirement (3) is still intended to ensure that the waivers do not take into account or require any case-by-case, patient-specific determinations (e.g., patient age, insurance, or financial status), while still allowing an ambulance provider or supplier to consider residency or tribal membership in granting waivers or reductions. That is, ambulance providers and suppliers can waive cost-sharing amounts for all residents, but charge cost-sharing amounts for nonresidents. 81 Fed. Reg. 88,376.

42 C.F.R. § 1003.110(6).

Although this exception does not protect inducements to seek care, other CMP exceptions may apply. For example, the preventative care exception at 1128A(i)(6)(D) of the Social Security Act protects incentives to seek preventative care. See also 42 C.F.R. § 1003.110 (definition of “remuneration”). And, as noted above, items of nominal value do not require an exception, even if intended to cause a beneficiary to select a particular provider or supplier.

See OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (2002) and OIG Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries, supra, note 3.


With respect to entities that sell a single category of items, the OIG notes, “We believe that it may be difficult for an entity that primarily sells a single category of products to meet the criterion that the offer of items or services not be tied to other reimbursable services if, for example, the entity sells only (or mostly) items that are reimbursable by Federal health care programs.” 81 Fed. Reg. 88,399.

The term “items or services” exclude cash, or cash equivalents (i.e., instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards). 81 Fed. Reg. 88,402.
CMS Publishes Final Stark Law Regulations

By Karl Thallner and Nicole Aiken, Reed Smith LLP

On October 30, 2015, as part of a larger final rule revising the Medicare Physician Fee Schedule (MPFS) and implementing other revisions to Part B for calendar year (CY) 2016, the Centers for Medicare & Medicaid Services (CMS) released final regulations under the physician self-referral law known as the Stark Law. See 80 Fed. Reg. 70886, 71300 (Nov. 16, 2015). The provisions of the final rule are effective on January 1, 2016, except for certain changes on calculating ownership percentages for physician-owned hospitals, which are effective January 1, 2017. The final rule, which is substantially similar to CMS’ proposal issued in July 2015,[1] creates two new exceptions, relaxes certain technical requirements, and clarifies some existing regulations. This article focuses on those changes to the Stark Law and the implications of those changes for providers seeking to ensure compliance with the Stark Law.

New Exceptions to the Stark Law

Recruitment and Retention of Non-Physician Practitioners

In its Phase III Rule,[2] CMS declined to expand the existing physician recruitment exception at 42 C.F.R. § 411.357(e) to cover the recruitment of non-physician practitioners (NPPs). Given the recent and significant changes in the health system and Medicare payment systems, as well as the continued projected shortages in the primary health care workforce, CMS has now adopted a new exception allowing recruitment assistance to physicians to assist with the employment of NPPs under certain circumstances.[3]

The new direct compensation exception at 42 C.F.R. § 411.357(x) permits remuneration from hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs) to a physician to assist in the bona fide employment of, or contracting with, an NPP by that physician to provide primary care or mental health services within the geographic area served by the hospital, FQHC, or RHC. The new exception is designed to facilitate primary care and mental health services and, as such, CMS will require that “substantially all” (i.e., 75%) of the patient services provided by a NPP recruited under this exception must be primary care or mental health services. The substance of the exception generally tracks the existing physician recruitment exception.

It is important to note that this exception is available to protect those arrangements under which a physician retains some of the compensation provided by the hospital, FQHC, or RHC. If the remuneration provided by a hospital, FQHC, or RHC to a physician is passed through directly to the NPP (i.e., the physician does not retain any of the remuneration to cover overhead or other expenses), then the Stark Law does not apply to the arrangement and it does not need to be structured to comply with this (or another) exception.

The most significant limitations under the new exception are the time limits imposed on the assistance offered by a hospital, FQHC, or RHC. Generally, a hospital, FQHC, or RHC may only assist the same physician with employing a NPP once every three years. Additionally, there is a two-
year limit on the assistance given by a hospital, FQHC, or RHC for a particular NPP. In short, the exception is designed to allow for start-up assistance and not long-term subsidies.

