Update on Fraud and Abuse Developments

Tennessee Bar Association
Health Law Forum
October 20, 2016

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AGENDA

Final Revisions to Stark Regulations
ACA 60 Day Repayment Rule
Stark Updates
Recent AKS Developments
Recent FCA Developments
OIG’s Affirmative Civil Monetary Penalty Actions
Stark Regulations – Final Revisions

- Significant changes to Stark Law
  - New Exceptions
    - NPP Recruitment and Retention - § 411.357(x)
    - Time Share Arrangements - § 411.357(y)
  - Technical Revisions to Stark Regulations
    - Holdover arrangements
    - Signature requirements
    - Physician-owned hospitals
    - Definitions
  - Clarifications to Stark Regulations
    - Writing requirement – “collection of documents”
    - One-year term
    - Split-bill arrangements
  - Exceptions for New Payment Methodologies
ACA 60-Day Repayment Rule

- FERA (2009) – reverse false claims
- ACA (2010) – obligation to report and return overpayments within 60 days of when overpayment has been “identified”
- U.S. ex rel. Kane v. Continuum Health Partners, Inc.
  - Denial of Motion To Dismiss
  - When is an overpayment “identified”?
- CMS final rule (February 2016)
  - Clarifies “identified”
  - Establishes a new “lookback” period
  - Outlines reporting and repayment obligations
ACA 60-Day Repayment Rule – CMS Final Rule

- An overpayment is not “identified” until a person has or should have, through “the exercise of reasonable diligence,” determined an overpayment has been received and has quantified its amount.

- Reasonable diligence
  - Must be undertaken upon receipt of “credible information” about a potential overpayment
    - Factual determination
  - Process should take no longer than 6 months absent extraordinary circumstances (e.g., unusually complex investigations, such as self-referral disclosures)
ACA 60-Day Repayment Rule – CMS Final Rule

- New lookback period
  - Overpayments identified within 6 years of the date the overpayment was received
  - Proposed rule = recommended a 10 year “lookback” period

- Reporting an Overpayment
  - “[P]roviders and suppliers must use an applicable claims adjustment, credit balance, self reported refund, or another appropriate process to satisfy the obligation to report and return overpayments.”

- Reporting an overpayment to either CMS’s Self-Referral Disclosure Protocol or the OIG’s Self-Disclosure Protocol satisfies the reporting obligation
  - Deadline for returning overpayments is suspended upon submissions
ACA 60-Day Repayment Rule – Recent Settlement

- August 2016 settlement – first FCA/60-day rule settlement
  - Mount Sinai Hospital System took almost 2 years to repay overpayment of $850,000 after learning it inadvertently double-billed Medicaid
  - Settled for $3 million
Stark Law Settlements
Stark Settlement

- January 2016
- Tri-City Medical Center agreed to pay over $3.2 million to resolve allegations of Stark Law and FCA violations after allegedly entering into 97 financial arrangements with physicians and physician groups between 2008 and 2010 that violated the Stark Law

““This settlement reinforces that hospitals will face consequences when they enter into financial arrangements with physicians that do not comply with the law.””

U.S. Attorney Laura E. Duffy of the Southern District of California
Stark Settlement

- July 28, 2016
- Lexington Medical Center (LMC)
- Facts: LMC allegedly violated Stark and FCA by entering into asset purchase agreements for the acquisition of physician practices or employment agreements with 28 physicians that took into account the volume or value of referrals, were not commercially reasonable, or provided compensation in excess of FMV
- Settlement: $17 million and CIA
AKS Developments

- OIG Fraud Alert to Physicians
- New Advisory Opinions
- Settlements
OIG Fraud Alert to Physicians

- OIG alerted physicians that compensation arrangements may violate the AKS if even one purpose of the arrangement is to compensate the physician for his or her past or future referrals of Federal health care program business.

- OIG encouraged physicians “to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.”
Charity Patient Assistance Program – Advisory Opinion 15-17

- OIG concluded charity’s proposal to unveil a new patient assistance program dedicated to supporting patients with a specified disease poses low risk under both the AKS and CMP provision prohibiting inducements to beneficiaries

- Arrangement
  - Limited to patients with Stage 3 or Stage 4 of disease
  - Patients must already have a treating provider, practitioner, or supplier, with a treatment regimen in place
  - Financial need in accordance with federal poverty guidelines
  - Charitable contributions to the program would come mostly from pharmaceutical manufacturers

- See also Advisory Opinion 15-16
Free Transportation and Lodging – Advisory Opinion – 16-02

