Key Stark Law Developments Every Compliance Officer Needs to Know

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Topics Covered

- New Stark Regulations & Impact on Physician Contracting
- Recent Cases and Settlements
- 60 Day Rule, Reporting Obligations & Compliance Challenges

2

New Stark Regulations & Impact on Physician Contracting

3

New Regulations: List of Key Changes
(October 30, 2015)

- Leniency on "written agreement" and "one-year term" requirements
- New exception for recruitment of mid-level clinicians
- New exception for timeshare arrangements
- Extensions on permitted "holdover" arrangements
- More latitude on missing signatures

4

Written Agreement/Term Requirements

- Depending on the facts and circumstances, a collection of documents, e.g., e-mails, drafts, invoices, cancelled checks, timesheets, etc. can constitute a "written agreement"
- The "one-year term" requirement can be satisfied if the arrangement lasted one year, even if the written agreement does not specify a term
- These are both "clarifications" of existing law, meaning that they apply retroactively too

5

Recruiting Mid-Levels

- Previously, there was just a "physician" recruitment exception
- Now, hospitals (and FQHC/RHC) can recruit mid-levels to provide primary care or mental health services to a physician's practice
- Covers PAs, NPs, clinical nurse, specialists, certified nurse, midwives, LCSWs and psychologists
- Up to 50% of compensation, once every 3 years (and other restrictions apply)
- What about 501(c)(3) hospitals?

6

Timeshare Arrangements

- Protects certain "timeshare" arrangements (not leases) between hospital or physician organization and a physician or medical group
- Space, equipment and other items are predominantly for evaluation and management (E/M) visits
- Any equipment is in the same building as E/M visits and used for diagnostic imaging only if incidental to E/M visit, and not used advanced imaging, radiation therapy or clinical laboratory services (other than CLIA-waived tests)
- Could this be used in hospital-licensed or provider-based space?

Holdovers on Expired Arrangements

- The old rule allowed expired leases and personal services arrangements to continue after expiration on the same terms for up to 6 months, if exception otherwise satisfied
- Their new rule extends the 6 months to an unlimited period of time
- But, beware of fair market value issues and changes in services and/or compensation

Signatures on Written Agreements

- The old rule allowed arrangements where only a signature was missing, for up to 90 days if inadvertent and 30 days if advertent
- Now, all arrangements are allowed, when only a signature is missing, for up to 90 days
- This grace period is still limited to once per physician every 3 years

Recent Cases and Settlements

How Should Compliance/Legal Respond?

Halifax Hospital

- Halifax Hospital is in Daytona Beach, Florida
- In 2014, paid $86 million to settle alleged Stark Law and Anti-Kickback violations, brought by a qui tam Relator.
  - The Relator was a Halifax compliance employee (not compliance officer) turned whistleblower.
  - Hospital/Physician Compensation Arrangements
- The government alleged that the prohibited referrals resulted in the submission of 74,838 claims and overpayment of $105,366,000.

Halifax Health

Executed contracts with six medical oncologists that included an incentive bonus that (allegedly) improperly included the value of prescription drugs and tests that the oncologists ordered and Halifax billed to Medicare.

- Bonus Pool = 15% of Halifax Hospital's "operating margin" from outpatient medical oncology services (*i.e.*, pool includes revenue from DHS referred by oncologists)
- Does not comply with exception for bona fide employment arrangements because: (1) FMV and (2) volume/value referral prohibition
- Share of pool paid to individual oncologists is based on each individual physician's personal productivity, not referrals
- However, pool includes "profits" from services referred, but not personally performed by oncologists.

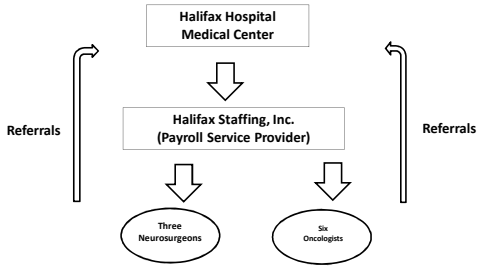
Halifax Health

- Complaint alleged that Halifax paid three neurosurgeons more than fair market value for their work.
  - Bonus = 100% of collections after covering base salary, no expense sharing
  - Total Compensation = as much as double neurosurgeons at 90th percentile

AMGA 90th	MGMA 90th	Dr. R. K.	Dr. WK.	Dr. FMV.
$844,703	$1,200,051	$1,725,302	1,160,163	1,897,524

13

Flow of Money & Referrals



14

Losses on Physician Services – OK?

DOJ asserts that paying physicians more than the professional collections they generate exceeds FMV, is not commercially reasonable, and takes referrals into account:

"Given that each neurosurgeon was paid total compensation that exceeded the collections received for neurosurgical physician services, Defendants could not reasonably have concluded that the compensation arrangements in those contracts were fair market value for the neurosurgical services or were commercially reasonable."