**Time-Share Arrangements**

Many DHS entities entering into time-share arrangements with physicians have done so utilizing the existing space rental exception found at 42 C.F.R. § 411.351(a). Among other things, an arrangement protected under that exception needs to provide for the exclusive use of space by the lessor—a requirement that is inherently challenging for some time-share arrangements to meet. Recognizing that certain time-share arrangements may not fit easily within the existing space rental exception, and acknowledging that time-share arrangements serve an important role in delivering health care services particularly in rural or underserved areas, CMS created a new exception specific to time-share arrangements at 42 C.F.R. § 411.351(y).[4]

The new exception includes elements familiar from the existing space rental exception. For example, the arrangement must be set out in writing, signed by the parties, and document the premises, equipment, personnel, supplies, and services covered by the arrangement, and the compensation to be paid under the arrangement must be set in advance and consistent with fair market value. The new exception also imposes additional requirements; for example, the equipment covered by the arrangement must be located in the office suite where the physician-licensee performs his or her services and the equipment covered by the arrangement cannot include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (with the exception of CLIA-waived laboratory tests).

There are important limitations on the circumstances under which the new exception can apply to protect a time-share arrangement. First, it only applies to those arrangements that do not establish a possessory leasehold interest in the property being rented under the time-share arrangement. Second, the new exception is only available to arrangements between a physician and a (i) hospital or (ii) a physician organization of which the physician is not an owner, employee or contractor. Third, all locations under the arrangement must be used on identical schedules. Fourth, compensation formulas based on a percentage of the revenue attributable to the services provided while using the time-share and per-unit fees will be prohibited. CMS expressly declined to prohibit compensation using time-based formulas (e.g., per hour or per day), however.

**Relaxation of Technical Requirements**

**Writing Requirement**

Many exceptions to the Stark Law require that the arrangement be set forth in writing. The prior regulations did not make clear, however, whether an arrangement had to be set forth in a single written agreement or whether it could be set forth through several writings. The revised regulatory language makes it clear that it is the arrangement as a whole that must be evidenced in writing, not that the parties need one written contract.[5] Rather, the writing requirement can be satisfied through a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Although the documents that could be used to show compliance with an exception will vary based on the facts of a particular arrangement, CMS provided several examples of the types of documents that providers can consider in determining whether an arrangement complies with the writing requirement of an applicable exception: board meeting minutes authorizing payments for specified services, written communications between the parties (including emails), fee schedules for specified services, check requests, invoices, time sheets documenting services performed, call coverage schedules or similar documents, accounts payable or receivable documenting payments, and checks issued for services or rent.
Arrangements for a Term of One-Year or More

Consistent with its view that arrangements do not need to be memorialized by one written contract, CMS has clarified that an arrangement does not need to include an explicit provision setting forth a term of the arrangement of at least one year. Similar to the “writing” requirement, a party can show compliance with the “one-year term” requirement through contemporaneous documentation establishing that the arrangement in fact lasted for at least one year.[6]

Holdover Arrangements

Previously, exceptions for space and equipment rentals and personal services arrangements[7] permitted a “holdover” of the arrangement for up to six months after an existing arrangement expired if that arrangement had been in place for at least one year and continued on the same terms as the prior arrangement. CMS has extended the six-month holdover period to an indefinite holdover period provided that an arrangement continues on the same terms and conditions as the original agreement and otherwise continuously satisfies the elements of an applicable exception, including the fair market value compensation requirement.[8]

Signature Requirement

Several exceptions to the Stark Law require that an arrangement be signed by the parties. Under the prior regulations, parties had 90 days to obtain a signature if failure to obtain a signature was inadvertent but only 30 days to obtain a signature if such failure was not inadvertent. The new regulations grant parties 90 days to obtain a missing signature, regardless of whether the failure to obtain such signature was inadvertent, although an entity can use the exception only once every three years for the same referring physician.[9]