- Administrative sanctions would not be imposed on an academic medical center’s (AMC’s) provision of free transportation and lodging due to a combination of “unique factors” even though provision of such services violates AKS and CMP provision prohibiting inducements to beneficiaries

- Unique factors
  - Continuity of care (patient benefit)
  - Reimbursement is “modest in nature offered only in limited circumstances”
  - No advertisement and offered only to the patients of the 12 affiliated, hospital-based clinics (Clinics)
  - Offered to all patients, regardless of payor
  - Costs would not be claimed as bad debt or shifted to payors
  - State will be responsible for overseeing and carry out the arrangement
    - AMC is state-owned and arrangement was intended to benefit Medicaid and CHIP beneficiaries

- Unclear how broad this advisory opinion will be applied, due to the “unique factors” that led to the OIG’s conclusion
Medigap Insurers and Preferred Hospital Networks – Advisory Opinions

- OIG has issued several favorable advisory opinions addressing preferred network arrangements (e.g., 16-04, 16-05)

- Arrangement
  - Medigap insurers (Insurers) contract with a preferred hospital organization (PHO)
  - PHO contracts with a national network of participating hospitals open to any qualified provider
  - PHO hospitals waive Part A inpatient deductibles for plan members
  - Insurers pay administrative fee to PHO for each qualified stay
  - Beneficiary with a qualified stay could receive a $100 premium credit when renewing plan
Medigap Insurers and Preferred Hospital Networks – Advisory Opinions (cont.)

- Conclusion = arrangement implicates AKS and CMP provision prohibiting inducements to beneficiaries but involved minimal risk because:
  - Per-service Medicare payments would not be affected
  - Benefits would be invisible to beneficiaries and therefore arrangement would unlikely increase utilization (cost-sharing would be covered by insurance)
  - PHO network is open to all qualified providers
  - No remuneration is provided to doctors and therefore medical judgment would be unaffected
  - Beneficiaries would not incur a penalty for choosing a non-network hospital
Co-payment Coupon Arrangements – Advisory Opinion 16-07

- OIG’s general position = co-payment coupons are remuneration that may induce the purchase of federally payable items because such coupons either:
  - Induce purchase of the items subject to the co-payment coupon or
  - Induce purchase of other federally payable products that are manufactured, marketed, or distributed by the manufacturer that issued the co-payment coupon

- Arrangement
  - Medicare Part D beneficiaries use savings card to receive a discount on out-of-pocket costs for a specific drug that is statutorily excluded from coverage
  - Process in place to prevent claims from being submitted for payment by Medicare Part D
    - Note: OIG does not rely on this, as it notes such measures are “not infallible”

- Administrative sanctions would not be imposed because:
  - Drug is statutorily excluded from Medicare Part D coverage so co-payment coupon would not induce the purchase of the items subject to the coupon
  - Requestor attested that arrangement will not be used as a vehicle to market other products, and thus will not induce the purchase of other federally payable products
AKS Settlement

- March 1, 2016
- Olympus Corp. of the Americas (OCA)
- Facts: US’s largest endoscope (and related equipment) distributor (OCA) and Olympus Latin America (OLA) (1) won new business and rewarded sales by giving doctors and hospitals kickbacks via consulting agreements, foreign travel, lavish meals, grants, and free endoscopes and (2) failed to have policies and practices in place to prevent the substantial kickbacks and bribes they paid
- Settlement:
  - $646 million (includes $310.8 for civil claims, $ 312.4 criminal penalty, and $22.8 criminal penalty paid by OLA for violations of the Foreign Corrupt Practices Act
  - OCA entered into a 3-year deferred prosecution agreement (DPA) that will allow it to avoid criminal prosecution as long as it complies with the DPA’s reform and compliance requirements
- Whistleblower: former chief compliance officer will receive over $51 million
FCA Developments
What is Material?
Universal Health Services v. United States ex rel. Escobar

- False Claims Act imposes penalties on anyone who “knowingly presents... a false or fraudulent claim for payment or approval” to the Federal government
- Implied certification theory – when a claim for payment is submitted, the claimant impliedly certifies compliance with all conditions of payment. Failure to disclose a violation of a material statutory, regulatory, or contractual requirement renders the claim “false or fraudulent”
- Pre-SCOTUS decision
  - Circuit split – some circuits applied the theory liberally (e.g., 1st Circuit), others rejected theory (e.g., 7th Circuit)
SCOTUS Decision – Escobar (cont.)