But, there is no requirement that providing physician services must be profitable:

- If compensation is FMV and is not adjusted for referrals, it should satisfy the Stark Law
- Some service lines have unprofitable payor mixes or low demand
- CMS recognizes the legitimacy of subsidizing physician compensation, e.g. in the E.D.
- Likewise, call coverage and hospitalist services often require subsidies

15

Halifax Takeaways

- How are bonuses structured and calculated?
- Do you have a fair market value (FMV) opinion?
- If physician compensation exceeds collections:
  - Do you have a commercial reasonableness analysis?
  - Do you have buy-in from legal and compliance?

16

Tuomey – Overview

October 16, 2015, Tuomey agreed to settle with the government for $72.4 million—less than a third of the $237 million that a federal appeals court said it would have to pay for illegal compensation arrangements with doctors.

Verdict would have been the largest ever against a community hospital and would have exceeded the system's annual revenue.

Tuomey acquired by Palmetto Health, a system based in Columbia, S.C. Tuomey previously signaled it planned to partner with Palmetto.

17

Tuomey – Contract

- 10 year term and part-time "employment" for only outpatient procedures
- Required all outpatient surgeries to be performed at Tuomey
- Yearly salary based on previous year's net collections
  - Bonus: 80% of net collections of professional fees and additional 7% of productivity bonus for other factors
- Agreement not to compete – prohibited physicians from performing surgeries elsewhere within 30 miles of the hospital (during and post-two years)
- Full time benefits: Including health insurance, malpractice premiums (covered physicians for office and inpatient services), cell phones, journals, CME

18

Tuomey – Valuations

- Cejka, a valuation firm evaluated the contracts for purposes of the fair market value requirement at inception.
  - Analysis indicated productivity levels of physician's were between the 50th and 75th percentiles
  - Compensation level exceeded the 90th percentile
  - Evaluation did not include full time benefits
  - Certain physicians, across the country, received between 49% and 63% of net collections, but Tuomey paid, on average, 131% of net collections

19

Tuomey

- Government expert analyzed the contracts at trial.
  - Impossible to ever make profit on these contracts
  - Full time benefits for minimal hours per week
- Non-Compete Agreement locked in referrals
  - Reactive to competing ambulatory surgery center and physician groups informing Tuomey they may perform surgeries in their own offices rather than at Tuomey.

20

Tuomey Takeaways

- Virtually all FCA cases are resolved through settlement agreements due to potential ramifications of losing – unusual that this case went to trial
  - Some cases settle after motions to dismiss are heard
- Physician employment does not necessarily insulate agreements from Stark liability
- If a proposed arrangement appears to have been developed in response to the fear of losing a referral stream, the government may look closely at issues of commercial reasonableness
- Long-term arrangements should be reviewed periodically for compliance
- Providers cannot blindly follow a fair market value or commercial reasonableness determination

21

60 Day Rule, Reporting Obligations & Compliance Challenges

22

Report & Return Overview

- ACA requires a person that receives an overpayment to report and return the overpayment by the later of:
  - 60 days after the overpayment was identified
  - The date any corresponding cost report is due
- An overpayment is any funds that a person receives or retains under subchapter XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such subchapter

23

Report & Return Overview: Enforcement

- False Claims Act
  - A retained overpayment is an "obligation"
  - Liability for:
    - knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government
    - knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government
- Includes improperly retaining Stark-prohibited Medicare payments, and improperly avoiding the Stark-required refunds

24

Identification

- "A 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."
- Reasonable diligence includes:
  - Proactive compliance
  - Reactive compliance (good faith investigation in response to credible information of a potential overpayment)
- Credibility of information based on facts and circumstances

Defaults in Reasonable Diligence

- 60-days can run from date the provider "should have identified" the overpayment, *i.e.* when:
  - "the person fails to exercise reasonable diligence" and
  - "the person in fact received an overpayment"
- Proposed rule would have required examining when a provider would have identified the overpayment

Report & Return Deadline

- Later of:
  - 60-days from identification
  - Date any corresponding cost report is due
- Repayment deadline is suspended by
  - OIG Self-Disclosure Protocol or Self-Referral Disclosure Protocol (from acknowledged submission to settlement, withdrawal, or removal from protocol)
  - Repayment plan (from request until rejected or any non-compliance with plan)

Stark Self-Disclosure

- Determining Whether or Not There is a Stark Violation
- Benefits and Drawbacks of Self-Referral Disclosure Protocol (SRDP) Process
- Timing for SRDP Resolutions (Regular v. Expedited)
- Lessons Learned / Compliance Challenges

28

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29