Clarifying Changes

“Takes into Account” the Volume or Value of Referrals

CMS declined to clarify what “takes into account” means, particularly compared against “varies with.” For a detailed discussion regarding the need for such guidance, particularly in the wake of Tuomey,[10] refer to the Reed Smith Client Alert: The Implications of CMS’ Proposed Stark Law Regulations.[11] CMS, however, did conform its terminology throughout the regulations regarding the manner in which an arrangement “takes into account” the volume or volume of referrals between the parties to state that the compensation provided under the arrangement “may not take into account (directly or indirectly)” the volume or value of any referrals. Affected provisions include 42 C.F.R. §§ 411.357(e) (physician recruitment), 411.357(m) (medical staff incidental benefits), 411.357(r) (obstetrical malpractice insurance subsidies), and 411.357(s) (professional courtesy).

Retention Payments in Underserved Areas

CMS clarified the text of 42 C.F.R. § 411.357(t) to reflect its intent that retention payments be based on the prior two years of a physician’s income, as stated during its implementation of the Phase III revisions to that section.[12]

Definition of “Remuneration”

CMS has adopted its proposed rule to make it clear that the definition of “remuneration” in 42 C.F.R. § 411.351 does not include an item, device or supply that is used for one or more of six purposes listed in the statute.[13] CMS also confirmed its existing policy that a physician’s use of hospital resources when treating hospital patients (e.g., exam rooms) does not qualify as “remuneration”
when the hospital bills for its resources and services and the physician bills for her professional fees. If the hospital and physician submit a global bill to a payer and then pays the physician for professional services, however, CMS views the relationship as involving remuneration between the parties and the Stark Law is implicated.

“Stand in the Shoes” Requirement

The Phase III Rule included a provision under which physicians must be, or may be, treated as “standing in the shoes” of their physician organizations for purposes of applying the exceptions regarding direct and indirect compensation arrangements.[14] The new rule clarifies that all physicians in a physician organization are considered parties to a compensation arrangement between the organization and a DHS entity for all purposes under a relevant exception, except for the signature requirements.[15] Thus, the compensation to a physician organization may not take into account referrals from any physicians in the physician organization, whether or not the physician stands in the shoes of the organization.

Definition of “Locum Tenens” Physicians

CMS has removed the phrase “stand in the shoes” from the definition of a “locum tenens” physician to emphasize that this definition is separate and distinct from the “stand in the shoes” requirement applicable to certain compensation arrangements.[16] This definition is located at 42 C.F.R. § 411.351.

Publicly Traded Securities

The existing exception allows a physician who owns publicly traded securities in a DHS entity to refer to that entity when the securities are, among other possibilities, traded under an automated interdealer quotation system operated by the National Association of Securities Dealers (NASD). As NASD no longer exists and it is no longer possible to purchase stock through the automated interdealer system that NASD formerly operated, CMS has revised the publicly traded securities exception to include securities listed for trading on an electronic stock market or an OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.[17]

Physician-Owned Hospitals

The Affordable Care Act (ACA) eliminated the former “whole hospital” Stark Law exception, except for certain grandfathered physician-owned hospitals, and imposed new requirements on those grandfathered hospitals. Those requirements include, among others, a requirement that a physician-owned hospital disclose the fact that it is partially owned or invested in by physicians in any public advertising for the hospital, including on the hospital’s website, and a limit on the percentage of physician investment in a physician-owned hospital to its March 23, 2010 level. The new Stark Law regulations include important clarifications regarding both requirements.

First, CMS provides more certainty regarding the type of statements that would be sufficient for a physician-owned hospital to disclose its physician ownership or investment.[18] The new regulations include a non-exhaustive list of the types of websites that CMS does not consider to be a “public website for the hospital.” Notably, social media websites, including an individual hospital page on a social media website, will not be considered a “public website for the hospital.” Also excluded are electronic patient payment portals, electronic patient care portals, and electronic health information exchanges.
CMS likewise clarified its definition of “public advertising for the hospital,” noting that it includes public communications that are paid for by the hospital and primarily intended to persuade patients to seek care at the hospital. It does not include, as an example, communications related to recruitment of staff or public service announcements.