- SCOTUS = unanimously decided the implied certification theory is valid, but narrowed the theory to “material” representations
  - Vacated the 1st Circuit’s judgment and remanded for further proceedings
- Facts = Mental health facility submitted claims for services provided to a state Medicaid beneficiary, who had an adverse reaction to a medication prescribed by a purported doctor at a mental health facility and subsequently died. It was later discovered that most of the employees who treated the patient were actually not licensed to provide mental health counseling or authorized to prescribe medication without supervision, even though the facility, by submitting its claim, represented such employees were all properly licensed
- Lower courts
  - District court = dismissed the case holding the respondents failed to state a claim under the “implied certification theory” because none of the regulations violated by the mental health facility were a condition of payment
  - 1st Circuit = reversed, holding (in part) every submission of a claim implicitly represents compliance with relevant regulations and compliance with such regulations requiring supervision was a “material” condition of payment
SCOTUS Decision – Escobar (cont.)

- **Holding**
  - Implied certification theory can be a basis for FCA liability “when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement. . . . [L]iability may attach if the omission renders those representations misleading.”

- **Materiality**
  - Liability does not turn on whether the legal requirements were expressly designated as conditions of payment
  - Not every violation of legal requirement designated as a condition of payment gives rise to liability
  - Liability is determined based on whether the defendant “knowingly violated a requirement that the defendant knows is material to the Government’s payment decision”
  - Facts must be pled “with plausibility and particularity” and pleading materiality “upon information and belief” is not sufficient

- FCA doesn’t define “false” or “fraudulent” claim so court applied the common-law meaning
Post- SCOTUS Decision - Escobar (cont.)

- Post-SCOTUS decision
  - Lower courts are imposing strict interpretation of SCOTUS’s materiality requirement for FCA allegations
  - Courts are interpreting Escobar to require more in the pleading - pleading “mere noncompliance” is no longer enough
- United States v. Swoben, No. 13-5676 (9th Cir. Aug. 10, 2016)
  - Argued before Escobar, decision rendered after Escobar
- State Farm Fire & Casualty Co. v. United States ex rel. Rigsby, No. 15-513 (May 31, 2016)
  - SCOTUS granted cert to resolve a 3-way circuit split on the standard for determining whether a relator’s claim should be dismissed for violation of the FCA’s seal requirement
United States v. Swoben

The 9th Circuit panel:

- Concluded the proposed 4th amended complaint alleged sufficient factual matter - Dismissed the district court’s judgment and remanded with instructions to allow relator to file a 4th amended complaint

Facts:

- Medicare Advantage organizations (MAOs) allegedly performed “biased retrospective medical record reviews” that were designed to identify and report only under-reported diagnosis codes (codes erroneously not submitted to CMS even though there was adequate record support) and not over-reported diagnosis codes (codes erroneously submitted to CMS without adequate record support)

- Relator alleged MAOs violated the FCA by certifying compliance with Medicare regulations requiring the MAOs to submit “accurate, complete, and truthful” risk adjustment data reflected in the submitted diagnosis codes.
United States v. Swoben (cont.)

- Relevant Holding
  - “When [MAOs] design retrospective reviews of enrollees’ medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS.”
  - Quoted Escobar – “half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations” under the FCA
FCA Settlements

- January 5, 2016
- Nashville Pharmacy Services, LLC
- Facts: From February 2011 through May 2012, Nashville-based pharmacy and owner allegedly automatically refilled prescriptions without a physician order, improperly waived co-payments without assessing whether customers could afford them, improperly using manufacturer copayment cards, and billing beneficiaries for medications dispensed after the beneficiaries died
- Settlement: up to $7.8 million
- Whistleblower was a former order entry technician
  - Will receive up to $1.4 million
FCA Settlements

- January 12, 2016
- Facts: Largest nursing home therapy provider and its rehabilitation therapy division allegedly violated the FCA by knowingly causing SNFs to submit false claims to Medicare for rehabilitation therapy services that never occurred, were not reasonable, or were not necessary and skilled.
- 4 SNFs involved in the activity also reached settlements with the DOJ for their role in submitting claims
- Settlement: $125 million
- Whistleblowers: will receive almost $24 million
FCA Settlements

- September 19, 2016
- North American Health Care Inc. (NAHC)
- Facts: NAHC, its chairman of the board, and its senior VP of Reimbursement Analysis allegedly violated the FCA by causing the submission of false claims to government health care programs for medically unnecessary rehabilitation therapy services provided to NAHC SNF residents
- Settlement: $30 million
Tenet Healthcare Corporation

