



FOLEY & LARDNER LLP

What's New in Stark? Advice for the Physician Organization

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Paying for Health Reform?

- Pres. Obama: “We've estimated that most of this [health care reform] plan can be paid for by finding savings within the existing health care system, a system that is currently full of waste and abuse.”
- PPACA includes additional \$250 billion over six years to fund fraud and abuse enforcement
 - Additional \$95 billion for FY 2011
- FY 2010 all agency enforcement budget of over \$311 billion

FCA Changes

- Multiple phases at chipping away at defenses
- FERA – Eliminates requirement that claim be presented to the United States (as had been read into 31 USC 3729(a)(1))
- PPACA Weakens public disclosure bar (*only* if disclosed in a *federal* criminal, civil, or administrative hearing, or a *federal* report, hearing, audit, or investigation.)
- Expansion of the definition of an original source (eliminates the direct knowledge requirement)

Overpayments – “60 Day Rule”

- Background:
 - Historically, no express duty to refund innocent overpayments (arguable on Part A)
 - DOJ/CMS disagreed
 - Language on “wrongful retention”
 - 2009 Fraud Enforcement and Recovery Act (FERA) expressly referenced improper retention of "obligations"

Overpayments – “60 Day Rule”

- § 6402(a): Express duty to refund and report Medicare and Medicaid overpayments
- By *the later* of 60 days after overpayment “identified” or the date cost report is due
- Failure to report and return is an “obligation” for the purpose of FCA

Overpayments – “60 Day Rule”

- What is an “overpayment”?
 - “funds that a person receives or retains under title XVIII or XIX [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled under such title”
 - Application to technical/documentation/COPs/ other errors vs.
 - Application to services not rendered/paid higher than performed
- When is it “identified”?
 - What level of confidence?
 - Ability to know actual amount?

Stark Changes

- Physician-Owned Hospitals (§§ 6001, 10601; Reconciliation Act § 1106)
 - Rural and “whole-hospital” exceptions severely limited
 - Available only for hospitals with Medicare provider agreement as of Dec. 31, 2010
 - Hospitals using the exception will not be able to increase *capacity or percentage of physician ownership or investment* after March 23, 2010

Stark Changes

- In-Office Ancillary Services (§ 6003)
 - Physician ordering certain DHS (MRI, CT, PET, others per CMS – none yet) must inform patients that they may obtain service from alternate provider
 - Must be in writing
 - Must include list of alternate suppliers furnishing same service in area where individual resides

Self-Disclosure Protocol (SDRP)

- In 2009, OIG announced no longer accept “Stark-only” disclosures (i.e., without “colorable” AKS violation)
- Perception that CMS lacked authority to accept settlement of < 100%
- § 6409: Self-Referral Disclosure Protocol (SDRP) (Published 9/26/2010)
- CMS may accept lower repayments through SDRP

Self-Disclosure Protocol (SDRP)

- Factors to be considered:
 - Nature and extent of “illegal or improper practice”
 - Timeliness of disclosure
 - Cooperation in providing additional information
 - “Litigation Risk”
 - “Other Factors”
- CMS gave little comfort that “technical” violations will be treated gently
- About 90 SRDP Submissions to date (as of July 2011)
- One Settlement to date (2/10/2011) - \$14.5MM (likely higher) potential exposure, settled for \$579K

Clarification of Definition of Entity

- **A DHS entity is one that (1) bills Medicare or (2) performs services that are billed as DHS**
 - Second component of definition was intended to address physician-owned service providers performing services billed by hospitals under arrangements
- **What does it mean to “perform services”?**
 - Does leasing equipment and services count?
 - CMS solicited comments in CY 2010 PFS final rule as to how it might clarify definition
 - CMS received only 9 comments and said that it would not engage in rulemaking to propose revising or clarifying the definition
 - Said parties may seek advisory opinion

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