Second, the new regulations clarify how to calculate the percentage of physician investment (the “bona fide investment level”) in physician-owned hospitals. Importantly, CMS established a new definition of “ownership or investment interest” specific to this exception. Under this new definition, all physician owners and investors, regardless of whether they refer patients to the hospital, are included for purposes of calculating the bona fide investment level of a physician-owned hospital. Moreover, direct (i.e., without any intervening persons between the hospital and the physician) or indirect (i.e., “an unbroken chain” of persons having ownership or investment interests between the hospital and the physician) ownership or investment interests will be considered for purposes of calculating the bona fide investment level.

The new regulations also clarify that a hospital’s actual knowledge of a specific indirect ownership or investment interest is not required to determine that such an interest exists. Notably, an indirect ownership or investment interest exists even if the hospital does not know, or acts in reckless disregard of, the precise components of the “unbroken chain.”

CMS recognized that some physician-owned hospitals may have relied on its earlier commentary concerning non-referring physicians and the bona fide investment level as part of its Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011. Because the new regulations may cause some hospitals that relied on this earlier guidance to no longer be in compliance with the exception, CMS is postponing the effective date of these changes until January 1, 2017 to allow those hospitals to come into compliance with the new regulations.

Conclusion and “Take-Aways”

The new exceptions, relaxation of certain technical requirements, and interpretive guidance provided by the new regulations may be helpful to avoid some violations of the Stark Law. However, the Stark Law is a strict liability statute and providers must remain vigilant in seeking to ensure compliance with its exceptions. With that in mind, we provide some compliance “take-aways” below.

New Recruitment and Retention of Non-Physician Practitioners Exception

- Hospitals and physicians looking to take advantage of the new exception need to keep in mind that it only applies to the recruitment of nurse practitioners, clinical nurse specialists, physician assistants, certified nurse-midwives, clinical social workers, and clinical psychologists.
- The exception only protects direct employment or independent contractor arrangements between a physician and a NPP. It does not extend to arrangements between a physician and an agency or other company that provides NPP services.
- The remuneration offered to a physician is limited to 50% of the NPP’s actual aggregate compensation and benefits. Additionally, providers should keep in mind that there is a two-year limit imposed on assistance given for a particular NPP.

New Time-Share Arrangements Exception

- The new exception applies only to time-share arrangements between physicians and hospitals or physician organizations. Other entities receiving a physician’s DHS referrals, such as
independent diagnostic testing facilities, cannot rely on this exception. However, the existing lease of office space exception would still be available for such arrangements.

- Parties to a time-share arrangement must ensure that the compensation formula under the arrangement is consistent with fair market value and does not rely on a “per-click” formula.

Relaxed Technical Requirements

- Providers should not relax their disciplined contracting processes aimed at ensuring that valid signed contracts are in place to support any payments to physicians. Although the “writing” and “one-year” requirements can be satisfied by multiple writings, it is unclear exactly what contemporaneous documentation will be sufficient to show satisfactory compliance in a given scenario. As CMS observes in its final rule, a single written contract documenting the details of an arrangement will continue to provide the “surest and most straightforward” means to establish compliance with an applicable exception.

- To avoid being in the position of having to rely on the 90-day signature grace period, it is still a best compliance practice to execute all agreements with physicians prior to the effective date of the arrangement.

- Because a holdover arrangement must continue to satisfy the elements of an applicable exception, including that the compensation or rent paid under the arrangement is at fair market value, the new indefinite holdover period does not absolve parties of the need to periodically review arrangements. In particular, parties should be wary of allowing arrangements to continue as holdover arrangements for significant periods of time as the compensation or rental rates may fall out of fair market value over time, causing the entire arrangement to fail to meet a needed Stark Law exception. Rather, providers should maintain discipline over their review of contracts nearing expiration, and renew any such contracts as needed.

- CMS states that its clarifications to the writing requirement are not a change in policy. As a result, providers can use the guidance provided by CMS in its commentary to the new Stark Law regulations to evaluate their historical arrangements, including when considering submitting a self-disclosure to the SRDP. Indeed, providers may find that CMS’ guidance allows them to avoid self-disclosure in many cases.

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