- Facts:
  - From 2000-2013, Tenet allegedly paid kickbacks and bribes, disguised as contracts for services such as interpretation services and Medicaid eligibility determinations, to the owners and operators of prenatal clinics serving primarily undocumented Hispanic women in exchange for over 20,000 Medicaid referrals for labor and delivery services to its hospitals.
  - Expectant mothers were allegedly told either (1) Medicaid only covered labor and delivery services if they delivered at one of Tenet’s hospitals or (2) that they were required to deliver at Tenet hospitals.
  - Believing they had no other choice, expectant mothers allegedly traveled long distances to deliver at a Tenet hospital, bypassing other hospitals.
  - Many of the alleged payments happened while Tenet was under a September 2006 CIA (resulting as part of a $900 million settlement).
  - Criminal information alleges executives at Tenet hospitals covered up the unlawful payments during the pendency of the CIA by, in part, failing to disclose reportable events, falsely certifying compliance with the CIA, and concealing material facts from Tenet lawyers and outside counsel in order to get contracts approved.
Recent Tenet Healthcare Corporation Settlement (cont.)

- **Civil Settlement** -
  - $368 million dollars to the Georgia and South Carolina Medicaid programs and the federal government
  - Whistleblower will receive $84.43 million of the combined settlement

- **Criminal Settlement**
  - **Guilty Pleas**
    - Two Tenet Atlanta-based hospitals plead guilty to conspiracy to defraud the federal government and to pay kickbacks and bribes in violation of the AKS
    - Plea agreement is subject to court approval
  - Will forfeit over $145 million to the federal government, which represents the amount paid by Medicare and the state Medicaid programs as part of the scheme
  - Tenet Health System Medical Inc. and a subsidiary of Tenet, entered into a non-prosecution agreement
    - Tenet must cooperate with the government’s investigation and enhance their compliance and ethics program and internal controls
    - 3 year term with potential 1 year renewal

- Tenet will also divest 3 Georgia hospitals
Hollister/Coloplast

- SPIIFF and other marketing programs designed to “convert” patients to their products
  - Alleged collusion between manufacturers of ostomy and continence products (Hollister and Coloplast) and DME suppliers
  - Coloplast hired individual from Hollister to mimic Hollister’s marketing scheme in 2009
  - *Qui Tam* filed by former Coloplast president, former Coloplast director, and Coloplast manager
Hollister/Coloplast (cont.)

- Government intervened and settled as to most defendants (not CCS Medical)
  - $11.5 million (Hollister, April 2016) and $3.1 million (Coloplast, December 2015)
  - Some claims against the defendants survived
- FCA suit went forward as to CCS Medical in Federal District Court in Massachusetts
  - Originally dismissed by court based on its interpretation and applicability of the discount safe harbor July 2016
  - DOJ filed a statement of interest setting forth its view that the discount safe harbor did not apply
- Court reversed dismissal August 2016
CMP Penalties

- During the first half of FY 2016, OIG reported:
  - expected recoveries of more than $2.77 billion
  - 1662 individuals and entities have been excluded from participation in Federal health care programs
- CMP recoveries have increased almost five fold over the past 3 years
- Effective August 1, 2016, FCA penalties will almost double
  - Per-claim penalties
    - Minimum: $10,781 (from $5,500)
    - Maximum: $21,563 (from $11,000)
Exclusion

- January 5, 2016
- American Therapeutic Corporation, American Sleep Institute, and MedLink Professional Management
- Facts: The three Florida-based companies were found to have (1) paid kickbacks to “patient brokers” who owned assisted living facilities and halfway houses in exchange for referring individuals known to be ineligible for treatment; (2) submitted or caused claims to be submitted to Medicare for medically unnecessary services; and (3) falsified medical documentation to obtain Medicare reimbursement
- Permanent exclusion from participating in Federal health care programs
Individual Liability

 Former Toumey CEO – Settlement for $1 million; excluded for 4 years

 Owner of Home Health Care Agency in Illinois – plead guilty to paying kickbacks; facing maximum prison sentence of five years; Home Bound Healthcare, Inc. paid $6.8 million

 Violation was the monthly payment to 20 doctors between $1,000-$4,000 in exchange for patient referrals where home care wasn’t medically necessary
Individual Liability

- Former Owner and Chief Executive of Sacred Heart Hospital in Chicago sentenced to 4 ½ years; ordered to forfeit $10.4 million and pay $770,000 in fines

- Nursing home operator in Chicago jailed – DOJ alleges $1 billion fraud and kickback scheme